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ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S Immigration and Customs Enforcement

IHSC Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials

Approved by (b)(6); (b)(7)(C) **DHSc**

Title: ERO – IHSC AD

Date signed: (b)(6); (b)(7)(C)

Latest Update: May 10, 2018

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Foreword

This *IHSC Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials* supplements the following IHSC Directive:

- IHSC Directive: 05-02, Occupational Health.

This guide supplements the ICE Occupational Safety and Health Program Requirements Handbook and explains concepts, assigns responsibilities, and details procedures for the prevention and control of exposures to blood and other potentially infectious materials in the health care setting.

The intended audience is health staff supporting health care operations within IHSC-staffed medical clinics in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this Guide is to provide health staff with procedures, tools, and resources to manage bloodborne pathogens (BBP) and other potentially infectious material (OPIM) as required by IHSC Directive: 05-02, Occupational Health.

IHSC is dedicated to promoting a safe and productive work environment. IHSC reduces exposures to BBP and OPIM through training, the use of administrative, workplace, and engineering controls, and personal protective equipment (PPE).

B. Responsibilities

The Public Health, Safety, and Preparedness (PHSP) Unit:

- Provides national oversight and technical assistance of IHSC's BBP Program.
- Reviews and updates this guide and IHSC Directive: 05-02, Occupational Health.
- Develops, reviews and updates the IHSC Exposure Control Plan (ECP) and the template for developing ECPs.
- Conducts periodic program assessment.

Health Services Administrator (HSA) and Compliance Officer (CO):

- Oversee the medical clinic ECP and the management of accidental exposures and injuries.
- Implement and monitor ECP for the medical clinic.
- Document and evaluate BBP exposures and provide the exposed staff with post-exposure recommendations.
- Ensure that health staff receive orientation and annual training.
- Review the ECP at least annually.
- Monitor hand hygiene practices quarterly.
- Facilitate completion of information requests for monitoring and following up on workforce health-related reports, interventions, and process improvements.

Health Staff:

- Adhere to the ECP.

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- Maintain awareness of prevention and management of exposures to BBP and OPIM.
- Promote and monitor exposure precautions in accordance with current national guidelines and standards as specified in training.

C. Acronyms

ACH – Air changes/hour

AII – Airborne infection isolation (room)

BBP – Bloodborne pathogen

CDC – U.S. Centers for Disease Control and Prevention

ECP – Exposure control plan

EPA – U.S. Environmental Protection Agency

FDA – U.S. Food and Drug Administration

HEPA – High efficiency particulate air (filtration)

HBV – Hepatitis B virus

HIV – Human immunodeficiency virus

JHA – Job hazard analysis

NIOSH – National Institute for Occupational Safety and Health

OPIM – Other potentially infectious material

OSHA – U.S. Occupational Safety and Health Administration

PPE – Personal protective equipment

CO – Compliance Officer

D. Definitions with Expanded Information

Administrative Controls – Methods of controlling employee exposures through enforcement of policies and procedures, modification of work assignment, training in specific work practices, and other administrative measures designed to reduce exposures.

Airborne Infection Isolation (AII) Precautions – Isolation of patients infected with infectious organisms spread through the air to minimize person-to-person transmission.

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Airborne Infection Isolation (AII) Room – A single occupancy patient-care room (formerly called a negative pressure isolation room). Environmental factors are controlled so the isolation room receives substantial air changes per hour (ACH). The number of ACH is greater, or equal to, 12 for new construction since 2001 and greater or equal to six ACH for construction before 2001. In addition, the single occupancy patient-care room is under negative pressure, i.e., the direction of air flow is from the outside adjacent space, or the corridor, into the room. All room air is preferably exhausted to the outside, or recirculated if the return air is filtered through a high efficiency particulate air (HEPA) filter.

Airborne Transmission – The dissemination of airborne particles can infect people over time if the distance is suitable, and the droplet nuclei are from one to five µm in diameter and dispersed through coughing or aerosolization of contaminated fluids.

Antiseptic agent – Antimicrobial substances that are applied to the skin to reduce the number of microbial flora. Examples include alcohols, chlorhexidine, chlorine, hexachlorophene, iodine, chloroxylenol (PCMX), guaternary ammonia compounds, and triclosan.

Antiseptic hand wash – Washing hands with water and soap or other detergents containing an antiseptic agent.

Antiseptic hand rub – Applying an antiseptic hand-rub product to all surfaces of the hands to reduce the number of microorganisms present.

Blood – Human blood, blood components, and products made from human blood.

Bloodborne Pathogens – Microorganisms that are present in human blood and can cause disease in humans (e.g., hepatitis B virus and human immunodeficiency virus).

Body Fluid – Fluid secreted by the body including, but not limited to, blood, semen, saliva, urine, and feces.

Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact. Other terms associated with the definition are communicable, infectious, and microorganisms.

Culture of Safety – The shared commitment of management and employees to ensure a safe work environment.

Direct Contact Transmission – Direct transfer of a microorganism from an infected person to another person.

Engineering Controls – Controls that isolate or remove a hazard from the workplace (e.g., ventilation, isolation, sharps disposal containers, and self-sheathing needles).

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Exposure – The condition of being subjected to something in the working environment (e.g., noise, dust, chemicals, radiation, and infectious agents) that could have an adverse health effect.

Exposure Incident – An incident involving chemical or biological exposure of the eye, mouth, other mucous membranes, non-intact skin, and/or parenteral contact with blood or other potentially infectious materials.

Hand Hygiene – Handwashing with one of the following four agents: (1) plain, non-antimicrobial, soap and water; (2) anti-septic hand wash (i.e., soap containing antiseptic agents and water); (3) antiseptic hand rub which is usually waterless anti-septic product, most often alcohol-based, and rubbed on all surfaces of hands; or (4) surgical hand antisepsis, or antiseptic hand wash/hand rub, performed preoperatively by surgical personnel to eliminate transient hand flora and reduce resident hand flora.

Handwashing Station – A station providing an adequate supply of running potable water, soap, and single use towels and/or hot-air drying machines, or a waterless hand wash solution.

High Efficiency Particulate Air (HEPA) Filter – A filter that is certified to remove ≥99.97% of particles 0.3 µm in size, including *M. tuberculosis*–containing droplet nuclei. The filters are for portable or stationary units and required for all room exhaust ventilation. The filters require expertise in installation and maintenance.

Infection Control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Near-miss – An event or situation that could have resulted in an accident, injury, or illness, but did not because of chance or a timely intervention.

Needleless Intravenous (IV) System – An IV system that administers medication through an access device without using needle connections.

Needle-stick Injury – A penetrating stab wound caused by a needle.

N95 Disposable Respirator – An air-purifying, filtering-facepiece respirator that is ≥95% efficient at removing 0.3 µm particles and is not resistant to oil. Education and fit testing is required before wearing an N95 respirator and the respirator is used to protect the wearer from exposures in the air. In addition, this type of respirator is not worn by a patient.

Occupational Exposure – Skin, eye, mucous membrane, or parenteral contact with blood, or other potentially infectious materials, occurring during the performance of work activities.

Other Potentially Infectious Material (OPIM) – Includes the following four types of materials: (1) secretions of semen or vaginal fluid, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any bodily fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) unfixed tissue or organ

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(other than intact skin) from a living or dead human; (3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV containing culture medium or other solutions; and (4) blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Personal Protective Equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases, and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, and steel toe boots.

Regulated Waste – Liquid or semi-liquid blood, caked or dried blood, or other potentially infectious materials capable of releasing these materials during handling or compression.

Respirator – A form of PPE with filtering capability that fits snug on the face, and over the nose and mouth, to prevent the wearer from inhaling hazardous airborne particles.

Safety Device/Sharps with Engineered Sharps Injury Protections - A non-needle sharp, or needle device, used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Sharps - An object that can penetrate the skin, including, but not limited to, needles, scalpels, lancets, broken glass, broken capillary tubes, and exposed ends of dental wires.

Sharps Injury – An injury caused by sharps, including, but not limited to, cuts, abrasions, or needle sticks.

Standard Precautions – Standard precautions are a set of infection control practices used to prevent transmission of diseases that can be acquired by contact with blood, body fluids, non-intact skin (including rashes), and mucous membranes. They are the basic level of infection control that should be used, as a minimum, in the care of all patients all of the time. Standard precautions are meant to reduce the risk of transmission of bloodborne and other pathogens from both recognized and unrecognized sources. The infection control/prevention practices may include hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection, or face shield. The equipment or items in the patient environment that are likely to have been contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for handling heavily-soiled equipment and properly clean and disinfect, or sterilize, reusable equipment before using on another patient).

Surgical Facemasks – A protective device that covers the patient's nose and mouth to protect health care workers from exposures to wearer-generated microorganisms.

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Symptom Screen – A procedure used during a clinical evaluation in which a person is asked if they have experienced any departure from normal in function, appearance, or sensation related to the health condition of interest.

Transmission-Based Precautions – Precautions that provide additional protections beyond standard precautions to interrupt the transmission of pathogens.

Work Practice Controls – Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

II. Exposure Control Plan (ECP)

An ECP is a location-specific plan with activities, practices, and procedures intended to minimize occupational exposures to blood and OPIM. The ECP accomplishes the following functions:

- Helps determine staff exposure to BBP;
- Communicates workplace hazards related to BBP;
- Offers advice on hepatitis B vaccinations;
- Uses exposure control measures such as:
    - Standard precautions,
    - Transmission-based precautions,
    - Administrative controls,
    - Engineering controls,
    - Work practice controls,
    - Personal protective equipment, and
    - Housekeeping and spill clean-up.
- Reports, evaluates, and follows up on exposure incidents;
- Documents and keeps records of exposures; and
- Trains employees.

III. Determining Staff Exposures and Communicating Hazards

Evaluating staff exposure to BBP and OPIM is part of the job hazard analysis (JHA). The JHA is described in the IHSC Occupational Health Guide: Personal Protective Equipment Program. A JHA assesses job tasks for hazards regardless of the use of

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PPE or other controls. The HSA must use the JHA to determine which staff have a potential for workplace BBP exposure. Staff with the potential for skin, eye, mucous membrane, or parenteral contact with blood or OPIM are included in the ECP. The HSA must ensure that health staff are aware of these BBP hazards and adhere to the control methods in the ECP.

IV. Hepatitis B Vaccination

The U.S. Occupational Safety and Health Administration (OSHA) BBP Standard requires that all employers offer the HBV vaccine to their employees who have the potential for workplace exposure to blood and OPIM. The HSA must ensure that health staff are aware of the importance of the HBV vaccine and its benefits. If a staff member refuses to get the HBV vaccine, or if it is contraindicated, the staff member must provide documentation to the HSA. Please refer to IHSC's occupational health guide, "Workforce Health" for additional details on HBV vaccine requirements.

V. Exposure Control Measures

A. Standard Precautions

Standard precautions reduce the spread of microorganisms by direct or indirect contact, and reduce the risk of illnesses caused by microorganisms. When deployed, standard precautions protect health staff from blood, body fluids, non-intact skin, and mucous membranes.

Health staff must apply standard precautions when caring for detainees or residents regardless of their diagnosis or presumed infectious status. Standard precautions, at a minimum, should include the following:

- Hand hygiene;
- Respiratory hygiene and cough etiquette; and
- Safe injection practices.

Hand Hygiene

Hand hygiene is the single most effective measure to prevent the spread of infectious illness from person to person. Readily accessible handwashing facilities are essential to the successful practice of hand hygiene. Sinks with running water and soap should be available in every IHSC-staffed medical clinic exam room. If not directly in the exam room, soap and running water must be immediately available outside the exam room, and there must be no barriers to access. Readily accessible antiseptic hand rub also supports hand hygiene practices. Hand hygiene training ensures health staff competency in washing hands with antiseptic hand wash as soon as possible after any exposure to BBP or OPIM, and after removing PPE.

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The CO monitors and documents health staff compliance with hand hygiene quarterly. Hand hygiene compliance indicators include cleaning hands:

- Before and after each patient interaction;
- Before and after handling equipment for patient care;
- Before and after going to the restroom;
- Before and after going on breaks and eating;
- After removing gloves and other PPE; and
- Before leaving work at the end of the day.

Table 1. Antiseptic Hand Wash

When to use antiseptic hand wash (when hand rub is not sufficient)
☐ When hands look or feel soiled and dirty. ☐ After contact with blood, bodily fluids, or contaminated surfaces (even if gloves are worn). ☐ After handling biohazard waste (even if gloves are worn). ☐ After enough consecutive uses of antiseptic hand rub that hands feel "grubby" from the build-up of emollients.
Instructions
1. Turn on the faucet and wet hands with water. 2. Apply a liberal amount of soap to hands, and rub them together vigorously for at least 15-20 seconds, covering all surfaces of the hands and between the fingers. 3. Rinse hands well with water and dry thoroughly with a clean disposable towel. 4. Use another clean towel to turn off the faucet.

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Table 2. Antiseptic Hand Rub

Instructions
1. Apply product to the palm of one hand and rub hands together, covering all surfaces of hands and fingers, until they are dry. 2. Follow manufacturer's recommendations regarding the volume of product and use. 3. Dispenser placement must comply with National Fire Protection Association (NFPA) recommendations according to the NFPA 101: Life Safety Code: – Corridor width is six feet or greater; – Dispensers are a minimum of four feet apart; – Maximum capacity 1.2 L in rooms and corridors; 2.0 L in suites; – Dispensers cannot be installed over electrical outlets/switches; – May be installed in carpeted areas only if there is a sprinkler smoke compartment; and – Maximum amount of ten gallons of solution per smoke compartment and five gallons in storage.

Respiratory Hygiene/Cough Etiquette

The following are elements of good respiratory hygiene and cough etiquette:

- Control coughs at their source by covering the mouth and nose with tissue when coughing, and placing a surgical mask on the source of the cough when necessary.
- Wash hands after contact with respiratory secretions.
- Practice spatial separation (ideally greater than three feet).
- Place persons with known or suspected respiratory infections in separate waiting areas if possible.
- Educate health staff, detainees, and visitors.
- Post signs that depict good respiratory hygiene and cough etiquette practices in languages appropriate to the population.

Safe Injection Practices

The following safe injection practices are part of standard precautions:

- Use needleless systems for IVs and medication delivery as available.

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- Use single dose vials as available.
- Use sterile, single-use, disposable safety needles and syringes for each use of a multiple dose vial or injection into a solution (e.g., IV fluid).
- Use sterile, single-use, disposable safety needles and syringes for each intravenous, intramuscular, subcutaneous, or intradermal administration.

B. Transmission-Based Precautions

- Health staff must implement transmission-based precautions when treating detainees and residents with documented or suspected infection, and highly transmissible or epidemiologically important pathogens, for which additional measures beyond standard precautions are needed.
- Health staff must empirically implement precautions when a condition is suspicious enough to test, or treat, for the causative agent (e.g., TB).
- In addition to standard precautions, health staff must use transmission-based precautions appropriate for the organism and mode of transmission.
- The implementation of more than one type of precaution is required for some disease processes, such as varicella which requires both contact and airborne precautions.
- For detailed guidance on the type and duration of transmission precautions by organism or syndromes, refer to the Guidelines for Environmental Infection Control in Health-Care Facilities -- Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

Signage

- Health staff must post signs whenever implementing transmission-based precautions to warn facility staff, health staff, and visitors, of the requirements for entry into the restricted area.
- Health staff must post signs on the door of an isolation room in use.
- Health staff must use clear, eye-catching, professionally designed laminated signs.

Contact Precautions

- Contact precautions are intended to prevent transmission of infectious agents spread by direct or indirect contact.
- Health staff must don gloves and a gown for patient contact prior to entering patient care rooms requiring contact precautions.

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- Health staff must don PPE whenever entering the detainee's or resident's environment, since the level of exposure cannot be predicted.
- Health staff must remove and dispose of PPE before exiting the patient care room.
- Health staff must decontaminate hands immediately upon exiting the patient care room.
- Health staff must use disposable or dedicated patient care equipment.
- Health staff should recommend that the facility uses disposable utensils and plates for serving meals during contact precautions.
- Health staff should recommend that a detainee or resident with contact precautions be housed in a private room with a separate bathroom, or if appropriate with a similarly infected cohort.
- If a private bathroom is not available, health staff should recommend to facility staff that shared bathrooms are disinfected after each use.

Droplet Precautions

- Droplet precautions are intended to prevent the transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions.
- Health staff must don a surgical face mask when entering a detainee's or resident's room requiring droplet precautions.
- Health staff should recommend that a detainee or resident with droplet precautions be housed in a private room or with a similarly infected cohort (although a single occupancy room is preferred).

Airborne Precautions

- Airborne precautions are intended to prevent transmission of infectious agents that remain infectious over long distances when suspended in the air.
- Airborne infection precautions require the use of an airborne infection isolation room with negative pressure ventilation.
- Health staff must don a fit-tested particulate respirator prior to entering the room.
- Health staff should recommend that if the infectious detainee or resident leaves the isolation room, he or she should don a tight-fitting surgical mask.

C. Control Measures

The HSA must implement administrative, work practice, and engineering controls to

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eliminate or minimize employee exposures. Engineering and work practice controls are used to prevent or minimize exposure to BBP and OPIM by isolating or removing the hazard, or practices, to reduce the possibility of exposure. Standardized blood and bodily fluid clean-up techniques must be practiced to prevent the spread of infectious diseases.

D. Personal Protective Equipment

PPE such as gloves, goggles, gowns, shoe covers and/or respirators are used for work activities that have anticipated BBP or OPIM exposures that cannot be controlled in other ways. For details on the IHSC PPE Program, refer to the IHSC Occupational Health Guide: Personal Protective Equipment Program.

Table 3. Examples of Control Measures

Administrative Controls • Institutional policies and procedures. • Modification of work assignments. • Training. • Provision of fiscal and human resources.
Work Practice Controls • Instructions to not recap sharps. • Respiratory hygiene and cough etiquette. • Avoidance of eating, drinking, or applying cosmetics in clinical or treatment areas. • Procedures involving blood or OPIM that minimize splashing, spraying, spattering, and generation of droplets.
Engineering Controls • Handwashing facilities. • Eye wash stations. • Safer needle devices. • Needleless systems. • Regulated medical waste containers. • Biohazard labeled containers. • Ventilation.
Personal Protective Equipment • Respirators. • Goggles or face shields. • Gloves. • Gowns and other protective clothing. • Foot covers.

VI. Labels and Signage

- The HSA or designee must affix warning labels on containers of regulated waste and other containers used to store, transport, or ship BBP or OPIM.

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- The HSA or designee must clearly identify refrigerators and freezers containing BBP or OPIM with signs on their doors.
- The HSA or designee must include the biohazard symbol on all warning labels and signs.
- Red bags, or red waste containers, are a universally accepted substitute for biohazard labels.

VII. Housekeeping and Spill Clean-up

Health staff must clean and decontaminate environmental and work surfaces immediately after the surfaces become contaminated with body fluids such as blood, vomit, urine, and feces. These fluids are considered infectious. Health staff must use procedures and equipment to prevent cross-contamination of other areas. Health staff must never use mops or paper towels to clean up blood or bodily fluid spills. Health staff must always wear PPE to clean up spills. Health staff must dispose of the contaminated material in the designated waste containers.

A. Spill Kits

The HSA must ensure that spill kits are readily available in the medical clinic, in patient care areas, and in other designated areas, for use in cases of spills of blood or other body fluids. Spill kits must contain PPE and equipment to clean up any potential bio hazardous material. Not all of the contents in the spill kit will be used for every spill. Face, skin, clothes, and shoes must be protected during spill clean-up. (Some pathogens, like hepatitis B, can live in dried blood for seven days). When a spill kit is used in the medical clinic, health staff must restock it before it is placed back in the medical clinic. For additional information on spill kits see "Spill Kit FAQ."

Spill Kits Contents

- Two pairs of non-latex nitrile, four milliliter (4 mL) thickness medical grade gloves;
- One disposable face shield;
- One disposable face mask;
- One pair of disposable shoe covers for gross contamination;
- One surgical cap for gross contamination;
- One disposable apron;
- One absorbent material pack;
- One pair of tongs or forceps to pick up broken glassware;

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- One dustpan/brush to clean up broken glassware;
- Two scoops or scrapers;
- One shovel;
- One can of EPA-registered disinfectant;
- Two red biohazard bags with ties;
- One black plastic bag for non-medical waste;
- One small bottle of hand sanitizer;
- One instruction sheet;
- One disposable towel;
- Four disposable absorbent rags; and
- Two disposable towelettes.

VIII. Post-Exposure Reporting, Evaluation and Follow Up

The OSHA BBP Standard requires rapid determination and response to an accidental exposure to blood or OPIM. The HSA must ensure that important post-exposure recommendations, reporting, and recording, occur after an employee pathogenic exposure. Please refer to the IHSC Occupational Health Guide: Workforce Health for details.

A. Sharps Injury Log

The HSA or designee must maintain a log of sharps injuries to record, track, and assess, the occurrence in the medical clinic. The log must include the following for each sharps injury:

- The date of the injury;
- The type and brand of the device involved;
- The work area where the injury occurred; and
- An explanation of how the injury occurred.

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IX. Program Monitoring

PHSP Unit staff collect information periodically from the HSA to monitor the implementation of the IHSC BBP program and to assess compliance with program requirements.

X. Training and Education

A. Health Staff

The HSA or designee must ensure that orientation and annual training that includes bloodborne pathogens, and other potentially infectious materials, is implemented and documented in accordance with IHSC directive 01-04 Medical Education and Development.

B. Detainees and Residents

Health staff should educate detainees and residents on infection prevention. The pamphlets, posters, and videos, used should be available in several languages. The following are important infection prevention topics for detainees and residents to learn:

- Hand hygiene and handwashing techniques;
- Respiratory hygiene and cough etiquette techniques;
- General hygiene practices; and
- Transmission-based precautions related to specific medical conditions.

XI. References and Resources

1) OSHA BBP Standard
2) OSHA Fact Sheet - Hepatitis B Vaccination Protection
3) OSHA Safety and Health Topics | Bloodborne Pathogens and Needlestick Prevention
4) OSHA Model Plans and Programs for the OSHA BBP and Hazard Communications Standards
5) Guidelines for Environmental Infection Control in Health-Care Facilities--Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)
6) ICE Safety & Health Branch

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7) ICE Occupational Safety and Health Program Requirements Handbook, accessible on the ICE Safety & Health Branch InSight page

8) NIOSH Information for Employers Complying with OSHA's BBP Standard

9) CDC Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program

10) National HIV/AIDS Clinicians' Consultation Center

11) NIOSH Workplace Safety & Health Topics | Bloodborne Infectious Diseases | HIV/AIDS, Hepatitis B, Hepatitis C

12) HICPAC | 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

13) CDC Healthcare-associated Infections (HAIs) - In Outpatient Settings

14) CDC MMWR Guideline for Hand Hygiene in Health-Care Settings

15) Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

IHSC Occupational Health Guide: Personal Protective Equipment Program

Approved by: (b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Date signed: (b)(6); (b)(7)(C)

Latest Update: May 10, 2018

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Foreword

This IHSC Occupational Health Guide: Personal Protective Equipment Program (PPE) supplements the following IHSC Directive:

- IHSC Directive: 05-02, *Occupational Health*.

This guide explains concepts, assigns responsibilities, and details procedures for the implementation of IHSC's PPE Program.

The intended audience is all IHSC clinical health staff that support health care operations within IHSC-staffed medical clinics.

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I. Overview

A. Purpose

The purpose of this guide is to provide health staff with the procedures and resources to implement the elements of the Personal Protective Equipment (PPE) Program as required by the IHSC directive: 05-02, *Occupational Health*.

IHSC is dedicated to promoting a safe work environment. IHSC implements programs to minimize employee hazards through training and the use of administrative controls, work practice controls, and engineering controls. PPE supplements these primary control methods.

B. Responsibilities

The IHSC Public Health, Safety, and Preparedness (PHSP) Unit:

- Provides national oversight of PPE program activities;
- Provides technical guidance to medical clinics on PPE program activities;
- Reviews and updates this guide and the IHSC directive: 05-02, *Occupational Health*; and
- Conducts periodic program assessments.

The IHSC Health Services Administrators (HSAs) and Compliance Officers (COs):

- Oversee and implement the medical clinic's PPE program;
- Oversee and verify the job hazard analysis (JHA);
- Purchase, or assist with purchasing, and maintain a supply of staff PPE needed for routine and emergency use;
- Ensure health staff receive initial and annual PPE training;
- Monitor the PPE program and report problems (COs only) to the HSA; and
- Facilitate completion of information requests for monitoring and following up on workforce health-related reports, interventions, and process improvements.

IHSC Health Staff are responsible for the following PPE:

- Participate in the JHA;
- Inspect, don, doff, maintain, and store PPE, as specified in the Occupational Safety and Health (OHSA) standard 1910.132 Personal Protective Equipment;

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- Dispose of contaminated single-use PPE in the designated waste receptacle prior to leaving the work area;
- Remove PPE before leaving clinic work areas (e.g., for break, to lunch rooms, the restroom, or facility corridors); and
- Adhere to national guidelines, regulations, and OHSA standard 1910.132 Personal Protective Equipment on PPE.

C. Acronyms

BBP – Bloodborne pathogens

CDC – U.S. Centers for Disease Control and Prevention

FDA – U.S. Food and Drug Administration

JHA – Job hazard analysis

NIOSH – National Institute for Occupational Safety and Health

OPIM – Other Potentially Infectious Materials

OSHA – U.S. Occupational Safety and Health Administration

PPE – Personal protective equipment

µm - The symbol for micrometer, or micron (um), which is a unit of length equaling 1×10−6 meter (System International, SI, standard prefix "micro-" = 10−6) or equal to one millionth of a meter (or about a tenth of the size of a droplet of mist).

D. Definitions with Expanded Information

Administrative Controls – Methods of controlling employee exposures through enforcement of policies and procedures, modification of work assignment, training in specific work practices, and other administrative measures designed to reduce exposures.

Bloodborne Pathogens – Pathogenic microorganisms that are present in human blood and can cause disease in humans (e.g., hepatitis B virus (HBV) and human immunodeficiency virus (HIV)).

Body Fluid – Fluid secreted by the body including, but not limited to blood, semen, saliva, urine, and feces.

Don – To put on (as in clothing or PPI).

Doff – To remove.

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Engineering Controls – Controls that isolate or remove a hazard from the workplace(e.g., ventilation systems, isolation, sharps disposal containers, self-sheathing needles).

Exposure – The condition of being subjected to something in the working environment (such as noise, dust, chemicals, radiation, infectious agents) that could have an adverse effect on health.

N95 Respirator – An N95 respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95% of very small (0.3 micron) test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. The N95 respirator is worn to protect the wearer from exposures in the air borne contaminates. N95 respirators that are cleared by FDA for use in health care settings are called "Surgical N95 Respirators." The N95 respirator is not worn by a patient (or people with chronic respiratory, cardiac, or other medical conditions that make breathing difficult), because the N95 respirator can make it more difficult for the wearer to breath.

Other Potentially Infectious Materials (OPIM) – Includes the following four types of materials: (1) secretions of semen or vaginal fluid, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any bodily fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) unfixed tissue or organ (other than intact skin) from a living or dead human; (3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV containing culture medium or other solutions; and (4) blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Personal Protective Equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases, and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, and steel toe boots.

Respirator – A form of PPE with filtering capability that fits snug on the face over the nose and mouth to prevent the wearer from inhaling hazardous airborne particles.

Surgical Mask – A protective device that covers the patient's nose and mouth to protect health care workers from exposures to wearer-generated microorganisms.

Work Practice Controls – Controls that reduce the likelihood of exposure by outlining or prescribing the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

E. PPE Description

PPE is clothing or equipment that is worn to protect a person's body parts, or the whole body, from exposures that may result in injuries or illnesses. Hazardous exposures in the workplace may be physical (e.g., radiation, noise), chemical (e.g.,

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disinfectants), and/or biological (e.g., tuberculosis). Protective clothing such as gloves, booties, shoes, and boots protect the body and limbs; protective goggles such as glasses and face shields protect the eyes and parts of the face; and respirators protect the wearer from inhaling air contaminants.

Prior to considering PPE, other means of controlling hazards should be implemented such as training and administrative controls, work practice controls, and engineering controls. Training is extremely important to the health and safety of employees. Administrative controls include policies and procedures, human and monetary resources, schedules, breaks, job rotation, and training. Work practice controls include safe work practices, avoiding hazardous activities, avoiding eating and drinking in work areas, and practicing good hygiene. Engineering controls include ventilation, isolation, and redesign of a process or procedure. PPE should only be considered after all hazards, capable of causing injury or impairment to the body, cannot be eliminated by other means. PPE is considered the last resort in occupational health and safety because PPE does not reduce or eliminate the source hazard; and if the PPE fails, or is used improperly, the employee may be exposed to a hazard.

F. **Types of PPE:**

- **Protective Clothing:** Employees should wear protective gowns, lab coats, aprons or jumpsuits to protect the skin and clothing from splash, spray, or mist hazards. These can be disposable (e.g., paper gowns) or reusable and washable (e.g., lab coats).

- **Eye and Face Protection:** Depending on the type of hazard, employees should use goggles to protect the eyes, or a face-shield to protect larger portions of the face (e.g., eyes, nose, and mouth), from the airborne contaminate or threat (e.g., splash, spray, or mist).

- **Respirators:** Depending on the type of airborne contaminate or threat, employees should use the designated respirator to protect from inhaling airborne pollutants.

- **Hand Protection**: Employees should use gloves to protect the hands from cuts, abrasions, burns, as well as to avoid skin contact with chemical, biological, and physical hazards. Employees should consider using the glove designed for a specific type of application for protection, since one type of glove does not protect against all potential hand hazards.

- **Foot Protection:** Employees should use shoe covers to protect personal footwear from chemicals or bodily fluids, and wear protective shoes and boots when there are electrical hazards or if a potential work crush hazard exists to the feet or toes.

II. Program Elements

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The eight elements of a PPE program, as mandated by OSHA, include the following:

1) Job hazard analysis,
2) Selection,
3) Purchase,
4) Storage,
5) Use and limitations,
6) Care,
7) Disposal, and
8) Training.

III. Job Hazard Analysis

A. Overview

The job hazard analysis (JHA) is the first step in determining what PPE to use. The JHA is the cornerstone of workplace health and safety. It educates employees and involves them in a way that encourages them to take responsibility for their own safety. It identifies work hazards that may be overlooked, minimized, or assumed to be inherent to the job. It identifies work hazards that may be currently controlled using PPE, but that could be better controlled with engineering, work practice, or administrative controls. A JHA is a simple three-step process:

1) List tasks associated with each job title or classification in the medical clinic;
2) Identify the hazards of the specific work tasks that, if left uncontrolled, could potentially result in harm;
3) Identify the controls, and the PPE, that will reduce or eliminate the hazards for each job task.

B. Method

The HSA must oversee the completion and accuracy of the JHA. The HSA must involve health staff in completing the JHA. Health staff must list their job title, or job classification, and the tasks that they perform as part of their daily clinic duties. Health staff must also list their less frequent weekly or monthly activities. The HSA must instruct health staff to identify the tasks that they perform with a focus on tasks that are complex, have high rates of injury or illness, have the potential to cause severe injury or illness, and have the potential for severe consequences if one mistake occurred.

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Next, health staff must identify hazards associated with the tasks within their job title or classification, paying particular attention to what could happen, even if the hazard has never occurred before.

Finally, health staff must list the controls and PPE that are, or should be, employed to reduce each hazard. The HSA must review the JHA results and verify that health staff accurately described their job duties, hazards, controls, and PPE.

C. Review and Update

The HSA must review and update the JHA as needed, and at least annually, to ensure all clinic activities are included. As new tasks or jobs are introduced, the HSA must add them to the JHA without waiting until the annual review. The HSA must involve new health staff in the JHA to ensure their awareness in the process of breaking jobs down into tasks to better identify hazards and controls.

IV. Selection, Purchase, and Storage

The HSA must select PPE based on the anticipated hazards and exposures identified in the JHA, as well as on fit, quality, durability, and employee comfort. The HSA must oversee the purchase of PPE to ensure that the number, type, and shelf life of the PPE supplies are adequate for health staff use. The HSA must ensure that supplies of PPE are monitored and inventoried to make certain they are not in short supply or expired. The HSA must ensure that all PPE the medical clinic purchases for the prevention of disease exposure are FDA approved.

The HSA must ensure that PPE supplies are stored in a clean, cool, dry area of the medical clinic and that health staff have ready access to PPE. Health staff must clean and store their reusable PPE in a clean, dry place to prevent cross-contamination. Health staff must replace reusable PPE when it is no longer in working condition.

V. Use and Limitations

PPE is used to prevent the wearer from a hazard that cannot be eliminated by other means of control in the environment. Health staff must inspect, don, doff, clean, store, and dispose of PPE according to OHSA standard 1910.132 Personal Protective Equipment.

PPE is not without its limitations. PPE adds safety hazards by restricting movement, vision, communication, and dexterity. PPE can also be hot and increase perspiration from covered body parts. There are psychological stressors that can result from frequent PPE use. PPE is considered the last resort in occupational health and safety because PPE does not reduce or eliminate the source hazard, and if the PPE fails, or is used improperly, the employee may be exposed to a hazard.

The following procedures (shown below) are for routine PPE donning and doffing. Some infectious diseases might require specific PPE and donning and doffing procedures. Selection of face protection will be dependent upon the potential pathogen exposure.

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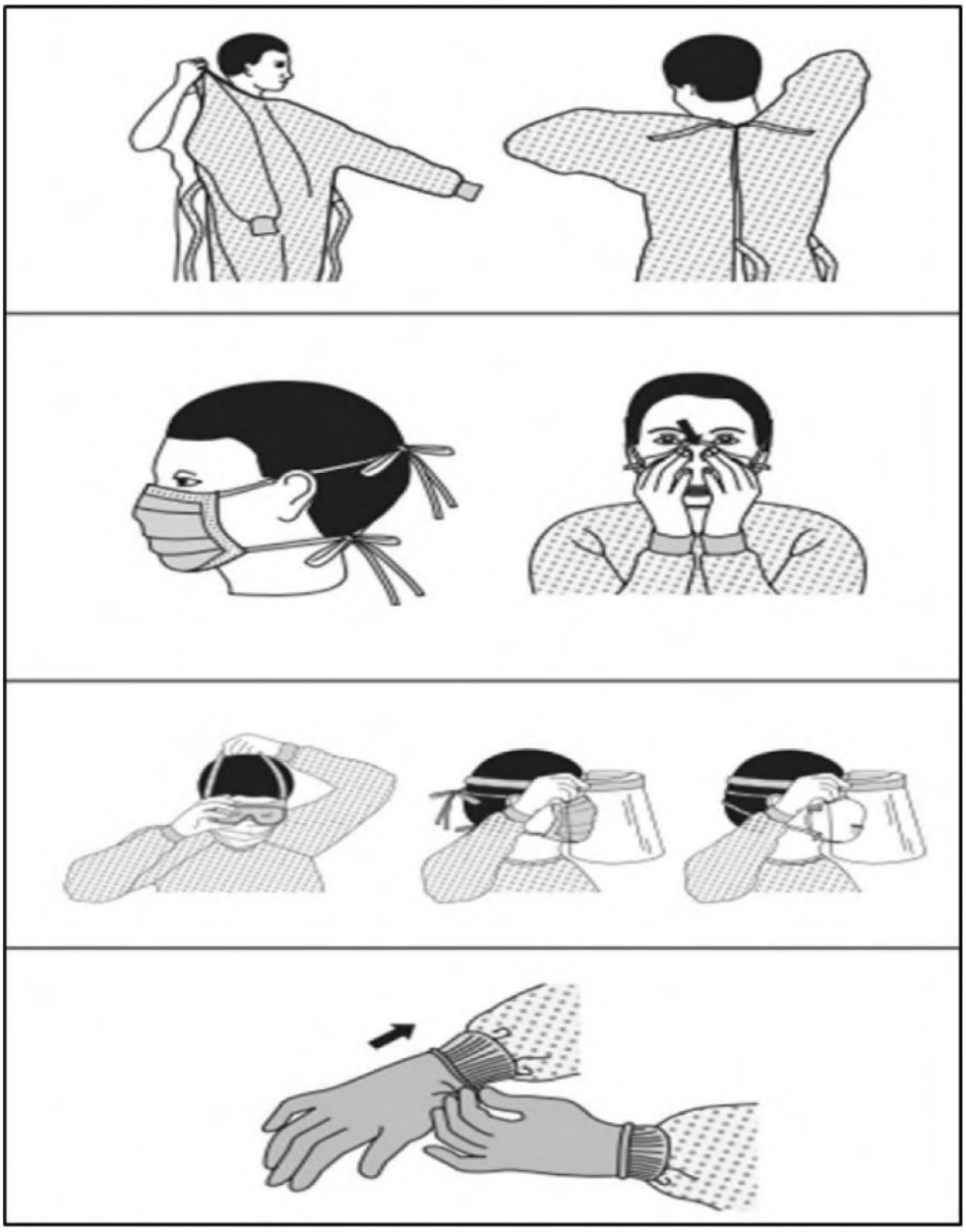
A. **Donning Sequence**

1) Put on a clean gown.

2) Inspect and put on a clean surgical mask or respirator; perform fit checks.

3) Put on clean goggles or a face shield, adjust to fit.

4) Put on a clean pair of gloves, extend to cover wrist of isolation gown.



B. **Doffing Sequence**

1) Assume that your PPE is contaminated.

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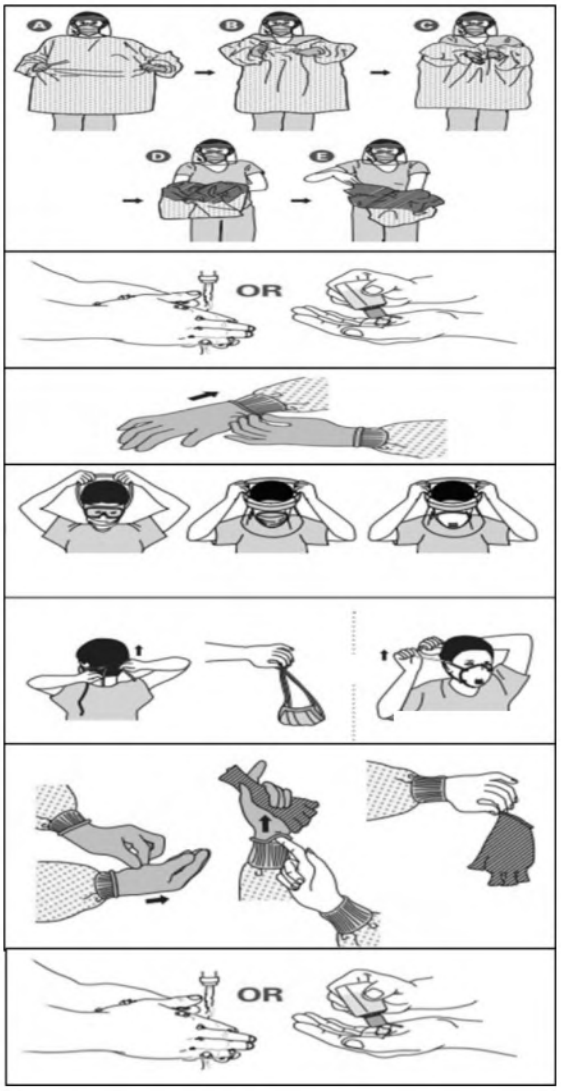
2) Grasp the gown in front and pull away from body. Only touch the outside of the gown with gloves. While removing the gown, fold or roll the gown inside out, and peel off your gloves at the same time, such that your bare hands only touch the inside of the gloves and the gown.

3) Wash hands or use hand sanitizer and don clean gloves.

4) Remove goggles or face shield for disposal or processing. If hands become contaminated during removal, wash hands or use hand sanitizer and don new clean gloves again.

5) Remove the surgical face mask or respirator without touching the front of the mask to avoid contamination. Dispose of it in the designated receptacle.

6) Remove gloves and dispose of them in the designated receptacle. Wash hands immediately after removing PPE and when leaving work.



Surgical Face Mask

or

Respirator

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VI. Training and Education

The HSA, or designee, must ensure that orientation and annual training that includes the PPE Program is implemented and documented in accordance with IHSC Directive 01-04, Medical Education and Development.

VII. Program Monitoring and Evaluation

The PHSP Unit staff periodically collect information from the HSA to monitor the implementation of the PPE Program and to ensure that the medical clinic is meeting the requirements of this program.

VIII. References and Resources

1) OSHA PPE Standard
2) OSHA Job Hazard Analysis
3) CDC Healthcare-associated Infections - Protecting Healthcare Personnel

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S Immigration and Customs Enforcement

IHSC Occupational Health Guide: Respiratory Protection Program

Approved by (b)(6); (b)(7)(C) **DHSc**

Title: ERO – IHSC AD

Date signed: (b)(6); (b)(7)(C)

Latest Update: May 9, 2018

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Foreword

This *IHSC Occupational Health Guide: 05-02 G-3 Respiratory Protection Program (RPP)* supplements the following IHSC Directive:

- IHSC Directive: 05-02, Occupational Health

This guide explains concepts, assigns responsibilities, and details procedures, for the implementation and maintenance of IHSC's RPP.

The intended audience is all health staff that support health care operations within IHSC-staffed medical clinics in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this guide is to provide health staff with procedures and resources to implement the elements of the IHSC RPP as required by the IHSC Directive: 05-02, Occupational Health.

IHSC is dedicated to promoting a safe work environment. IHSC reduces employee exposures to airborne hazards through the primary control methods of training, administrative controls, work practices, and engineering controls. Respiratory protection is a form of personal protective equipment (PPE) that is used when these primary control methods cannot remove airborne hazards.

B. Responsibilities

The IHSC Public Health, Safety, and Preparedness (PHSP) Unit:

- Provides national oversight of the IHSC's RPP activities;
- Provides technical guidance to medical clinics with RPP activities;
- Reviews and updates this guide and IHSC directive 05-02, Occupational Health; and
- Conducts periodic program evaluations.

The Health Services Administrator (HSA) and Compliance Officer (CO):

- Oversee and implement the medical clinic RPP.
- Purchase and maintain a supply of Food and Drug Administration (FDA) approved respirators in a variety of brands, models, and sizes, with a current shelf life.
- Ensure health staff receive orientation and annual training.
- Designate competent personnel to perform respirator fit testing.
- Monitor RPP program and report problems.
- Facilitate completion of information requests for monitoring and following up on workforce health-related reports, interventions, and process improvements.

Health Staff are responsible for the following RPP components:

- Complete the respiratory medical evaluation prior to initial fit testing.
- Complete the respirator fit test annually.
- Complete required initial and annual training.
- Inspect, don, doff, and dispose of respirators as specified in the IHSC Directive: 05-02, Occupational Health.
- Adhere to designated national guidelines, regulations, and standards on respiratory protection.

C. Acronyms

CDC – U.S. Centers for Disease Control and Prevention

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FDA – U.S. Food and Drug Administration

JHA – Job hazard analysis

NIOSH – National Institute for Occupational Safety and Health, CDC

OSHA – U.S Occupational Safety and Health Administration

PPE – Personal protective equipment

D. Definitions with Expanded Information

Administrative Controls – Methods of controlling employee exposures through enforcement of policies and procedures, modification of work assignment, and training.

Don – To put on as in clothing or personal protective equipment (PPE).

Doff – To take off clothing or PPE from the face or body.

Fit Test – Procedures performed by a qualified person that demonstrate that a wearer attains a good face seal with a specific size and brand of respirator.

Engineering Controls – Controls that isolate or remove a hazard from the workplace (e.g., ventilation systems, isolation, sharps disposal containers, self-sheathing needles).

Exposure – The condition of being subjected to something in the working environment (such as noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Respirator Medical Evaluation – A medical evaluation to determine a person's ability to wear a respirator while performing certain work activities with airborne hazards.

N95 Respirator – An N95 respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95% of very small (0.3 micron) test particles. If properly fitted, the filtration capabilities of N95 respirators exceed those of face masks. The N95 respirator is worn to protect the wearer from exposures in the air borne contaminates. N95 respirators that are cleared by FDA for use in health care settings are called "Surgical N95 Respirators." The N95 respirator is not worn by a patient (or people with chronic respiratory, cardiac, or other medical conditions that make breathing difficult), because the N95 respirator can make it more difficult for the wearer to breath.

Personal Protective Equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, and infectious

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diseases, and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, and steel-toe boots.

Qualitative Fit Test – A pass/fail fit test; reliant on individual perception and response to a sweet or bitter test agent when determining the size and brand of respirator that provides an optimum face seal.

Rainbow Passage – A paragraph read during a fit test to mimic normal speaking behaviors that may compromise the face seal of a respirator: "When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow."

Respirator – A form of PPE with filtering capability that fits snug on the face over the nose and mouth to prevent the wearer from inhaling hazardous airborne particles.

Sensitivity Test – A test performed, prior to the fit test, to determine if a person can taste a bitter or sweet aerosol and how much is needed for the person to taste it, which can vary from person to person.

Surgical Mask – A protective device that covers the patient's nose and mouth to protect health care workers from exposures to wearer-generated microorganisms.

Work Practice Controls – Controls that reduce the likelihood of exposure by outlining or prescribing the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

II. Program Elements

A. Written Procedures

The HSA, or designee, must develop and maintain local written procedures describing how the clinic implements and adheres to the elements of the RPP.

B. Assessment of Air Hazards

Respirator selection is based on the type and concentration of airborne hazard encountered by an employee when performing assigned job duties. The airborne hazard assessment is part of the job hazard analysis (JHA) described in detail in *IHSC's occupational health guide: 05-02 G-2 Personal Protective Equipment Program.* The primary airborne hazards health staff may encounter during patient care activities are air transmissible organisms, including, but not limited to, tuberculosis, influenza, and varicella.

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C. Respirator Medical Evaluation

Federal OSHA regulations require a respirator medical evaluation to ensure a staff member's ability to tolerate the physical and mental demands of wearing a respirator in an occupational setting. The respirator medical evaluation includes a medical questionnaire that is reviewed by a professionally licensed health care provider and must be completed prior to fit testing.

- **All staff**. All health staff must complete the respirator medical evaluation by completing the OSHA Respirator Medical Evaluation Questionnaire.

- **Federal staff**. Federal staff should complete the Online Respirator Medical Evaluation (ORME) available at https://resp-eval.foh.psc.gov/login/. A licensed medical provider through the Health and Human Services agency's Federal Occupational Health reviews the ORME. Federal staff who complete the ORME will receive a written medical determination for respirator use that they must print out and provide to the HSA prior to respirator fit testing. Federal staff who do not complete the online process (i.e., the ORME), or are unable to receive a medical determination for respirator use through the ORME, can complete a hard copy of the OSHA Respirator Medical Evaluation Questionnaire

- **Contract staff.** Contract staff cannot use the online format and should complete an OSHA Respirator Medical Evaluation Questionnaire through their service vendor's occupational health program. Per OSHA regulations, non-federal licensed health care professionals should be able to receive an evaluation at no cost.

- The licensed health care professional should provide the employer with a written medical determination for respirator use after reviewing the questionnaire, or medical examination. The medical evaluation document must include three elements:
    1. Whether the employee is medically able to wear the respirator and if he or she has any medical limitations for using the respirator;
    2. The need, if any, for the employee to have a follow-up medical evaluation; and
    3. A statement that the licensed health care professional has provided the staff with a copy of their written recommendation.

- Contract staff should submit the written medical determination for wearing a respirator, signed by the health care professional, to the employer and HSA.

- Staff should not submit a copy of the completed OSHA Respirator Medical Evaluation Questionnaire, or any confidential medical information, to the employer or HSA.

- The OSHA Respirator Medical Evaluation Questionnaire is not required to be completed annually. However, health staff must be reevaluated if one of the

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following four conditions occur:

1. The staff member reports medical signs or symptoms that are related to his or her ability to use a respirator, such as a heart condition, lung disease, or claustrophobia;
2. The supervisor, government technical monitor (GTM), or the person with oversight for the RPP, informs the employer, or GTM, that the staff member needs to be reevaluated;
3. Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for the staff to be reevaluated; and/or
4. A change occurs in workplace conditions that increase the burden on the staff while using the respirator. For example, the job becomes more physically demanding, the staff must wear additional protective clothing, or the staff must work in extreme temperatures.

- Some conditions that may preclude a person from wearing a respirator include certain respiratory diseases, arrhythmias, claustrophobia, certain medications, certain neurological disorders, and certain endocrine disorders.

D. Respirator Fit Testing

Federal staff fit testing. OSHA regulations require annual respirator fit testing. For fit testing federal staff, the HSA must implement OSHA fit test protocols, provide equipment and supplies, and ensure personnel are available to perform annual fit testing. The HSA must choose competent personnel, who possess an understanding of respirators and the fit test process, to conduct fit testing. There is no official fit test training available; however, fit testing training tools are located on the PHSP SharePoint web site under "Occupational Health" then "Tools and Resources".

Contract staff fit testing. Contract staff must use their employer's fit testing procedures and provide the HSA with documentation of the results including the make, model, and size of respirator(s) for which the staff was successfully fit tested.

Requirements for a successful fit test. A prerequisite for a successful fit test is a satisfactory face seal that prevents air contaminants from reaching the breathing zone of the wearer. One size and brand of respirator does not fit every facial size and shape. The respirator mask-to-face seal requires careful scrutiny to ensure the inhalation of contaminants is avoided. An effective face seal is difficult for individuals with facial hair. Beards and mustaches must not interfere with the face seal. Persons with relatively long or small faces, or larger noses, may also encounter difficulty obtaining a successful face seal. The HSA must ensure that a selection of brands, models, and sizes of respirators are available to accommodate staff with varying facial characteristics.

Health staff must be fit tested:

- Prior to initial use;

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- Annually;
- If a different respirator size, style, make, or model is used; and
- If a person experiences changes in physical condition that could affect respirator fit such as, significant weight gain or loss (10%), major dental or cosmetic surgery, and/or facial injury or scarring.

A comprehensive fit test includes the following five components:

1. Availability of a variety of respirator brands, models, and sizes;
2. Availability of the two fit test agents saccharin and bitrex;
3. Sensitivity testing the day before the fit test to ensure that the person being fit tested detects the fit test agent;
4. Fit test exercises and reading of the "Rainbow Passage" (see Section D, Definitions); and
5. Documentation of fit test results including the make, model, and size of respirator(s) for which the staff member was successfully fit tested.

E. Respirator Selection

The HSA must select a variety of respirator brands, models, and sizes that are both NIOSH and FDA approved for protection against the airborne infection hazards encountered in the medical clinic. NIOSH classifies and certifies respirators for general and specific use. FDA certifies respirators to protect the wearer specifically from exposure to diseases. All respirators used to protect health staff must be NIOSH and FDA approved. Useful information about health care respiratory protection is available on the NIOSH Healthcare-Related FAQs website.

F. Respirator Inspection, Use, and Replacement

Prior to each use, health staff must inspect their respirator to ensure there are no defects in the face-piece or headbands. If a deficiency is discovered, the respirator must be discarded for a new one. Health staff must don the respirator and perform a face seal check prior to entering the hazardous environment. (Procedural details can be found on OSHA's website). Health staff must use the respirator for the tasks they perform that pose an airborne hazard.

N-95 respirators used in the health care setting are not manufactured for repair or reuse. Multiple donnings of the same respirator impacts the fit and integrity of the respirator. When the fit or integrity of the respirator is questionable or compromised, health staff run the risk of exposure to airborne hazards. Respirators must never be shared. Respirators must always be discarded when visibly soiled, they contain excess moisture, or cause the wearer increased resistance to breathing.

III. Training and Education

The HSA, or CO, must ensure that initial and annual training, that includes bloodborne pathogens and other potentially infectious materials, is provided and documented in

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accordance with IHSC Directive 01-04, Medical Education and Development.

IV. Program Monitoring and Evaluation

The PHSP Unit staff periodically collect information from the HSA to monitor the implementation, and maintains after implementation, of the RPP and to ensure that the medical clinic is meeting the requirements of the program.

V. References and Resources

(1) OSHA | Respiratory Protection

(2) OSHA Respiratory Protection Standard

(3) OSHA Fit Test Protocols

(4) Respiratory Infection Control OSHA Fact Sheet

(5) OSHA | Small Entity Compliance Guide for the Respiratory Protection Standard

(6) OSHA | Hospital Respiratory Protection Program Toolkit: Resources for Respirator Program Administrators

(7) NIOSH Healthcare-Related FAQs

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

IHSC Occupational Health Guide: Workforce Health

Approved by: (b)(6); (b)(7)(C) MPH

Title: ERO-IHSC AD

Date signed: (b)(6); (b)(7)(C)

Date revised: May 16, 2018

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Foreword

This IHSC Occupational Health Guide: *05-02 G-4 Workforce Health* supplements the following IHSC Directive:

- IHSC Directive: 05-02, Occupational Health

This guide, the fourth guide under the 05-02 directive, explains concepts, assigns responsibilities, and details procedures, for implementing the elements of IHSC's Workforce Health Program.

The intended audience is all health staff that support health care operations within IHSC-staffed medical clinics in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this guide is to provide health staff with the details and resources to implement and comply with elements of a workforce health program as required by IHSC Directive: 05-02, Occupational Health.

The IHSC Workforce Health (WH) Program elements include initial and ongoing monitoring of staff health records to include tuberculosis (TB) infection status, promotion of vaccinations against diseases frequently encountered in a health care setting, medical surveillance, workforce health documentation, recording and reporting of occupational injuries and illnesses, and occupational health training.

B. Responsibilities

The Public Health, Safety, and Preparedness (PHSP) Unit:

- Provides national oversight of IHSC's WH Program;
- Provides technical assistance related to the program;
- Reviews and updates this guide and IHSC Directive: 05-02, Occupational Health; and
- Conducts periodic program evaluations.

The Health Services Administrator (HSA) and Compliance Officer (CO):

- Oversee the WH Program for the medical clinic;
- Perform ongoing monitoring of WH records;
- Collect and maintain WH documents for inclusion in the staff member's health file;
- Document, investigate, and track occupational injuries, illnesses, and exposures;
- Ensure health staff receive initial and annual training on WH related topics;
- Perform ongoing monitoring of health and safety indicators for the health staff;
- Monitor OSHA requirements for injury and illness reporting and recording of all health staff;
- Monitor employee radiation exposures and serve as the subject matter expert for radiation safety; and
- Facilitate completion of information requests for monitoring and following up on workforce health-related reports, interventions, and process improvements.

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The Health Staff:

- Provide documentation of initial, annual, and periodic TB screening;
- Report an occupational injury, illness, or exposure to the HSA as soon as possible;
- Obtain initial and annual training on WH related topics; and
- Adhere to the WH requirements mandated in IHSC Directive: 05-02, Occupational Health.

C. Acronyms

ACIP – Advisory Committee on Immunization Practices

CDC – The Centers for Disease Control and Prevention

CO – Compliance officer

CXR – Chest x-ray

DTAP – Diphtheria, tetanus, acellular pertussis vaccine

FDA – The Food and Drug Administration

IGRA – Interferon-gamma release assay

HIV – Human immunodeficiency virus

MSDS – Material safety data sheet

NIOSH – The National Institute for Occupational Safety and Health

OSHA – The Occupational Safety and Health Administration

PEP – Post-exposure prophylaxis

PPE – Personal protective equipment

TST – Tuberculosis skin test

TB – Tuberculosis

D. Definitions with Expanded Information

Booster effect (or phenomenon) – A TB infected person does not react to an initial tuberculosis skin test (TST) because the person's immune system does not react to it. However, if a second TST is placed, it "boosts" the persons immune

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system and a positive reaction will result. This positive reaction does not represent a recent infection, rather it is an old infection, and the reaction only happens with the TST, not the IGRA.

TST conversion – Going from negative to positive after an exposure to TB.

Catastrophe – One or more fatalities from a work-related incident, or the inpatient hospitalization of three or more employees as a result of a work-related incident.

Exposure – The condition of being subjected to something (e.g., an infectious agent) that could have an adverse health effect.

Injury or illness – OSHA defines an injury or illness as an abnormal condition or disorder. Injuries include cases such as, but not limited to, a cut, fracture, sprain, or amputation. Illness includes both acute and chronic illnesses such as, but not limited to, a skin disease, respiratory disorder or poisoning.

Symptom screening – A clinical evaluation performed by a health care provider that includes questions and various assessments that are telling of a condition, disease onset, or a departure from normal.

Symptomatic – A term applied to a patient with health-related complaints (i.e., symptoms) that might indicate the presence of disease.

Vaccine – A suspension containing antigenic molecules, derived from a microorganism, given to stimulate an immune response to an infectious disease.

Workers' compensation – Refers to the Federal Employees' Compensation Act (FECA) which is a law that provides compensation benefits to civilian employees of the U.S. for disability due to personal injury - including occupational diseases - sustained while in the performance of duty.

II. Tuberculosis Screening

A. At Time of Hire

ICE detention facilities are classified as non-minimal risk, unless there is evidence of ongoing transmission in accordance with the CDC TB Guidelines (Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from the CDC). Based on this classification, IHSC health staff must be screened initially and annually for TB infection by their usual source of health care. The HSA must ensure that newly-hired health staff complete this requirement within 30 days of their start date and provide documentation of their current TB infection status to the HSA. The accepted two TB infection screening methods are:

1. Two-step tuberculin skin test (TST) within three weeks of each other.

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2. Single-step FDA-approved Interferon-Gamma Release Assay (IGRA).

If both TST results are negative, or if the IGRA is negative, the person is considered not TB infected at the time of hire.

- The TST booster effect: A person infected with TB years ago may have a negative reaction to an initial TST and a positive reaction to the second TST. This is attributed to the immune stimulation from the first TST and is called the "booster effect." The two-step TST method confirms old TB infection and should not be interpreted as a TST conversion (i.e., going from negative to positive after an exposure). The IGRA test does not create the "booster effect."

- Staff member with TB infection: If the first or second TST result is positive, or if the IGRA is positive, the person is considered TB infected. The staff member must provide documentation of the TB infection and any work restrictions to the HSA. A newly-hired staff member with TB infection is encouraged to seek diagnosis and treatment guidance from their personally accessed source for health care.

B. Annual TB Screening

On the anniversary of a staff member's start date, staff without prior TB infection must complete an annual TB infection screening with either a TST or IGRA through their personally accessed source of health care. It is preferable that staff use the same TB screening method from year to year. The staff member must provide documentation of the results to the HSA. The HSA, CO, or designee, must use the PHSP workforce injury tool to report the occurrence of TB test conversions within seven working days, as this may indicate ongoing TB transmission or a breakdown of infection controls within the facility.

In addition, on the anniversary of a staff member's start date, the staff member with a TB infection must complete an annual symptom screening for TB disease through their personally accessed source of health care and provide the documentation to the HSA for inclusion in their workforce health file. Staff with TB infection should never repeat the TST or IGRA. IHSC staff also do not need to obtain an annual CXR if the following two conditions are met: (1) their most recent CXR was normal, and (2) they have no signs or symptoms of TB disease.

C. Periodic TB Screening

Health staff may be required to verify their TB infection status following an unprotected exposure to a contagious TB patient, or if there is a known transmission in the facility. If evidence of ongoing transmission exists, health staff must be periodically screened for TB infection until there is no evidence of ongoing transmission. Health staff should undertake TB infection screening, by TST or IGRA, through their personally accessed source of health care. TB

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infection resulting from a work-related occupational exposure - as evidenced by either a positive skin test or diagnosis by a health care provider – must be recorded on two forms: (1) OHSA's Form 301, Injury and Illness Incident Form and (2) on IHSC's Workforce Injury Reporting Tool. The IHSC Workforce Injury Reporting Tool replaces OSHA Form 300, Log of Work-Related Injuries and Illnesses.

III. Highly Recommended Vaccinations for Health Care Workers

Based on documented nosocomial transmission, health care workers are at significant risk for acquiring or transmitting hepatitis B, measles, mumps, rubella, varicella, and seasonal influenza. All of these diseases are vaccine-preventable. Therefore, the following five single and combination vaccines are highly recommended for health staff, unless they have documented presumptive immunity:

1. Hepatitis B;
2. Varicella;
3. Measles, mumps, rubella (MMR);
4. Diphtheria, tetanus, acellular pertussis (DTAP); and
5. Annual seasonal influenza.

Health staff must provide immunization documentation, or titer (IgG) results, for these diseases to the HSA for placement in the staff health file. For more details, refer to CDC's Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC).

A. Hepatitis B Vaccination

The OSHA Bloodborne Pathogens (BBP) Standard requires employers to provide staff, at risk for occupational exposure to blood and other potentially infectious material, the hepatitis B vaccination series. The HSA provides health staff information about the risks of exposure to hepatitis B on the job and the importance of the vaccine. Health staff must take one of three actions after completing BBP training:

1. Complete the hepatitis B vaccination series. Newly-hired federal employees, with no history of hepatitis B vaccination, should obtain the vaccination through their personal source of health care; contract staff should follow the instructions of their employer;
2. Provide documentation of the hepatitis B vaccination series, or the titer (IgG) results, that confirm immunity to the hepatitis B virus; or
3. Decline the vaccination series for medical contraindications or self-declination and provide documentation of declination on the IHSC Hepatitis B Declination Form.

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B. Annual Influenza Vaccination

Health care personnel with influenza (clinical or asymptomatic), and in direct contact with detainees/residents, may transmit influenza that could result in serious complications. Therefore, civilian staff members providing direct care to detainees/residents are strongly encouraged to obtain the annual seasonal influenza vaccine from their personal source of health care. Annual influenza vaccinations are required for all Public Health Service (PHS) officers.

The HSA should promote annual seasonal influenza vaccination and educate health staff about the benefits of an annual flu vaccine. IHSC civilian staff are also encouraged to be vaccinated against emerging influenza viruses as appropriate and in accordance with the recommendations of the Advisory Committee on Immunization Practices (APIC), available at the CDC's "Influenza (Flu)" website for lay persons and at the CDC's website for health professionals, "Seasonal Influenza Vaccination Resources for Health Professionals".

All health staff members who receive the influenza vaccine, civilian and PHS, must provide documentation of receiving the annual influenza vaccine to the HSA. The HSA must place documentation in the staff health file.

C. Pregnant Employees and Vaccinations

Pregnant staff should discuss the potential occupational exposures they may encounter in the medical clinic with their obstetrician to make informed decisions about vaccination. Hepatitis B vaccination should be considered if not otherwise contraindicated. The live attenuated influenza vaccine is contraindicated in pregnant women, but the inactivated influenza vaccine is indicated. For more information, refer to CDC's Vaccines and Immunizations - Guidelines for Vaccinating Pregnant Women.

IV. Reproductive Hazards in the Workplace

There are workplace hazards that may affect the female reproductive system, the ability to become pregnant, and the potential for a successful pregnancy outcome. There are workplace hazards that may affect the male reproductive system as well. Some of the hazards that may be present are chemicals (e.g., ethylene oxide, lead, nitrous oxide, xylene, toluene), ionizing radiation, certain viruses and infections, certain drugs, heavy lifting, frequent bending, prolonged standing or sitting, night work, and long work hours. The HSA must ensure that health staff are aware of potential reproductive hazards in the medical clinic. The HSA must provide staff members with the safety data sheets (SDS) for chemicals that staff are exposed to. Staff may take a copy to share with their health care provider. Staff members are encouraged to discuss concerns about reproductive hazards with the HSA as well as their personal health care provider. For more information refer to the National Institute for Occupational Safety and Health (NIOSH) webpages at The Effects of Workplace Hazards on Female Reproductive Health or The Effects of Workplace Hazards on Male Reproductive Health.

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V. Monitoring Workforce Radiation Exposures

OSHA requires employers to monitor staff radiation exposures. Staff members working with or around x-ray emitting equipment may be exposed to ionizing radiation. The HSA must issue a radiation dosimeter to all staff working with, and/or near, x-ray equipment. The HSA, or CO, is also responsible for monitoring radiation exposure levels of all applicable staff members including pregnant staff members. An employee's declaration of pregnancy must be in writing. It is the right of the staff member to determine if pregnancy should and will be declared; the staff member should not be asked nor forced to declare pregnancy by anyone, even if the staff member appears to be visibly showing signs of pregnancy.

The HSA, or CO, is responsible for the following five actions related to radiation exposure monitoring:

1. Collecting dosimeters from staff and sending them for radiation dose measurements on a quarterly basis, or monthly for pregnant staff;
2. Monitoring staff exposure levels and initiating investigations on doses greater than 500 millirem of ionizing radiation per quarter;
3. Maintaining the staff radiation dose record in the staff health file;
4. Ensuring that staff exposure to radiation does not exceed 5.0 rem per year; and
5. Monitoring a pregnant staff member's radiation exposure to ensure the exposure does not exceed 500 millirem of radiation during the entire pregnancy and no more than 50 millirem during a single month of pregnancy.

VI. Medical Surveillance

Medical surveillance is the process of assessing changes in an individual staff member's health status, as well as changes in the health of the staff as a group, over time. If adverse outcomes are discovered in individuals, or adverse trends are discovered in groups of staff, this may indicate that hazard avoidance controls are not effective. The HSA must oversee medical surveillance (e.g., TB infection status, other occupational illness status, radiation exposures) in the medical clinic by monitoring staff health status throughout the year.

VII. Staff Health File

The HSA, or designee, must maintain a staff health file for each IHSC health staff member in a locked cabinet in accordance with the following laws: (a) The Privacy Act of 1974, 5 USC 552a, in the DHS | Handbook for Safeguarding Sensitive Personally Identifiable Information; (b) the Office of Personnel Management, Employee Medical Records System of Records, 75 Federal Register 35099 (June 21, 2010); and (c) in the Department of Labor, Office of Workers' Compensation Programs, Federal Employees' Compensation Act File System of Records, 77 Federal Register 1738, (January 11, 2012); and (d) in any other applicable system. The staff member's health file should contain the following documents:

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- Initial and annual TB infection screening results;
- Vaccination records and/or declination documentation as applicable;
- OSHA's Form 301, Injury and Illness Incident Form (Appendix B);
- BBP exposure documentation;
- Annual respirator medical clearance;
- Annual respirator fit test results; and
- Other staff health documents.

All staff health files will be maintained for the period of the staff member's service to IHSC. At the completion of the staff member's service to IHSC, the HSA should send the staff member's health files to the IHSC Personnel Unit (IPU). Upon receipt of the staff member's health files, IPU should transfer the records to the National Personnel Records Center or to the next employing federal agency.

VIII. Privacy and Recordkeeping

Please refer to the IHSC Directive: 05-02, Occupational Health, for guidance on complying with privacy and recordkeeping laws and policies.

IX. Occupational Injury and BBP Post-Exposure Management

Health staff must immediately report an injury and/or exposure to blood and/or other potentially infectious material to their supervisors. When a staff member is injured or exposed while on the job, health staff should notify local emergency medical services if needed. Staff requiring urgent post-exposure prophylaxis (PEP) following a BBP exposure should be released from the shift duty so they can promptly seek PEP care through a personal source of health care, which may be at an urgent care center or emergency department. Visit the CDC's website for the "Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis". Health staff must be referred to their personal source of health care for all medical attention other than life saving care.

A. BBP Post-Exposure Management

If exposures to BBP and other potentially infectious material occur, staff should immediately receive post-exposure management either from a personal medical provider or at the nearest urgent care center or emergency department. Post-exposure management should include counseling and an evaluation of any reported illness. The HSA must document the incident in accordance with OSHA's BBP Standard for inclusion in the staff member's health file. The HSA, or designee, will provide the staff member with a copy of the staff member's health record and results of the source individuals serology - if known and available. The HSA, or CO, should advise the exposed staff member to provide the attending personal health care provider with the following information:

1. Copy of the OSHA BBP Standard;

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2. Documentation of the route of exposure;
3. Description of the circumstances under which the exposure occurred;
4. Results of source individual's HIV, HBV, and Hepatitis C virus serology, if known and available; and
5. The staff member's health record related to exposure or post-exposure management.

B. HIV Post-Exposure Prophylaxis and Follow-Up Testing

When a staff member suspects exposure to HIV from an infected detainee, the staff member should be advised by the HSA, CO, nurse manager, supervisor, or designee, of the need to seek medical care for initiating PEP as soon as possible, and no greater than 72 hours after the exposure incident. For additional information, refer to CDC's webpages at "HIV/AIDS PEP" and "Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis".

The OSHA BBP Standard mandates HIV testing at six weeks, 12 weeks, and six months after exposure to a confirmed HIV-infected person. It also requires CD4+ counting, Western Blot and HIV antigen tests.

C. Hepatitis B and C Post-Exposure Management

When staff are exposed to hepatitis B or C, the staff should begin post-exposure management as soon as possible, but no longer than 24 hours after the exposure incident. For additional information regarding hepatitis B and C exposures, refer to the Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.

D. BBP Post-Exposure Follow Up

Following an exposure to blood or other potentially infectious material, the HSA must meet with the exposed staff member for confidential follow up and complete the following actions while referencing the HIV Post-Exposure Checklist*.

1. Document the route(s) of exposure;
2. Describe the circumstances of the exposure;
3. Identify and document the source individual (if available and not prohibited by state or local law);
4. Inform the source individual of the incident and obtain consent for hepatitis and HIV testing (unless known to be seropositive) if permitted by law;
5. Provide the source individual's test results to the exposed staff member after being informed of the laws and regulations regarding confidentiality; and
6. Advise the staff member to follow up with a personal source of health care for further testing and post-exposure management.

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NOTE: This information is guidance only, the checklist is not an official form and should not be held in the staff member's health file, and should not be marked with the staff member's name and/or other personally identifiable information. If the HSA would like to formally document that follow up was completed, a memo for the staff member's health file is an option.

X. Recording and Reporting Requirements for Staff Work-Related Injury, Illness, or Death

The OSHA Recording and Reporting Occupational Injuries and Illness Standard mandates the employer to document all work-related injuries, illnesses, and deaths. See OSHA Injury & Illness Recordkeeping Forms for forms and instructions. Consistent with OSHA regulations, the entity that provides day-to-day oversight of the work performed at a worksite is required to comply with OSHA recording and reporting requirements for all workers at the worksite. Therefore, the HSA, or CO, must record and report occupational injuries and illnesses for federal employees and contract staff in accordance with the specifications outlined in this directive, unless the contracted employee's supervisor works on-site. If the contracted employee's supervisor works on-site, the HSA should refer contract staff to their supervisors for recording and reporting of occupational injuries or illnesses. When a staff member is injured on the job, they must report it to their supervisor or government technical monitor immediately. The HSA or CO must ensure that all documentation of employee or contractor injury, illness, or death, complies with the Privacy Act, applicable ICE privacy policies, and IHSC directives. The HSA must retain OSHA records for five years.

If the injury or illness is wholly caused by non-work factors, then it is not work-related and will not be recorded in the OSHA records. If work contributed to the illness in some way, then it is work-related and must be evaluated for its recordability. When questionable, report the incident to your local OSHA Area Office director who will decide whether or not to investigate the incident.

A. Recording Work-Related Deaths, Injuries, or Illnesses

OSHA's Form 301, Injury and Illness Incident Form

The HSA, or CO, must document all work-related injuries, illnesses, or deaths, on OSHA's Form 301, Injury and Illness Incident Form, within seven days of the incident or notification. General recording criteria include the any of the following types of incidents:

- Work-related event contributing to an employee death, days away from work, work restriction, or job transfer;
- Loss of consciousness;
- Medical treatment beyond first aid;
- The diagnosis of a significant injury or illness by a medical provider; and

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- Work related needlesticks, and cuts from sharp objects, that are contaminated with another person's blood or other potentially infectious material.

For a list of several work-related exceptions to recording and reporting, as well as defining criteria for medical treatment, first aid, and restricted work, refer to OSHA Injury and Illness Recordkeeping and Reporting Requirements. The HSA must place OSHA's Form 301 in the staff member's health file. The HSA, or CO, must also record contract personnel injuries on OSHA's Form 301, unless the contract employer supervisor works on-site and manages the recording and reporting of occupational injuries and illnesses. The staff member may request a copy of OSHA's Form 301, Injury and Illness Incident Form, to provide to their medical provider for treatment and follow up.

Workforce Injury Reporting Tool (functioning as OSHA's Form 300, Log of Work-Related Injuries and Illnesses)

OSHA requires employers to keep a log of work-related injuries throughout the year on OSHA's Form 300, Log of Work-Related Injuries and Illnesses – which IHSC replaces with its own reporting tool, the Workforce Injury Reporting Tool. OSHA's Form 300 summarizes all recordable work-related injuries and illnesses from OSHA's Form 301 and provides a means of tracking these incidents during the year. The HSA, or CO, must document all work-related injuries on the Workforce Injury Reporting Tool on the PHSP Unit SharePoint page. The Workforce Injury Reporting Tool can filter records marked as OSHA-recordable or OSHA-reportable incidents to function in replace of OSHA's Form 300, the Log of Work-Related Injuries and Illnesses.

The HSA must retain IHSC's electronic equivalent of OSHA's Form 300 for a minimum of five years. The HSA or CO must update the Workforce Injury Reporting Tool (functioning as OSHA's Form 300) within seven working days of notification of a work-related injury or illness. The Workforce Injury Reporting Tool may contain personal identifiable information, unless it involves a privacy concern related incident, in which case, the HSA or CO must remove all personable identifiable information and enter only "privacy case" with a case number for reference back to the original OSHA form 301, Injury and Illness Incident Form.

The following examples of privacy case injuries or illnesses that must *not* include personal identifiable information include incidents involving:

- sexual assaults,
- HIV infections,
- mental illness,
- needlesticks, or
- any case incident at the request of the affected employee.

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The HSA, or CO, must continue to update the Workforce Injury Reporting Tool for lost workdays, restricted work activity, or job transfers related to all work-related injuries or illnesses for up to 180 days - excluding the day of the injury or illness, but including weekends and holidays. The HSA or CO must maintain the information on the Workforce Injury Reporting Tool on a calendar year basis. However, lost workdays running into a new calendar year must be continued on the new log, until the employee returns to work or reaches the 180-day limit for recording.

OSHA's Form 300A, Summary of Work-Related Injuries and Illnesses

OSHA requires employers to summarize all of the injuries and illnesses that occur during the course of the calendar year on OSHA's Form 300A, Summary of Work-Related Injuries and Illnesses, or document that no work-related injuries or illnesses occurred during the calendar year. At the end of each calendar year, the HSA, or CO, must compile the incident information from the Workforce Injury Reporting Tool and complete OSHA's Form 300A. The HSA, or CO, must ensure that OSHA's Form 300A does *not* include any personal identifiable information.

The HSA, or CO, must post OSHA's Form 300A from the previous year in the medical clinic from February 1 until April 30 each year. During this time period, the HSA, or CO, must post OSHA's Form 300A in a conspicuous place where employees will notice it. The HSA, and CO, must ensure that it does not get covered up by other announcements or posted materials.

B. Reporting Work-Related Deaths, Injuries or Illnesses

Deaths

OSHA requires all work-related deaths, or deaths occurring within 30 days of a work-related incident, to be reported to the nearest OSHA Area Office within eight hours of the death or notification of the death. Upon notification of the death, the following personnel must undertake the following actions:

1. **HSA:** The HSA must immediately notify their supervisor by telephone;
2. **Regional HSA:** The Regional HSA must immediately continue notifications by contacting the Chief, Health Operations Unit via telephone;
3. **Chief, Health Operations Unit:** must immediately continue notifications by contacting the Deputy Assistant Director (DAD) via telephone;
4. **Deputy Assistant Director:** The DAD then contacts the Assistant Director (AD) by telephone; and
5. **Assistant Director**: The AD, or designee, must promptly notify the ICE Safety and Sustainability Division Chief.

The HSA must also notify the OSHA Area Office within 8 hours of incident. The initial report to OSHA can be made verbally over the telephone, or in person, to the OSHA Area Office nearest to the site of the incident. If the OSHA Area

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Office is closed, the initial report to OSHA can also be made using their toll-free central telephone number, 1-800-321-6742.

Hospital Admissions, Amputations, or Loss of an Eye

OSHA requires all work-related injuries that result in inpatient hospitalizations, amputations, or the loss of an eye to be reported to the nearest OSHA Area Office within 24 hours of the incident. Upon notification of the incident, the HSA must immediately notify the supervisor by telephone, who should continue immediate notifications by telephone through the supervisory chain to the IHSC AD. Secondly, the HSA must notify the OSHA Area Office within 24 hours of the incident. The AD or designee must promptly notify the ICE Safety and Sustainability Division Chief.

Catastrophes

Catastrophes are one or more fatalities from a work-related incident, or the inpatient hospitalization of three or more staff members from a work-related incident, as defined by OSHA. OSHA requires all deaths, or hospital admissions resulting from a catastrophic work-related incident, to be reported to the nearest OSHA Area Office within eight hours of the incident. Upon notification of the incident, the HSA must immediately notify the supervisor by telephone, who should continue immediate notifications by telephone through the supervisory chain to the IHSC AD. Secondly, the HSA must notify the OSHA Area Office within eight hours of the incident. The AD or designee must promptly notify the ICE Safety and Sustainability Division Chief.

XI. Post-Incident Review and Follow Up

A. Investigations

Every accident, injury, or exposure has causes, conditions, and potential uncontrolled hazards. The HSA and CO must analyze each incident and gather information to identify these root causes and conditions. The PHSP Unit provides assistance with an investigation of a staff member accident or injury upon request.

B. Tracking Trends

The HSA, or CO, must review the Workforce Injury Reporting Tool on at least a quarterly basis, to identify patterns or trends in staff injuries or illnesses. The HSA, or CO, must investigate trends in a similar way that incidents are investigated to determine root causes or potentially uncontrolled hazards.

C. Corrective Action Plans

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Based on incident investigations and trend analysis, the HSA, or CO, must develop corrective action plans for situations where hazards are not being controlled or preventive measures are not being observed or utilized. The PHSP Unit assists with these plans upon request. The HSA, or CO, must contact the detention facility administrator responsible for safety when corrective action plans require detention facility actions or modifications.

D. Workers' Compensation

The process for determining whether a report/claim must be filed with Workers' Compensation must be evaluated separately from the OSHA recordkeeping process. Staff members should refer all questions related to workers' compensation to their respective employer's human capital office.

XII. Program Monitoring

The PHSP Unit periodically collects information from the HSA to monitor the required elements of the IHSC Workforce Health Program within the medical clinic.

XIII. Training and Education

The HSA, or designee, must ensure that initial and annual training that includes occupational health is provided and documented in accordance with IHSC Directive: 01-04, Medical Education and Development.

XIV. References and Resources

(1) Occupational Safety and Health (OSH) Act of 1970

(2) OSHA Recording and Reporting Occupational Injuries and Illness Standard

(3) CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management

(4) OSHA Forms for Recording Work-Related Injuries and Illnesses

(5) Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis

(6) *CDC's Vaccines and Immunizations - Guidelines for Vaccinating Pregnant Women*

(7) CDC Seasonal Influenza Vaccination Resources for Health Professionals

(8) ICE Occupational Safety and Health (OSH) Program Requirements Handbook, accessible at the Safety and Health Branch InSight page.

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OM 15-013
EFFECTIVE DATE: 06 OCT 2015

By Order of the IHSC Deputy Assistant Director, Clinical Services and Medical Director
CAPT (b)(6); (b)(7)(C) **MD/s/**

TO: IHSC Commissioned Corps Officers, Civilian Federal Employees and Contract Personnel

SUBJECT: IHSC Immunization Protocol for ICE Family Residential Centers

1. **APPLICABILITY.** This memorandum is applicable to all Commissioned Corps officers, civilian government employees, and contractors assigned to the ICE Health Service Corps (IHSC). Please reference OM 15-007, dtd 03 July 2105, for additional information on juvenile immunization protocol.

2. **PURPOSE.** To set forth the policies and procedures for immunizations of family units while in the custody of ICE at Family Residential Centers (FRCs).

3. **RESPONSIBILITIES.** The IHSC medical authority assigned to an IHSC FRC, in collaboration with the administrative authority, will coordinate the provision of immunizations to residents.

4. **PROCEDURES**

   The following guidance is predicated upon standard immunization schedules as published and maintained at: http://www.cdc.gov/vaccines/schedules/ and http://www.immunize.org/cdc/schedules/. These guidelines have been jointly approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians.

   This OM prioritizes immunization practices to address vaccination needs based on the primary countries of origin of FRC residents and takes into consideration an average one-month length of stay coupled with the need to control common communicable diseases within FRCs. All pediatric residents will be offered and scheduled vaccinations, per the appropriate immunization schedule, within seven (7) days of facility arrival unless the resident has a documented medical contraindication, the resident declines vaccination and a refusal form is completed, or immunization records documenting prior vaccination are provided.

   a. Vaccinating Pediatric Residents

      (1) The current immunization schedules can be located at: http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

      (2) Combination vaccines should be used whenever possible to minimize the number of injections. A child may receive multiple vaccines at one time, as clinically indicated.

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(3) Proquad vaccine (MMR and varicella vaccines) is Food and Drug Administration (FDA) approved for children 12 months through 12 years of age.

(4) A tuberculin skin test (TST) can be administered before or simultaneously with Proquad or the MMR vaccines. TST administration must be delayed for 6 weeks if Proquad or MMR vaccines were recently administered. If it is accidentally administered, it is not dangerous to the patient's health, but the TST results cannot be considered valid.

(5) A lapse in the recommended time sequence does not require the immunization series be restarted. Rather, continue the immunization schedule from the last set of immunizations.

(6) If a resident's immunization status is unknown or uncertain, the resident is considered unimmunized and the age-appropriate catch-up immunization schedule should be initiated.

(7) A self-reported history of prior disease (such as varicella) does not imply immunity and the child should be assessed based on vaccination status; however, exceptions may be made based on clinical judgment by the local medical authority on a case by case basis (e.g., if the history is corroborated by scars consistent with chickenpox). Antibody titers may be obtained in order to determine immunity.

(8) An attempt should be made to give all allowable vaccines at the same time.

b. Vaccinating Adult Residents

(1) The current adult immunization schedules can be located at:
http://www.cdc.gov/vaccines/schedules/hcp/adult.html
http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule.pdf

(2) The only routine immunizations offered to adults are varicella and influenza.

(3) Other immunizations may be given as clinically indicated, on a case-by-case basis.

c. Vaccine Information Statement (VIS)

(1) A current VIS will be provided to the mother/child for any vaccination given.

(2) VISs in multiple languages are available: http://www.immunize.org/vis/.

(3) Vaccination Consent Form. IHSC form 793 (Medical Consent) will be used to document informed consent for any immunizations administered to an adult or child.

d. Administering Vaccines

(1) Vaccine specific administration information can be found at:
http://www.immunize.org/catg.d/p3085.pdf

(2) Vaccination Process for Children

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(a) Intake screening: The parent will be questioned about the child's vaccination history and whether vaccination records are in their possession. A vaccination appointment is scheduled for all children by day seven (7) utilizing *e* Clinical Works (*e*CW) clinical rules engine.

(b) Health assessment: The parent will be questioned about the child's vaccination history.

If previously vaccinated but no vaccination records are in their possession:

- The provider will explain the importance of obtaining the record within the next 14 days (via fax).
- The vaccination appointment previously scheduled to occur on day seven (7) will be completed by the provider completing the health assessment or by an immunization nurse and annotated to reflect that immunizations are being refused due to prior vaccination and that the resident is seeking a copy of their vaccination record.
- Upon closing the day seven (7) immunization encounter, *e*CW will schedule a follow-up immunization encounter at Day 14.
- The provider will explain that if the mother is unable to obtain the record, they will have the option to have their child vaccinated at the 14 day follow-up immunization appointment.
- Written instructions explaining how residents can have their vaccination records sent to family residential facility will be provided in Spanish or will be translated, as appropriate, in the residents' native language.
- At the 14 day follow-up appointment, any vaccination records received via fax will be reviewed. All requisite vaccinations will be offered. A provider will place immunization orders if the mother accepts vaccination, or a refusal form will be completed if vaccinations are declined.

If vaccination records cannot be obtained or if the child has not been previously vaccinated:

- During the health assessment, the provider will order necessary immunizations to be given at the day seven (7) immunization encounter.
- The vaccinations previously ordered will be offered at the day seven (7) immunization encounter.
- If a parent declines immunization, a refusal form will be completed.

(3) Vaccination Process for Adults

(a) During the health assessment, all adults will be questioned regarding their varicella history.

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(b) If the resident reports a prior history of varicella, this will be documented in *e*CW and no further action will be taken.

(c) If the resident reports no prior history of varicella, the resident will be provided education about the varicella vaccine and vaccination will be offered if no medical contraindications are present.

(d) If the resident elects to receive the vaccine, the provider conducting the health assessment will order the vaccine. Once the order is placed in *e*CW, the provider will send an Action to the Medical Records Technician (MRT). The MRT will schedule the resident's immunization appointment.

(e) If the resident elects to not receive the varicella vaccine, a refusal form will be completed.

e. Vaccine Adverse Events

(1) Vaccine adverse events will be reported through the Vaccine Adverse Event Reporting System (VAERS) within 7 days of the adverse event. https://vaers.hhs.gov/index

(2) The adverse event information may be submitted online at https://vaers.hhs.gov/esub/step1, or by fax or mail.

f. Documentation

All vaccinations administered will be documented in the resident's health record as well as any state vaccination database in accordance with applicable state and federal regulations.

5. **No Privacy Act Statement.** This memorandum is an internal statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

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4.3 Medical Care

I. Purpose and Scope

This detention standard ensures that detainees have access to appropriate and necessary medical, dental and mental health care, including emergency services.

This detention standard applies to the following types of facilities housing ICE/ERO detainees:

- Service Processing Centers (SPCs);
- Contract Detention Facilities (CDFs); and
- State or local government facilities used by ERO through Intergovernmental Service Agreements (IGSAs) to hold detainees for more than 72 hours.

Procedures in italics are specifically required for SPCs, CDFs, and Dedicated IGSA facilities. Non-dedicated IGSA facilities must conform to these procedures or adopt, adapt or establish alternatives, provided they meet or exceed the intent represented by these procedures.

For all types of facilities, procedures that appear in italics with a marked (**) on the page indicate optimum levels of compliance for this standard.

Various terms used in this standard may be defined in standard "7.5 Definitions."

II. Expected Outcomes

The expected outcomes of this detention standard are as follows (specific requirements are defined in "V. Expected Practices").

1. Detainees shall have access to a continuum of health care services, including screening, prevention, health education, diagnosis and treatment.

   ***Medical facilities within the detention facility shall achieve and maintain current accreditation with the National Commission on Correctional Health Care (NCCHC), and shall maintain compliance with those standards.*

2. The facility shall have a mental health staffing component on call to respond to the needs of the detainee population 24 hours a day, seven days a week.

3. The facility shall provide communication assistance to detainees with disabilities and detainees who are limited in their English proficiency (LEP). The facility will provide detainees with disabilities with effective communication, which may include the provision of auxiliary aids, such as readers, materials in Braille, audio recordings, telephone handset amplifiers, telephones compatible with hearing aids, telecommunications devices for deaf persons (TTYs), interpreters, and note-takers, as needed. The facility will also provide detainees who are LEP with language assistance, including bilingual staff or professional interpretation and translation services, to provide them with meaningful access to its programs and activities.

   All written materials provided to detainees shall generally be translated into Spanish. Where practicable, provisions for written translation shall be made for other significant segments of the population with limited English proficiency.

   Oral interpretation or assistance shall be provided to any detainee who speaks another language in which written material has not been translated or who is illiterate.

   Newly-admitted detainees shall be informed orally or in a manner in which the detainee understands about how to access, appeal or communicate concerns about health services.

4. Detainees shall be able to request health services on a daily basis and shall receive timely follow-up.

5. Detainees shall receive continuity of care from

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time of admission to time of transfer, release or removal. Detainees, who have received medical care, released from custody or removed shall receive a discharge plan, a summary of medical records, any medically necessary medication and referrals to community-based providers as medically-appropriate.

6. A detainee who is determined to require health care beyond facility resources shall be transferred in a timely manner to an appropriate facility. A written list of referral sources, including emergency and routine care, shall be maintained and updated annually.
7. A transportation system shall provide timely access to health care services that are not available at the facility. Procedures for use of this transportation system shall include: a) prioritization of medical needs; b) urgency (such as the use of an ambulance instead of standard transportation); c) transfer of medical information and medications; and d) safety and security concerns of all persons.
8. A detainee who requires close, chronic or convalescent medical supervision shall be treated in accordance with a written treatment plan conforming to accepted medical practices for the condition in question, approved by a licensed physician, dentist or mental health practitioner.
9. Twenty-four hour emergency medical and mental health services shall be available to all detainees.
10. Centers for Disease Control and Prevention (CDC) guidelines for the prevention and control of infectious and communicable diseases shall be followed.
11. Occupational Safety and Health Administration (OSHA) and applicable state guidelines for managing bio-hazardous waste and decontaminating medical and dental equipment shall be followed.
12. Detainees with chronic conditions shall receive care and treatment, as needed, that includes monitoring of medications, diagnostic testing and chronic care clinics.
13. The facility administrator shall notify ICE/ERO, in writing, of any detainee whose medical or mental health needs require special consideration in such matters as housing, transfer or transportation.
14. Each detainee shall receive a comprehensive medical, dental and mental health intake screening as soon as possible, but no later than 12 hours after arrival at each detention facility. Detainees who appear upon arrival to raise urgent medical or mental health concerns shall receive priority in the intake screening process.
15. Each detainee shall receive a comprehensive health assessment, including a physical examination and mental health screening, by a qualified, licensed health care professional no later than 14 days after entering into ICE custody or arrival at facility. For the purposes of the comprehensive medical examination, a qualified licensed health provider includes the following: physicians, physician assistants, nurses, nurse practitioners, or others who by virtue of their education, credentials and experience are permitted by law to evaluate and care for patients.
16. Qualified, licensed health care professionals shall classify each detainee on the basis of medical and mental health needs. Detainees shall be referred for evaluation, diagnosis, treatment and stabilization as medically indicated.
17. At no time shall a pregnant detainee be restrained, absent truly extraordinary circumstances that render restraints absolutely necessary.
18. Detainees experiencing severe, life-threatening intoxication or withdrawal symptoms shall be transferred immediately for either on-site or off-site emergency department evaluation.

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19. Pharmaceuticals and non-prescription medicines shall be secured, stored and inventoried.

20. Prescriptions and medications shall be ordered, dispensed and administered in a timely manner and as prescribed by a licensed health care professional. This shall be conducted in a manner that seeks to preserve the privacy and personal health information of detainees.

21. Health care services shall be provided by a sufficient number of appropriately trained and qualified personnel, whose duties are governed by thorough and detailed job descriptions and who are licensed, certified, credentialed and/or registered in compliance with applicable state and federal requirements.

22. Detention and health care personnel shall be trained initially and annually in the proper use of emergency medical equipment and shall respond to health-related emergency situations.

23. Information about each detainee's health status shall be treated as confidential, and health records shall be maintained in accordance with accepted standards separately from other detainee detention files and be accessible only in accordance with written procedures and applicable laws. Health record files on each detainee shall be well organized, available to all practitioners and properly maintained and safeguarded.

24. Informed consent standards shall be observed and adequately documented. Staff shall make reasonable efforts to ensure that detainees understand their medical condition and care.

25. Medical and mental health interviews, screenings, appraisals, examinations, procedures and administration of medication shall be conducted in settings that respect detainees' privacy in accordance with safe and/orderly operations of the facility.

26. A detainee's request to see a health care provider of the same gender should be considered; when not feasible, a same-gender chaperone shall be provided. When care is provided by a health care provider of the opposite gender, a detainee shall be provided a same-gender chaperone upon the detainee's request.

27. Detainees in Special Management Units (SMUs) shall have access to the same or equivalent health care services as detainees in the general population, as specified in standard "2.12 Special Management Units."

28. ***Adequate space and staffing for the use of services of the ICE Tele-Health Systems, inclusive of tele-radiology (ITSP) and tele-medicine, shall be provided.*

29. All detainees shall receive medical and mental health screenings, interventions and treatments for gender-based abuse and/or violence, including sexual assault and domestic violence.

30. This standard and the implementation of this standard will be subject to internal review and a quality assurance system in order to ensure the standard of care in all facilities is high.

III. Standards Affected

This detention standard replaces "Medical Care" dated 12/2/2008.

IV. References

American Correctional Association, *Performance-based Standards for Adult Local Detention Facilities*, 4th Edition: 4-ALDF-2A-15, 4C-01 through 4C-31, 4C-34 through 4C-41, 4D-01 through 4D-21, 4D-23 through 4D-28, 2A-45, 7D-25.

American College of Obstetricians and Gynecologists, *Guidelines for Women's Health Care* (3rd edition. 2007); "Special Issues in Women's Health" (2005).

American Public Health Association *Standards for*

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Health Services in Correctional Institutions, *Health Services for Women*.

Centers for Disease Control and Prevention website, www.cdc.gov (for the most current guidelines and recommendations on tuberculosis case management and control, HIV management, health care acquired infections, infection control, influenza management, respiratory protection, infectious diseases of public health significance, emerging infectious diseases, and correctional health)

United States Department of Health and Human Services, HIV Clinical Guidelines Portal, http://aidsinfo.nih.gov/Guidelines/default.aspx (for the most current national guidelines on HIV Management)

Infectious Diseases Society of America, http://www.idsociety.org/Content.aspx?id=9088 (for the most current infectious diseases practice guidelines prepared or endorsed by the Infectious Diseases Society of America)

National Commission on Correctional Health Care, *Standards for Health Services in Jails* (2014).

Exec. Order 13166.

ICE/ERO *Performance-based National Detention Standards 2011:*

- "1.2 Environmental Health and Safety," particularly in regard to storing, inventorying and handling needles and other sharp instruments; standard precautions to prevent contact with blood and other body fluids; sanitation and cleaning to prevent and control infectious diseases; and disposing of hazardous and infectious waste;
- "2.11 Sexual Abuse and Assault Prevention and Intervention";
- "4.2 Hunger Strikes";
- "4.6 Significant Self-harm and Suicide Prevention and Intervention"; and
- "4.7 Terminal Illness, Advance Directives and Death."

ICE Health Service Corps (IHSC) *Policies and Procedures Manual*.

The Joint Commission.

www.flu.gov

www.aids.gov

"*Standards to Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities*," 79 Fed. Reg. 13100 (Mar. 7, 2014).

V. Expected Practices

A. General

Every facility shall directly or contractually provide its detainee population with the following:

1. Initial medical, mental health and dental screening;
2. Medically necessary and appropriate medical, dental and mental health care and pharmaceutical services;
3. Comprehensive, routine and preventive health care, as medically indicated;
4. Emergency care;
5. Specialty health care;
6. Timely responses to medical complaints; and
7. Hospitalization as needed within the local community.
8. Staff or professional language services necessary for detainees with limited English proficiency (LEP) during any medical or mental health appointment, sick call, treatment, or consultation.

***Medical facilities within the detention facility shall achieve and maintain current accreditation with the National Commission on Correctional Health Care (NCCHC), and shall maintain compliance with those standards.*

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B. Designation of Authority

A designated health services administrator (HSA) or the equivalent in non-IHSC staffed detention facilities shall have overall responsibility for health care services pursuant to a written agreement, contract or job description. The HSA is a physician or health care professional and shall be identified to detainees.

The designated clinical medical authority (CMA) at the facility shall have overall responsibility for medical clinical care pursuant to a written agreement, contract or job description. The CMA shall be a medical doctor (MD) or doctor of osteopathy (DO). The CMA may designate a clinically trained professional to have medical decision making authority in the event that the CMA is unavailable.

When the HSA is other than a physician, final clinical judgment shall rest with the facility's designated CMA. In no event shall clinical decisions be made by non-clinicians.

The HSA shall be authorized and responsible for making decisions about the deployment of health resources and the day-to-day operations of the health services program. The CMA together with the HSA establishes the processes and procedures necessary to meet the medical standards outlined herein.

All facilities shall provide medical staff and sufficient support personnel to meet these standards. A staffing plan will be reviewed at least annually which identifies the positions needed to perform the required services.

Health care personnel perform duties within their scope of practice for which they are credentialed by training, licensure, certification, job descriptions, and/or written standing or direct orders by personnel authorized by law to give such orders.

The facility administrator, in collaboration with the CMA and HSA, negotiates and maintains arrangements with nearby medical facilities or health care providers to provide required health care not available within the facility, as well as identifying custodial officers to transport and remain with detainees for the duration of any off-site treatment or hospital admission.

C. Communicable Disease and Infection Control

1. General

Each facility shall have written plans that address the management of infectious and communicable diseases, including screening, prevention, education, identification, monitoring and surveillance, immunization (when applicable), treatment, follow-up, isolation (when indicated) and reporting to local, state and federal agencies.

Plans shall include:

a. coordination with local public health authorities;

b. ongoing education for staff and detainees;

c. control, treatment and prevention strategies;

d. protection of detainee confidentiality;

e. media relations, in coordination with the local Public Affairs Officer (PAO);

f. procedures for the identification, surveillance, immunization, follow-up and isolation of patients;

g. hand hygiene

h. management of infectious diseases and reporting them to local and/or state health departments in accordance with established guidelines and applicable laws; and

i. management of bio-hazardous waste and decontamination of medical and dental equipment that complies with applicable laws and standard "1.2 Environmental Health and Safety."

Facilities shall comply with current and future plans implemented by federal, state or local authorities addressing specific public health issues including

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communicable disease reporting requirements. Infectious and communicable disease control activities shall be reviewed and discussed in the quarterly administrative meetings as described in Section V.DD of this detention standard. Designated medical staff shall report to the IHSC Public Health, Safety, and Preparedness Unit all detainees diagnosed with a communicable disease of public health significance.

2. Tuberculosis (TB) Management

As indicated in this standard below in section "J. Medical and Mental Health Screening of New Arrivals," screening for TB is initiated at intake and in accordance with Center for Disease Control and Prevention (CDC) guidelines.

All new arrivals shall receive TB screening within 12 hours of intake and in accordance with CDC guidelines (www.cdc.gov/tb). For detainees that have been in continuous law enforcement custody, symptom screening plus documented TB screening within one year of arrival may be accepted for intake screening purposes.

Annual or periodic TB testing shall be implemented in accordance with CDC guidelines; annual TB screening method should be appropriately selected with consideration given to the initial screening method conducted or documented during intake.

Detainees with symptoms suggestive of TB, or with suspected or confirmed active TB disease based on clinical and/or laboratory findings, shall be placed in a functional airborne infection isolation room with negative pressure ventilation and be promptly evaluated for TB disease. Patients with suspected active TB shall remain in airborne infection isolation until determined by a qualified provider to be noncontagious in accordance with CDC guidelines.

For all patients with confirmed and suspected active tuberculosis, designated medical staff shall:

a. Report all cases to local and/or state health departments within one working day of meeting reporting criteria and in accordance with established guidelines and applicable laws, identified by the custodial agency and the detainee's identifying number of that agency (ICE detainees are reported as being in ICE custody and are identified by their alien numbers).

b. Report all detainees with suspected or confirmed TB to the ICE Health Service Corps (IHSC), Public Health, Safety, and Preparedness Unit within one working day of initial identification with suspected or confirmed TB disease.

   Reporting shall include names, aliases, date of birth, alien number, case status/classification, available diagnostic and lab results, treatment status (including drugs and dosages), treatment start date, a summary case report, and a point of contact and telephone number for follow-up.

c. Promptly report any movement of TB patients, including hospitalizations, facility transfers, releases, or removals/deportations to the local and/or state health department and the IHSC Public Health, Safety, and Preparedness Unit.

When treatment is indicated, multi-drug, anti-TB therapy shall be administered using directly observed therapy (DOT) in accordance with American Thoracic Society (ATS) and CDC guidelines. For patients with drug-resistant or multi-drug-resistant TB, the state or local health department shall be consulted to establish a customized treatment regimen and treatment plan. Patients receiving anti-TB therapy shall be provided with a 15 day supply of medications and appropriate education when transferred, released or deported, in an effort to prevent interruptions in treatment until care is continued in another location.

Treatment for latent TB infection (LTBI) shall not be initiated unless active TB disease is ruled out.

Designated medical staff shall coordinate with the IHSC Epidemiology Unit and the local and/or state health department to facilitate an international referral and continuity of therapy. Designated

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medical staff shall collaborate with the local and/or state health department on tuberculosis and other communicable diseases of public health significance.

3. Significant Communicable Disease

Designated medical staff shall notify the IHSC Public Health, Safety, and Preparedness Unit of any ICE detainee with a significant communicable disease and of any contact or outbreak investigations involving ICE detainees exposed to a significant communicable disease without known immunity. Significant communicable diseases include, but are not limited to, varicella (chicken pox), measles, mumps, pertussis (whooping cough), and typhoid.

4. Bloodborne Pathogens

Infection control awareness shall be communicated on a regular basis to correctional and medical staff, as well as detainees. Detainees exposed to potentially infectious body fluids (e.g., through needle sticks or bites) shall be afforded immediate medical assistance, and the incident shall be reported as soon as possible to the clinical director or designee and documented in the medical file. All detainees shall be assumed to be infectious for bloodborne pathogens, and standard precautions are to be used at all times when caring for all detainees.

Each facility shall establish a written plan to address exposure to bloodborne pathogens; the management of hepatitis A, B, and C; and the management of HIV infection, including reporting.

a. Hepatitis

   A detainee may request hepatitis testing at any time during detention

b. HIV

   A detainee may request HIV testing at any time during detention. Persons who must feed, escort, directly supervise, interview or conduct routine office work with HIV patients are not considered at risk of infection. However, persons regularly exposed to blood are at risk. Facilities shall develop a written plan to ensure the highest degree of confidentiality regarding HIV status and medical condition. Staff training must emphasize the need for confidentiality, and procedures must be in place to limit access to health records to only authorized individuals and only when necessary.

   The accurate diagnosis and medical management of HIV infection among detainees shall be promoted. An HIV diagnosis may be made only by a licensed health care provider, based on a medical history, current clinical evaluation of signs and symptoms and laboratory studies.

c. Clinical Evaluation and Management
   Medical personnel shall provide all detainees diagnosed with HIV/AIDS medical care consistent with national recommendations and guidelines disseminated through the U.S. Department of Health and Human Services, the CDC, and the Infectious Diseases Society of America. Medical and pharmacy personnel shall ensure that all Food and Drug Administration (FDA) medications currently approved for the treatment of HIV/AIDS are accessible. Medical and pharmacy personnel shall develop and implement distribution procedures to ensure timely and confidential access to medications.

   Many of these guidelines are available through the following links:
   http://aidsinfo.nih.gov/Guidelines/default.aspx
   http://www.cdc.gov/hiv/resources/guidelines/index.htm#treatment
   http://www.idsociety.org/Content.aspx?id=9088

   Medical and pharmacy personnel shall ensure the facility maintains access to adequate supplies of FDA-approved medications for the treatment of HIV/AIDS to ensure newly admitted detainees shall be able to continue with their treatments without interruption. Upon release, detainees currently receiving highly active antiretroviral therapy and other drugs shall receive up to a 30-

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day supply of their medications as medically appropriate.

When current symptoms are suggestive of HIV infection, the following procedures shall be implemented.

1) Clinical evaluation shall determine the medical need for isolation.

   Detainees with HIV shall not be separated from the general population, either pending a test result or after a test report, unless clinical evaluation reveals a medical need for isolation. Segregation of HIV-positive detainees is not necessary for public health purposes.

2) Following a clinical evaluation, if a detainee manifests symptoms requiring treatment beyond the facility's capability, the provider shall recommend the detainee's transfer to a local hospital or other appropriate facility for further medical testing, final diagnosis and acute treatment as needed, consistent with local operating procedures.

3) Any detainee with active tuberculosis shall also be evaluated for possible HIV infection.

4) New HIV-positive diagnoses must be reported to government bodies according to state and local laws and requirements; the HSA is responsible for ensuring that all applicable state requirements are met.

   The "Standard Precautions" section of standard "1.2 Environmental Health and Safety" provides more detailed information.

D. Notifying Detainees about Health Care Services

In accordance with standard "6.1 Detainee Handbook," the facility shall provide each detainee, upon admittance, a copy of the detainee handbook and local supplement, in which procedures for access to health care services are explained.

Health care practitioners should explain any rules about mandatory reporting and other limits to confidentiality in their interactions with detainees. Informed consent shall be obtained prior to providing treatment (absent medical emergencies). Consent forms and refusals shall be documented and placed in the detainee's medical file.

In accordance with the section on Orientation in standard "2.1 Admission and Release," access to health care services, the sick call and medical grievance processes shall be included in the orientation curriculum for newly admitted detainees.

E. Translation and Language Access for Detainees with Limited English Proficiency

Facilities shall provide appropriate interpretation and language services for LEP detainees related to medical and mental health care. Where appropriate staff interpretation is not available, facilities will make use of professional interpretation services. Detainees shall not be used for interpretation services during any medical or mental health service. Interpretation and translation services by other detainees shall only be provided in an emergency medical situation.

Facilities shall post signs in medical intake areas in English, Spanish, and languages spoken by other significant segments of the facility's detainee population listing what language assistance is available during any medical or mental health treatment, diagnostic test, or evaluation.

F. Facilities

1. Examination and Treatment Area

Adequate space and equipment shall be furnished in all facilities so that all detainees may be provided basic health examinations and treatment in private while ensuring safety.

A holding/waiting area shall be located in the medical facility under the direct supervision of custodial officers. A detainee toilet and drinking

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fountain shall be accessible from the holding/waiting area.

2. Medical Records

Medical records shall be kept separate from detainee detention records and stored in a securely locked area within the medical unit.

3. Medical Housing

If there is a specific area, separate from other housing areas, where detainees are admitted for health observation and care under the supervision and direction of health care personnel, consideration shall be given to the detainee's age, gender, medical requirements and custody classification and the following minimum standards shall be met:

a. Care

1) Physician at the facility or on call 24 hours per day;

2) Qualified health care personnel on duty 24 hours per day when patients are present;

3) Staff members within sight or sound of all patients;

4) Maintenance of a separate medical housing record distinct from the complete medical record; and

5) Compliance with all established guidelines and applicable laws.

Detainees in medical housing shall have access to other services such as telephone, legal access and materials, consistent with their medical conditions.

Prior to placing a detainee with a mental illness in medical housing, a determination shall be made by a medical or mental health professional that placement in medical housing is medically necessary.

b. Wash Basins, Bathing Facilities and Toilets

1) Detainees shall have access to operable washbasins with hot and cold running water at a minimum ratio of 1 for every 12 detainees, unless state or local building codes specify a different ratio.

2) Sufficient bathing facilities shall be provided to allow detainees to bathe daily, and sufficient bathing facilities shall be physically accessible for detainees with disabilities, as required by the applicable accessibility standard. Water shall be thermostatically controlled to temperatures ranging from 100 F to 120 F degrees.

3) Detainees shall have access to operable toilets and hand-washing facilities 24 hours per day and shall be permitted to use toilet facilities without staff assistance. Unless state or local building or health codes specify otherwise:

a) toilets shall be provided at a minimum ratio of 1 to every 12 detainees in male facilities and 1 for every 8 in female facilities, and

b) all housing units with three or more detainees shall have a minimum of two toilets.

G. Pharmaceutical Management

Each detention facility shall have and comply with written policy and procedures for the management of pharmaceuticals, to include:

1. a formulary of all prescription and nonprescription medicines stocked or routinely procured from outside sources;

2. identification of a method for promptly approving and obtaining medicines not on the formulary;

3. prescription practices, including requirements that medications are prescribed only when clinically indicated, and that prescriptions are reviewed before being renewed;

4. procurement, receipt, distribution, storage, dispensing, administration and disposal of

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medications;

5. secure storage and disposal and perpetual inventory of all controlled substances (DEA Schedule II-V), syringes, and needles;
6. medicine administration error reports to be kept for all administration errors;
7. all staff responsible for administering or having access to pharmaceuticals to be trained on medication management before beginning duty;
8. all pharmaceuticals to be stored in a secure area with the following features:
   a. a secure perimeter;
   b. access limited to authorized medical staff (never detainees);
   c. solid walls from floor to ceiling and a solid ceiling;
   d. a solid core entrance door with a high security lock (with no other access); and
   e. a secure medication storage area;
9. administration and management in accordance with state and federal law;
10. supervision by properly licensed personnel;
11. administration of medications by properly licensed, credentialed, trained personnel under the supervision of the health services administrator (HSA), clinical medical authority (CMA), both; and
12. documentation of accountability for administering or distributing medications in a timely manner, and according to licensed provider orders.

H. Nonprescription Medications

The facility administrator and HSA shall jointly approve any nonprescription medications that are available to detainees outside of health services (e.g., sold in commissary, distributed by housing officers, etc.), and shall jointly review the list, on an annual basis at a minimum.

I. Medical Personnel

All health care staff must be verifiably licensed, certified, credentialed, and/or registered in compliance with applicable state and federal requirements. Copies of the documents must be maintained on site and readily available for review. A restricted license does not meet this requirement.

J. Medical and Mental Health Screening of New Arrivals

As soon as possible, but no later than 12 hours after arrival, all detainees shall receive, by a health care provider or a specially trained detention officer, an initial medical, dental and mental health screening and be asked for information regarding any known acute or emergent medical conditions. Any detainee responding in the affirmative shall be sent for evaluation to a qualified, licensed health care provider as quickly as possible, but in no later than two working days. Detainees who appear upon arrival to raise urgent medical or mental health concerns shall receive priority in the intake screening process. For intrasystem transfers, a qualified health care professional will review each incoming detainee's health record or health summary within 12 hours of arrival, to ensure continuity of care.

For LEP individuals, interpretation for the screening will be conducted by facility staff with appropriate language capabilities or through professional interpretation services, as described in Section E of this standard ("Translation and Language Access for Detainees with Limited English Proficiency").

If screening is performed by a detention officer, the facility shall maintain documentation of the officer's special training, and the officer shall have available for reference the training syllabus, to include education on patient confidentiality of disclosed information.

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The screening shall inquire into the following:

1. any past history of serious infectious or communicable illness, and any treatment or symptoms;
2. history of physical and mental illness;
3. pain assessment;
4. current and past medication;
5. allergies;
6. past surgical procedures;
7. symptoms of active TB or previous TB treatment;
8. dental care history;
9. use of alcohol, tobacco and other drugs, including an assessment for risk of potential withdrawal;
10. possibility of pregnancy;
11. other relevant health problems identified by the CMA responsible for screening inquiry;
12. observation of behavior, including state of consciousness, mental status, appearance, conduct, tremor, sweating;
13. history of suicide attempts or current suicidal/homicidal ideation or intent;
14. observation of body deformities and other physical abnormalities;
15. inquire into a transgender detainee's gender self-identification and history of transition-related care, when a detainee self-identifies as transgender;
16. past hospitalizations;
17. chronic illness (including, but not limited to, hypertension and diabetes);
18. dietary needs; and
19. any history of physical or sexual victimization or perpetrated sexual abuse, and when the incident occurred.

Where there is a clinically significant finding as a result of the initial screening, an immediate referral shall be initiated and the detainee shall receive a health assessment no later than two working days from the initial screening.

For further information and guidance, see standard "2.1 Admission and Release."

Initial screenings shall be conducted in settings that respect detainees' privacy and include observation and interview questions related to the detainee's potential suicide risk and mental health. For further information, see standard "4.6 Significant Self-harm and Suicide Prevention and Intervention."

If, at any time during the screening process, there is an indication of need of, or a request for, mental health services, the HSA must be notified within 24 hours. The CMA, HSA or other qualified licensed health care provider shall ensure a full mental health evaluation, if indicated. Mental health evaluations must be conducted within the timeframes prescribed in "O. Mental Health Program" of this standard.

All facilities shall have policies and procedures in place to ensure documentation of the initial health screening and assessment.

The health intake screening shall be conducted using the IHSC Intake Screening Form (IHSC 795A) or equivalent and shall be completed prior to the detainee's placement in a housing unit. The Intake Screening Form attached as Appendix 4.3.A mirrors form IHSC 795A and may be used by facilities to ensure compliance with screening requirements in these standards.

Upon completion of the In-Processing Health Screening form, the detention officer shall immediately notify medical staff when one or more positive responses are documented. Medical staff will then assess priority for treatment (e.g. urgent, today or routine).

Limited-English proficient detainees and detainees who are hearing impaired shall be provided

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interpretation or translation services or other assistance as needed for medical care activities.

Language assistance may be provided by another medical staff member competent in the language or by a professional service, such as a telephone interpretation service.

K. Substance Dependence and Detoxification

All detainees shall be evaluated through an initial screening for use of and/or dependence on mood- and mind-altering substances, alcohol, opiates, hypnotics, sedatives, etc. Detainees who report the use of such substances shall be evaluated for their degree of reliance on and potential for withdrawal from the substance.

The CMA shall establish guidelines for evaluation and treatment of new arrivals who require detoxification.

Detainees experiencing severe or life-threatening intoxication or withdrawal shall be transferred immediately to an emergency department for evaluation.

Once evaluated, the detainee will be referred to an appropriate facility qualified to provide treatment and monitoring for withdrawal, or treated on-site if the facility is staffed with qualified personnel and equipment to provide appropriate care.

L. Privacy and Chaperones

1. Medical Privacy

Medical and mental health interviews, screenings, appraisals, examinations, procedures, and administration of medication shall be conducted in settings that respect detainees' privacy.

2. Same-Gender Providers and Chaperones

A detainee's request to see a health care provider of the same gender should be considered; when not feasible, a same-gender chaperone shall be provided.

When care is provided by a health care provider of the opposite gender, a detainee shall be provided a same-gender chaperone upon the detainee's request.

A same-gender chaperone shall be provided, even in the absence of a request by the detainee, when a medical encounter involves a physical examination of sensitive body parts, to include breast, genital, or rectal examinations, by a provider of the opposite gender.

Only medical personnel may serve as chaperones during medical encounters and examinations.

M. Comprehensive Health Assessment

Each facility's health care provider shall conduct a comprehensive health assessment, including a physical examination and mental health screening, on each detainee within 14 days of the detainee's arrival unless more immediate attention is required due to an acute or identifiable chronic condition. Physical examinations shall be performed by a physician, physician assistant, nurse practitioner, RN (with documented training provided by a physician) or other health care practitioner as permitted by law.

Facility medical personnel are encouraged to use the form "Physical Examination/Health Appraisal" attached as Appendix 4.3.B when conducting the comprehensive health assessment.

If documentation exists of such a health assessment within the previous 90 days, the facility health care provider upon review may determine that a new appraisal is not required.

The CMA shall be responsible for review of all comprehensive health assessments to assess the priority for treatment.

Detainees diagnosed with a communicable disease shall be isolated according to national standards of medical practice and procedures.

N. Medical/Psychiatric Alerts and Holds

Where a detainee has a serious medical or mental

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health condition or otherwise requires special or close medical care, medical staff shall complete a Medical/Psychiatric Alert form (IHSC-834) or equivalent, and file the form in the detainee's medical record. Where medical staff furthermore determine the condition to be serious enough to require medical clearance of the detainee prior to transfer or removal, medical staff shall also place a medical hold on the detainee using the Medical/Psychiatric Alert form (IHSC-834) or equivalent, which serves to prevent ICE from transferring or removing the detainee without the prior clearance of medical staff at the facility. The facility administrator shall receive notice of all medical/psychiatric alerts or holds, and shall be responsible for notifying ICE/ERO of any medical alerts or holds placed on a detainee that is to be transferred.

Potential health conditions meriting the completion of a Medical/Psychiatric Alert form may include, but are not limited to:

1. medical conditions requiring ongoing therapy, such as:
   a. active TB
   b. infectious diseases
   c. chronic conditions
2. mental health conditions requiring ongoing therapy, such as:
   a. suicidal behavior or tendencies
3. ongoing physical therapy
4. pregnancy

O. Mental Health Program

1. Mental Health Services Required

Each facility shall have an in-house or contractual mental health program, approved by the appropriate medical authority that provides:

a. intake screening Form IHSC 795A (or equivalent) for mental health concerns;

b. referral as needed for evaluation, diagnosis, treatment and monitoring of mental illness by a competent mental health professional.

c. crisis intervention and management of acute mental health episodes;

d. transfer to licensed mental health facilities of detainees whose mental health needs exceed the capabilities of the facility; and

e. a suicide prevention program.

2. Mental Health Provider

The term "mental health provider" includes psychiatrists, physicians, psychologists, clinical social workers and other appropriately licensed independent mental health practitioners

3. Mental Health Evaluation

Based on intake screening, the comprehensive health assessment, medical documentation, or subsequent observations by detention staff or medical personnel, any detainee referred for mental health treatment shall receive an evaluation by a qualified health care provider no later than 72 hours after the referral, or sooner if necessary. If the practitioner is not a mental health provider and further referral is necessary, the detainee will be evaluated by a mental health provider within the next business day.

Such evaluation and screenings shall include:

a. reason for referral;

b. history of any mental health treatment or evaluation;

c. history of illicit drug/alcohol use or abuse or treatment for such;

d. history of suicide attempts;

e. current suicidal/homicidal ideation or intent;

f. current use of any medication;

g. estimate of current intellectual function;

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h. mental health screening, to include prior history physical, sexual or emotional abuse;

i. impact of any pertinent physical condition, such as head trauma;

j. recommend actions for any appropriate treatment, including but not limited to the following:

   1) remain in general population with psychotropic medication and counseling,

   2) "short-stay" unit or infirmary,

   3) Special Management Unit, or

   4) community hospitalization; and

k. recommending and/or implementing a treatment plan, including recommendations concerning transfer, housing, voluntary work and other program participation.

4. Referrals and Treatment

Any detainee referred for mental health treatment shall receive an evaluation by a qualified health care provider no later than 72 hours after the referral, or sooner if necessary. If the practitioner is not a mental health provider and further referral is necessary, the detainee will be evaluated by a mental health provider within the next business day.

The provider shall develop an overall treatment/management plan.

If the detainee's mental illness or developmental or intellectual disability needs exceed the treatment capability of the facility, a referral for an outside mental health facility may be initiated.

Any detainee prescribed psychiatric medications must be regularly evaluated by a duly-licensed and appropriate medical professional, at least once a month, to ensure proper treatment and dosage;

5. Medical Isolation

The CMA may authorize medical isolation for a detainee who is at high risk for violent behavior because of a mental health condition. The CMA shall be responsible for the daily reassessment of the need for continued medical isolation to ensure the health and safety of the detainee.

Medical isolation shall not be used as a punitive measure.

6. Involuntary Administration of Psychotropic Medication

Involuntary administration of psychotropic medication to detainees shall comply with established guidelines and applicable laws, and shall be performed only pursuant to the specific, written and detailed authorization of a physician. Absent declared medical emergency, before psychotropic medication is involuntarily administered, it is required that the HSA contact ERO management, who shall then contact respective ICE Office of Chief Counsel to facilitate a request for a court order to involuntarily medicate the detainee.

Prior to involuntarily administering psychotropic medication, absent a declared medical emergency, the authorizing physician shall:

a. review the medical record of the detainee and conduct a medical examination;

b. specify the reasons for and duration of therapy, and whether the detainee has been asked if he/she would consent to such medication;

c. specify the medication to be administered, the dosage and the possible side effects of the medication;

d. document that less restrictive intervention options have been exercised without success;

e. detail how medication is to be administered;

f. monitor the detainee for adverse reactions and side effects; and

g. prepare treatment plans for less restrictive alternatives as soon as possible.

Also see section "Z: Informed Consent and

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Involuntary Treatment" later in this detention standard.

P. Referrals for Sexual Abuse Victims or Abusers

If any security or medical intake screening or classification assessment indicates that a detainee has experienced prior sexual victimization or perpetrated sexual abuse, staff shall, as appropriate, ensure that the detainee is immediately referred to a qualified medical or mental health practitioner for medical and/or mental health follow-up as appropriate.

When a referral for medical follow-up is initiated, the detainee shall receive a health evaluation no later than two working days from the date of assessment. When a referral for mental health follow-up is initiated, the detainee shall receive a mental health evaluation no later than 72 hours after the referral.

For the purposes of this section, a "qualified medical practitioner" or "qualified mental health practitioner" means a health or mental health professional, respectively, who in addition to being qualified to evaluate and care for patients within the scope of his/her professional practice, has successfully completed specialized training for treating sexual abuse victims.

Q. Annual Health Examinations

Any detainee in ICE custody for more than one year continuously shall receive health examinations on an annual basis. Such examinations may occur more frequently for certain individuals, depending on their medical history and/or health conditions. Detainees shall have access to age- and gender-appropriate exams annually, including re-screening for TB.

R. Dental Treatment

An initial dental screening shall be performed within 14 days of the detainee's arrival. The initial dental screening may be performed by a dentist or a properly trained qualified health provider.

1. Emergency dental treatment shall be provided for immediate relief of pain, trauma and acute oral infection.
2. Routine dental treatment may be provided to detainees in ICE custody for whom dental treatment is inaccessible for prolonged periods because of detention for over six months, including amalgam and composite restorations, prophylaxis, root canals, extractions, x-rays, the repair and adjustment of prosthetic appliances and other procedures required to maintain the detainee's health. Dental exams and treatment shall be performed only by licensed dental personnel.

S. Sick Call

Each facility shall have a sick call procedure that allows detainees the unrestricted opportunity to freely request health care services (including mental health and dental services) provided by a physician or other qualified medical staff in a clinical setting. This procedure shall include:

1. clearly written policies and procedures;
2. sick call process shall be communicated in writing and verbally to detainees during their orientation;
3. regularly scheduled "sick call" times shall be established and communicated to detainees;
4. an established procedure shall be in place at all facilities to ensure that all sick call requests are received and triaged by appropriate medical personnel within 24 hours after a detainee submits the request. All written sick call requests shall be date and time stamped and filed in the detainee's medical record. Medical personnel shall review the request slips and determine when the detainee shall be seen based on acuity of the problem. In an urgent situation, the housing unit officer shall notify medical personnel immediately.

If the procedure requires a written request slip, such

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slips shall be provided in English and the most common languages spoken by the detainee population of that facility. Limited-English proficient detainees and detainees who are hearing impaired shall be provided interpretation/translation services or other assistance as needed to complete a request slip.

All detainees, including those in SMUs, regardless of classification, shall have access to sick call. See standard "2.12 Special Management Units" for details.

All facilities shall maintain a permanent record of all sick call requests.

T. Emergency Medical Services and First Aid

1. Each facility shall have a written emergency services plan for delivery of 24-hour emergency health care. This plan shall be prepared in consultation with the facility's CMA or the HSA, and must include the following:
   a. an on-call physician, dentist and mental health professional, or designee, that are available 24 hours per day;
   b. a list of telephone numbers for local ambulances and hospital services available to all staff;
   c. an automatic external defibrillator (AED) shall be maintained for use at each facility and accessible to staff;
   d. all detention and medical staff shall receive cardio pulmonary resuscitation (CPR, AED), and emergency first aid training annually;
   e. detention and health care personnel shall be trained annually to respond to health-related situations within four minutes; and
   f. security procedures that ensure the immediate transfer of detainees for emergency medical care.
2. The health services administrator ensures that medical staff have training and competency in implementing the facility's emergency health care plan appropriate for each staff's scope of practice or position. The facility administrator ensures that non-medical staff have appropriate training and competency in implementing the facility's emergency plan appropriate for each staff's position. Training and competency assessment shall include the following areas::
   a. recognizing of signs of potential health emergencies and the required responses;
   b. administering first aid, AED and cardiopulmonary resuscitation (CPR);
   c. obtaining emergency medical assistance through the facility plan and its required procedures;
   d. recognizing signs and symptoms of mental illness and suicide risk; and
   e. the facility's established plan and procedures for providing emergency medical care including, when required, the safe and secure transfer of detainees for appropriate hospital or other medical services, including by ambulance when indicated. The plan must provide for expedited entrance to and exit from the facility.
3. When a non-medical employee is unsure whether emergency care is required, he/she shall immediately notify medical personnel to make the determination.
4. Medical and safety equipment shall be available and maintained, and staff shall be trained in proper use of the equipment.
5. The facility administrator, in consultation with the designee for environmental health and safety, determines the number, contents, and placement of first aid kits, and establishes protocols for monthly inspections of first aid kits.

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6. Victims of sexual abuse shall have timely access to emergency medical treatment and crisis intervention services in accordance with standard "2.11 Sexual Abuse and Assault, Prevention and Intervention."

U. Delivery of Medication

Distribution of medication (including over the counter) shall be performed in accordance with specific instructions and procedures established by the HSA in consultation with the CMA. Written records of all prescribed medication given to or refused by detainees shall be maintained.

1. If prescribed medication must be delivered at a time when medical staff is not on duty, the medication may be distributed by detention officers, where it is permitted by state law to do so, who have received proper training by the HSA or designee.
2. The facility shall maintain documentation of the training given any officer required to distribute medication, and the officer shall have available for reference the training syllabus or other guide or protocol provided by the health authority.
3. Detainees may not deliver or administer medications to other detainees.
4. All prescribed medications and medically necessary treatments shall be provided to detainees on schedule and without interruption, absent exigent circumstances.
5. Detainees who arrive at a detention facility with prescribed medications or who report being on such medications, shall be evaluated by a qualified health care professional as soon as possible, but not later than 24 hours after arrival, and provisions shall be made to secure medically necessary medications.
6. Detainees shall not be charged for any medical services to include pharmaceuticals dispensed by medical personnel

V. Health Education and Wellness Information

Qualified health care personnel shall provide detainees health education and wellness information on topics including, but not limited to, the following:

1. dangers of self-medication;
2. personal and hand hygiene and dental care;
3. prevention of communicable diseases;
4. smoking cessation;
5. self-care for chronic conditions; and
6. benefits of physical fitness.

W. Special Needs and Close Medical Supervision

Consistent with Standard 4.8 "Disability Identification, Assessment, and Accommodation" and the IHSC Detainee Covered Services Package, detainees will be provided medical prosthetic devices or other impairment aids, such as eyeglasses, hearing aids, or wheelchairs.

When a detainee requires close medical supervision, including chronic and convalescent care, a written treatment plan, including access to health care and other care and supervision personnel, shall be developed and approved by the appropriate qualified licensed health care provider, in consultation with the patient, with periodic review. Likewise, staff responsible for such matters as housing and program assignments and disciplinary measures shall consult with the responsible qualified licensed health care provider or health services administrator.

Exercise areas shall be available to meet exercise and physical therapy requirements of individual detainee treatment plans.

Transgender detainees who were already receiving hormone therapy when taken into ICE custody shall have continued access. All transgender detainees shall

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have access to mental health care, and other transgender-related health care and medication based on medical need. Treatment shall follow accepted guidelines regarding medically necessary transition-related care.

For special needs related to female detainees, see standard "4.4 Medical Care (Women).

X. Notifications of Detainees with Serious Illnesses and Other Specified Conditions

The facility administrator and clinical medical authority shall ensure that the Field Office Director is notified as soon as practicable of any detainee housed at the facility who is determined to have a serious physical or mental illness or to be pregnant, or have medical complications related to advanced age, but no later than 72 hours after such determination. The written notification shall become part of the detainee's health record file.

1. Serious Physical Illness

For purposes of this subsection only, the following non-exhaustive categories of medical conditions may be considered to constitute serious physical illness –

- any terminal illness;
- active cancer, including but not limited to aliens undergoing chemotherapy;
- Acquired Immuno- Deficiency Syndrome (AIDS) or diagnosed HIV-positive conditions requiring medication;
- multi-drug-resistant (MDR) or extensively drug-resistant (XDR) tuberculosis disease;
- any condition that requires dialysis;
- any condition that requires tube-feedings, mechanical ventilation, an implanted cardiac device, or an oxygen tank;
- any chronic deteriorating condition requiring multiple medications, to include progressive immune-suppressive conditions;
- any active condition that has caused repeated loss of consciousness;
- any condition that requires an imminent medical procedure or other medical intervention to prevent deterioration;
- any condition or infirmity that requires continuous or near-continuous medical care, such as those who are bedbound or incapable of caring for themselves; or any ongoing or recurrent conditions that have required a recent or prolonged hospitalization, typically for greater than 14 days, or a recent and prolonged stay in the medical clinic of a detention or correctional facility, typically for greater than 30 days;
- conditions requiring frequent care that is beyond the medical capabilities of detention facilities where the alien may be housed;
- any condition that would preclude the alien from being housed, typically for greater than 30 days, in a non-restrictive setting (such as a general population housing unit, as opposed to a special management unit or a medical clinic); or
- any other physical illness determined to be serious by facility medical personnel or by IHSC.

2. Serious Mental Illness

For the purposes of this section, the following non-exhaustive categories of conditions should be considered to constitute a serious mental illness:

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(a) conditions that a qualified medical provider has determined to meet the criteria for a "serious mental disorder or condition" pursuant to applicable ICE policies, including:

- a mental disorder that is causing serious limitations in communication, memory, or general mental and/or intellectual functioning (e.g. communicating, conducting activities of daily life, social skills); or a severe medical condition(s) (e.g. traumatic brain injury or dementia) that is significantly impairing mental function; or
- one or more of the following active psychiatric symptoms and/or behavior: severe disorganization, active hallucinations or delusions, mania, catatonia, severe depressive symptoms, suicidal ideation and/or behavior, marked anxiety of impulsivity.

- significant symptoms of one of the following:
  - Psychosis or Psychotic Disorder;
  - Bipolar Disorder;
  - Schizophrenia or Schizoaffective Disorder;
  - Major Depressive Disorder with Psychotic Features;
  - Dementia and/or a Neurocognitive Disorder; or
  - Intellectual Development Disorder (moderate, severe, or profound).

b) any ongoing or recurrent conditions that have required a recent or prolonged hospitalization, typically for greater than 14 days, or a recent and prolonged stay in the medical clinic of a detention or correctional facility, typically for greater than 30 days;

c) any condition that would preclude the alien from being housed, typically for greater than 30 days, in a non-restrictive setting (such as a general population housing unit, as opposed to a special management unit or a medical clinic);

d) any other mental illness determined to be serious by IHSC.

3. Pregnancy

The notification requirement in this section applies to all women who have been medically certified as pregnant, regardless of the stage of the pregnancy.

Y. Restraints

Restraints for medical or mental health purposes may be authorized only by the facility's CMA or designee, after determining that less restrictive measures are not appropriate. In the absence of the CMA, qualified medical personnel may apply restraints upon declaring a medical emergency. Within one-hour of initiation of emergency restraints or seclusion, qualified medical staff shall notify and obtain an order from the CMA or designee.

a. The facility shall have written procedures that specify:

1) the conditions under which restraints may be applied;

2) the types of restraints to be used;

3) the proper use, application and medical monitoring of restraints;

4) requirements for documentation, including efforts to use less restrictive alternatives; and

5) after-incident review.

The use of restraints requires documented approval and guidance from the CMA. Record-keeping and reporting requirements regarding the medical approval to use restraints shall be consistent with other provisions within these standards, including documentation in the detainee's A-file, detention

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and medical file.

Z. Continuity of Care

The facility HSA must ensure that a plan is developed that provides for continuity of medical care in the event of a change in detention placement or status.

The detainee's medical needs shall be taken into account prior to any transfer of the detainee to another facility. Alternatives to transfer shall be considered, taking into account the disruption that a transfer will cause to a detainee receiving medical care. Upon transfer to another facility, the medical provider shall prepare and provide a Medical Transfer Summary as required by "C. Responsibilities of the Health Care Provider at the Sending Facility," found in Standard 7.4 "Detainee Transfers." In addition, the medical provider shall ensure that at least 7 day (or, in the case of TB medications, 15 day and in the case of HIV/AIDS medications, 30 day) supply of medication shall accompany the detainee as ordered by the prescribing authority.

Upon removal or release from ICE custody, the detainee shall receive up to a 30 day supply of medication as ordered by the prescribing authority and a detailed medical care summary as described in "BB. Medical Records" of this standard. If a detainee is on prescribed narcotics, the clinical health authority shall make a determination regarding continuation, based on assessment of the detainee. The HSA must ensure that a continuity of treatment care plan is developed and a written copy provided to the detainee prior to removal.

AA. Informed Consent and Involuntary Treatment

Involuntary treatment is a decision made only by medical staff under strict legal restrictions. When a detainee refuses medical treatment, and the licensed healthcare provider determines that a medical emergency exists, the physician may authorize involuntary medical treatment. Prior to any contemplated action involving non-emergent involuntary medical treatment, respective ICE Office of Chief Counsel shall be consulted.

1. Upon admission at the facility, documented informed consent shall be obtained for the provision of health care services.
2. All examinations, treatments, and procedures are governed by informed consent practices applicable in the jurisdiction.
3. A separate documented informed consent is required for invasive procedures, including surgeries, invasive diagnostic tests, and dental extractions.
4. Prior to the administration of psychotropic medications, a separate documented informed consent, that includes a description of the medication's side effects, shall be obtained.
5. If a consent form is not available in a language the detainee understands, professional interpretation services will be provided as described in Section E ("Translation and Language Access for Detainees with Limited English Proficiency") and documented on the form.
6. If a detainee refuses treatment and the CMA or designee determines that treatment is necessary, ICE/ERO shall be consulted in determining whether involuntary treatment shall be pursued.
7. If the detainee refuses to consent to treatment, medical staff shall make reasonable efforts to explain to the detainee the necessity for and propriety of the recommended treatment.
8. Medical staff shall ensure that the detainee's questions regarding the treatment are answered by appropriate medical personnel.
9. Medical staff shall explain the medical risks if treatment is declined and shall document their treatment efforts and refusal of treatment in the detainee's medical record. Detainees will be asked to sign a translated form that indicates that they have refused treatment.

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10. The clinical medical authority and facility administrator shall look into refusals of treatment to ensure that such refusals are not the result of miscommunication or misunderstanding.
11. Facilities should make efforts to involve trusted individuals such as clergy or family members should a detainee refuse treatment.
12. A detainee who refuses examination or treatment may be segregated from the general population when such segregation is determined medically necessary by the CMA. Segregation shall only be for medical reasons that are documented in the medical record, and may not be used for punitive purposes. Such segregation shall only occur after a determination by a component mental health professional has taken place that shows the segregation shall not adversely affect the detainee's mental health.
13. In the event of a hunger strike, see standard "4.2 Hunger Strikes."

Standard "4.7 Terminal Illness, Advance Directives and Death" provides details regarding living wills and advance directives, organ donations and do not resuscitate (DNR) orders.

BB. Medical Records

1. Health Record File

The HSA shall maintain a complete health record on each detainee that is:

a. Organized uniformly in accordance with appropriate accrediting body standards;
b. Available to all practitioners and used by them for health care documentation; and
c. Properly maintained and safeguarded in a securely locked area within the medical unit.

2. Confidentiality and Release of Medical Records

All medical providers, as well as detention officers and staff shall protect the privacy of detainees' medical information in accordance with established guidelines and applicable laws. These protections apply, not only to records maintained on paper, but also to electronic records where they are used. Staff training must emphasize the need for confidentiality and procedures must be in place to limit access to health records to only authorized individuals and only when necessary.

Information about a detainee's health status and a detainee's health record is confidential, and the active medical record shall be maintained separately from other detention records and be accessible in accordance with applicable laws and regulations.

The HSA shall provide the facility administrator and designated staff information that is necessary as follows:

a. to preserve the health and safety of the detainee, other detainees, staff or any other person;
b. for administrative and detention decisions such as housing, voluntary work assignments, security and transport; or
c. for management purposes such as audits and inspections.

When information is covered by the Privacy Act, specific legal restrictions govern the release of medical information or records.

Detainees who indicate they wish to obtain copies of their medical records shall be provided with the appropriate request form. ICE/ERO, or the facility administrator, shall provide limited-English proficient detainees and detainees who are hearing impaired with interpretation or translation services or other assistance as needed to make the written request, and shall assist in transmitting the request to the facility HSA.

Upon his/her request, while in detention, a detainee or his/her designated representative shall receive information from their medical records. Copies of health records shall be released by the HSA directly to a detainee or their designee, at no cost to the detainee, within a reasonable timeframe after receipt

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by the HSA of a written authorization from the detainee.

A written request may serve as authorization for the release of health information, as long as it includes the following information, and meets any other requirements of the HSA:

a. address of the facility to release the information;

b. name of the individual or institution to receive the information;

c. detainee's full name, A-number (or other facility identification number), date of birth and nationality;

d. specific information to be released with inclusive dates of treatment; and

e. detainee's signature and date.

Following the release of health information, the written authorization shall be retained in the health record.

Detainees are to be informed that if they are released or removed from custody prior to laboratory results being evaluated, the results shall be made available by contacting the detention facility and providing a release of information consent.

3. Inactive Health Record Files

Inactive health record files shall be retained as permanent records in compliance with locally established procedures and the legal requirements of the jurisdiction.

4. Transfer and Release of Detainees

ICE/ERO and the HSA shall be notified when detainees are to be transferred or released. Detainees shall be transferred, released or removed, with proper medication to ensure continuity of care throughout the transfer and subsequent intake process, release or removal (see "W. Continuity of Care," above). Those detainees who are currently placed in a medical hold status must be evaluated and cleared by a licensed independent practitioner (LIP) prior to transfer or removal. In addition, the CMA or designee must inform the facility administrator in writing if the detainee's medical or psychiatric condition requires a medical escort during removal or transfer.

a. Notification of Medical/Psychiatric Alerts or Holds
   Upon receiving notification that a detainee is to be transferred, appropriate medical staff at the sending facility shall notify the facility administrator of any medical/psychiatric alerts or holds that have been assigned to the detainee, as reflected in the detainee's medical records. The facility administrator shall be responsible for providing notice to ICE/ERO of any medical alerts or holds placed on a detainee that is to be transferred.

b. Notification of Transfers, Releases and Removals
   The HSA shall be given advance notice by ICE/ERO prior to the release, transfer or removal of a detainee, so that medical staff may determine and provide for any medical needs associated with the transfer, release or removal.

c. Transfer of Medical Information

   1) When a detainee is transferred to another detention facility, the sending facility shall ensure that a Medical Transfer Summary accompanies the detainee, as required in "C. Responsibilities of the Health Care Provider at the Sending Facility" found in Standard 7.4 "Detainee Transfers.". Upon request of the receiving facility, the sending facility shall transmit a copy of the full medical record within 5 business days, and sooner than that if determined by the receiving facility to be a medically urgent matter.

   2) Upon removal or release from ICE custody, the detainee shall be provided medication, referrals to community-based providers as medically appropriate, and a detailed medical care summary. This summary should include

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instructions that the detainee can understand and health history that would be meaningful to future medical providers. The summary shall include, at a minimum, the following items:

a) patient identification;

b) tuberculosis (TB) screening results (including results date) and current TB status if TB disease is suspected or confirmed;

c) current mental, dental, and physical health status, including all significant health issues, and highlighting any potential unstable issues or conditions which require urgent follow-up;

d) current medications, with instructions for dose, frequency, etc., with specific instructions for medications that must be administered en route;

e) any past hospitalizations or major surgical procedures;

f) recent test results, as appropriate;

g) known allergies;

h) any pending medical or mental health evaluations, tests, procedures, or treatments for a serious medical condition scheduled for the detainee at the sending facility. In the case of patients with communicable disease and/or other serious medical needs, detainees being released from ICE custody are given a list of community resources, at a minimum;

i) copies of any relevant documents as appropriate;

j) printed instructions on how to obtain the complete medical record; and

k) the name and contact information of the transferring medical official.

The IHSC Form 849 or equivalent, or the Medical Transfer Summary attached as Appendix 4.3.C, which mirrors IHSC Form 849, may be used by facilities to ensure compliance with these standards.

CC. Terminal Illness or Death of a Detainee

Procedures to be followed in the event of a detainee's terminal illness or death are in standard "4.7 Terminal Illness, Advance Directives and Death." The standard also addresses detainee organ donations.

DD. Medical Experimentation

Detainees shall not participate in medical, pharmaceutical or cosmetic research while under the care of ICE.

This stipulation does not preclude the use of approved clinical trials that may be warranted for a specific inmate's diagnosis or treatment when recommended and approved by the clinical medical director. Such measures require documented informed consent.

EE. Administration of the Medical Department

1. Quarterly Administrative Meetings

The HSA shall convene a meeting quarterly at minimum, and include other facility and medical staff as appropriate. The meeting agenda shall include, at minimum, the following:

a. an account of the effectiveness of the facility's health care program;

b. discussions of health environment factors that may need improvement;

c. review and discussion of communicable disease and infectious control activities;

d. changes effected since the previous meetings; and

e. recommended corrective actions, as necessary.

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Minutes of each meeting shall be recorded and kept on file.

2. Health Care Internal Review and Quality Assurance

The HSA shall implement a system of internal review and quality assurance. The system shall include:

a. participation in a multidisciplinary quality improvement committee;

b. collection, trending and analysis of data along with planning, interventions and reassessments;

c. evaluation of defined data;

d. analysis of the need for ongoing education and training;

e. on-site monitoring of health service outcomes on a regular basis through the following measures:

   1) chart reviews by the responsible physician or his/her designee, including investigation of complaints and quality of health records;

   2) review of practices for prescribing and administering medication;

   3) systematic investigation of complaints and grievances;

   4) monitoring of corrective action plans;

   5) reviewing all deaths, suicide attempts and illness outbreaks;

   6) developing and implementing corrective-action plans to address and resolve identified problems and concerns;

   7) reevaluating problems or concerns, to determine whether the corrective measures have achieved and sustained the desired results;

   8) incorporating findings of internal review activities into the organization's educational and training activities;

   9) maintaining appropriate records of internal review activities; and

   10) ensuring records of internal review activities comply with legal requirements on confidentiality of records.

3. Peer Review

The HSA shall implement an intra-organizational, external peer review program for all independently licensed medical professionals. Reviews shall be conducted at least annually.

FF. Examinations by Independent Medical Service Providers and Experts

On occasion, medical and/or mental health examinations by a practitioner or expert not associated with ICE or the facility may provide a detainee with information useful in administrative proceedings.

If a detainee seeks an independent medical or mental health examination, the detainee or his/her legal representative shall submit to the Field Office Director a written request that details the reasons for such an examination. Ordinarily, the Field Office Director shall approve the request for independent examination, as long as such examination shall not present an unreasonable security risk. Requests for independent examinations shall be responded to as quickly as practicable. If a request is denied, the Field Office Director shall advise the requester in writing of the rationale.

Neither ICE/ERO nor the facility shall assume any costs of the examination, which will be at the detainee's expense. The facility shall provide a location for the examination but no medical equipment or supplies and the examination must be arranged and conducted in a manner consistent with maintaining the security and good order of the facility.

GG. Tele-Health Systems

***The facility, when equipped with appropriate technology and adequate space, shall provide for the*

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use of services of the ICE Tele-Health Systems, inclusive of tele-radiology (ITSP), tele-psychiatry and tele-medicine.

1. The cost of the equipment, equipment maintenance, staff training and credentialing (as outlined in the contract), arrangements for x-ray interpretation and administration by a credentialed radiologist; and data transmission to and from the detention facility, shall be provided by the facility and charged directly to ICE.
2. The facility administrator shall coordinate with the ITSP to ensure adequate space is provided for the equipment, connectivity is available, and electrical services are installed.
3. Immediate 24-hour access, seven days a week, to equipment for service and maintenance by ITSP technicians shall be granted.
4. A qualified tele-health coordinator shall be appointed and available for training by the ITSP. Qualified, licensed and credentialed medical staff shall be available to provide tele-health services as guided by state and federal requirements and restrictions.

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Medical Forms:

- Appendix 4.3.A: Intake Screening
- Appendix 4.3.B: Physical Examination/Health Appraisal
- Appendix 4.3.C: Medical Transfer Summary

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INTAKE SCREENING

Identification

Patient was identified by (check 2 sources): ☐ Wrist Band ☐ Picture ☐ Verbally ☐ ID Badge ☐ Other:
Chaperone Present? ☐ Yes ☐ No If yes, give chaperone name:
Date of arrival at facility: Time of arrival: Time of initial screening:
If transferred from another facility, did medical transfer summary accompany the patient? ☐ Yes ☐ No ☐ Not Applicable
Was the Pre-Screening Note reviewed? ☐ Yes ☐ No

Subjective

Communication Assessment:

What language do you speak? ☐ English ☐ Spanish ☐Other:
Interpreter provided? ☐ Yes ☐No If yes, name or INT number:
If No, patient speaks: ☐ English fluently ☐ Provider fluent in patient's native language ☐ No interpreter available at this time
Do you have any difficulty with: ☐ Hearing ☐ Speech ☐ Vision Check if yes. If yes, what accommodation do you need to help you read, communicate, or navigate the facility?

Disability Screening:

Do you have any difficulty with walking, standing, or climbing stairs? ☐ Yes ☐ No If yes, explain:
Do you have any difficulty reading or writing? ☐ Yes ☐ No If yes, explain:
What was the highest grade completed in school?
Do you have any difficulty understanding directions? ☐ Yes ☐ No If yes, explain:

Medical Screening:

How do you feel today? (Explain in his/her own words)			
Are you currently having any pain? ☐ Yes ☐ No If yes, complete pain assessment below			
a. Character of pain:	b. Location:	c. Duration:	d. Intensity: (0-10 pain scale)
e. What relieves pain or makes it worse?			
Do you have any current or past medical problems? ☐ Yes ☐ No If yes, explain:			

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

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Medical Screening (continued)

Are you currently or in the past year have you taken any medication on a regular basis, including over the counter and herbal? ☐Yes ☐No If yes, list medications:
Do you have your medications with you? ☐Yes ☐No If yes, list medications and disposition:
Do you have any allergies to medication or food? ☐Yes ☐No If yes, list all:
Are you now or have you ever been treated by a doctor for a medical condition to include hospitalizations, surgeries, infectious or communicable diseases? ☐Yes ☐No If yes, explain:
Do you now or have you ever had Tuberculosis (TB)? ☐Yes ☐No
In the past 2 months, have you experienced any of the following signs or symptoms continuously for more than 2 weeks: Cough? ☐Yes ☐No Coughing up blood? ☐Yes ☐No Chest pain? ☐Yes ☐No Loss of appetite? ☐Yes ☐No Fever, chills, or night sweats for no known reason? ☐Yes ☐No Unexplained weight loss? ☐Yes ☐No
Symptom screening with positive responses(s) is concerning for active TB: ☐Yes ☐No If yes, explain:
Referred to provider for further evaluation. ☐Yes ☐No
Have you had any recent sudden changes with your vision or hearing? ☐Yes ☐No If yes, explain:
Do you have any specific dietary needs? ☐Yes ☐No If yes, explain:
Have you traveled outside of the US within the past 30 days? ☐Yes ☐No If so, where?
Have you ever had or have you ever been vaccinated against Chicken Pox? ☐Yes ☐No ☐Admits prior infection

LGBT Screening

Are you gay, lesbian, bisexual, transgender, intersex or gender non-conforming? ☐ Yes ☐ No
If transgender, what is your gender self-identification?

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

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Female Patient Only

Are you pregnant? ☐ Yes ☐ No ☐ Not Applicable If yes, date of last menstrual period:
Are you currently breastfeeding? ☐ Yes ☐ No If yes, when is the last day you breastfed?
Have you had unprotected sexual intercourse in the past 5 days? ☐ Yes ☐ No If yes, would you like to speak to a medical provider about emergency contraception to prevent a possible pregnancy? ☐ Yes ☐ No **If yes, contact a medical provider immediately for guidance.**

Oral Screening

Are you having any significant dental problems? ☐ Yes ☐ No If yes, explain:
Do you have dentures, partials, braces, etc? ☐ Yes ☐ No If yes, do you have these items with you?

Mental Health Screening

Have you ever been diagnosed with mental illnesses or mental health conditions? ☐ Yes ☐ No If yes, what illness?
Have you ever received counseling, medication or hospitalization for mental health problems (to include outpatient treatment)? ☐ Yes ☐ No If yes, explain. **Refer for follow-up and appropriate treatment as necessary.**
Do you have a history of self-injurious behavior? ☐ Yes ☐ No If yes: ☐ Cutting ☐ Self-mutilation ☐ Other Most recent **If yes, refer for follow-up and appropriate treatment as necessary.**
Have you ever tried to kill or harm yourself? ☐ Yes ☐ No If yes, when did the attempt occur? Method: ☐ Gun ☐ Hanging ☐ Cutting skin ☐ Pills ☐ Other **If attempt was within the last 90 days, make referral to mental health immediately.**
Are you currently thinking about killing or harming yourself? ☐ Yes ☐ No **If yes, make referral to mental health immediately.**
Do you have a history of assaulting or attacking others? ☐ Yes ☐ No
Do you know of someone in this facility whom you wish to attack or harm? ☐ Yes ☐ No If yes, who is this person? **If yes, make referral to mental health immediately.**
Do you now or have you ever heard voices that other people don't hear, seen things or people that others don't see, or felt others were trying to harm you for no logical or apparent reason? ☐ Yes ☐ No If yes, explain:

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Sexual Abuse and Assault Screening

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Have you been a victim of physical or sexual abuse or assault? ☐ Yes ☐ No If yes, explain:

If yes, refer for medical or mental health evaluation as appropriate.

Do you feel that you are in danger of being physically or sexually assaulted while you are in custody? ☐ Yes ☐ No If yes, explain:

If yes, refer for follow-up and appropriate treatment as necessary.

Have you ever sexually assaulted or abused another person? ☐ Yes ☐ No If yes, explain:

If yes, refer for medical or mental health evaluation as appropriate.

Trauma History Screening

Have you had a physical or emotional trauma due to abuse or victimization? ☐ Yes ☐ No

Have you ever experienced, witnessed or been confronted with an event that involved actual or threatened death or serious injury (can include domestic violence, sexual assault, robbery, natural disaster, war, serious illness, terrorism). ☐ Yes ☐ No

If yes, answer the following:

- Was your response to this event intense fear, helplessness or horror? ☐ No ☐ Some ☐ Moderate ☐ Extreme
- Has this experience caused significant distress or impairment in your life? ☐ No ☐ Some ☐ Moderate ☐ Extreme
- Has it affected your interpersonal relationships, work or other areas? ☐ No ☐ Some ☐ Moderate ☐ Extreme
- Is this experience currently causing significant distress or impairment in your life? ☐ No ☐ Some ☐ Moderate ☐ Extreme

If the patient experienced any of the above, refer for follow-up and appropriate treatment as necessary.

Cultural/Religious Assessment

Is there anything important to know about your religious or cultural beliefs that are of concern to you while in detention? ☐ Yes ☐ No
If yes, explain:

Substance Use/Abuse Screening

Have you ever been treated for drug and/or alcohol problems?	☐ Yes ☐ No
Have you ever suffered withdrawal symptoms from drug and/or alcohol use?	☐ Yes ☐ No
Are you able to stop using drugs or alcohol if you want?	☐ Yes ☐ No
Have you ever blacked out or experienced memory loss from drinking or drug use?	☐ Yes ☐ No
Have drug or alcohol use negatively impacted your life (family, work, relationships, criminal charges)?	☐ Yes ☐ No

If yes to any of the above questions, explain:

Refer for follow-up and appropriate treatment as necessary.

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

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Substance Use/Abuse Screening (continued)

In the past three months, have you used tobacco, alcohol, illegal drugs, or misused prescription drugs? ☐Yes ☐No
If yes, complete the following (refer for follow-up and appropriate treatment as necessary).

Substance Used/Route of Use	Date of Last Use	Amount/Quantity Last Used

Objective

Patient does not appear to have abnormal physical, mental, and/or emotional characteristics. ☐Yes ☐No
Patient does not appear to have barriers to communication. ☐Yes ☐No
Patient is oriented to: Person ☐Yes ☐No Place ☐Yes ☐No Time ☐Yes ☐No
If you observe any of the following, check the appropriate box and document findings below: Appearance: ☐Sweating ☐Shaking/tremors ☐Anxious ☐Disheveled ☐Ill appearance Findings:
Behavior: ☐Disorderly ☐Appropriate ☐Insensible ☐Agitation ☐Inability to focus/concentrate Findings:
State of Consciousness: ☐Alert ☐Responsive ☐Lethargic Findings:
Ease of Movement: ☐Body deformities ☐Gait Findings:
Breathing: ☐Persistent cough ☐Hyperventilation Findings:
Skin: ☐Lesions ☐Jaundice ☐Rashes ☐Infestations ☐Nits (lice) ☐Bruises ☐Scars ☐ ☐Tattoos Needle Marks or Indications of Drug Use Findings:
Developmental or Physical Disabilities: ☐Developmental Delay ☐Para/quadriplegia ☐Stroke ☐Amputation ☐Cardiac condition Findings:
Assistive Devices: ☐Glasses/Contacts ☐Hearing aid(s) ☐Denture(s)/Partial(s) ☐Orthopedic brace ☐Prosthetic ☐Cane Findings:
☐None Observed
Comments/Other Findings:

Vital Signs

T _____ P _____ Resp _____ BP _____ HT _____ WT _____ HCG Results: ☐Pos ☐Neg ☐N/A

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

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Assessment

Initial Medical Screening:

☐ No findings requiring referral
☐ Findings requiring referral identified. See disposition below.
☐ List all findings:

Plan

Disposition:

☐ General population
☐ General population with referral for: ☐ Medical ☐ Mental health care
☐ Isolation until medically evaluated
☐ Referral for immediate: ☐ Medical ☐ Mental health ☐ Dental care
Details of referral:

Care/Intervention/Follow-up:

☐ Physical examination/Health Assessment will be performed within 14 days.
☐ Physical exam will be scheduled for patient.
☐ Tuberculin Skin Test (TST) administered ☐ Left forearm ☐ Right forearm
☐ Chest X-Ray (CXR) completed with appropriate shielding
☐ TST or CXR not needed. Transfer Summary accompanying patient documents negative screening within timeframe allowed by policy.
☐ The following care/treatment was provided during this Intake Screening.

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Patient Education:

☐ Tuberculosis screening and need for tuberculin skin test (TST) or chest x-ray (CXR) explained to patient prior to performance.
☐ Access to medical, dental, and mental health care explained to patient as well as grievance process.
☐ Given the Dealing with Stress brochure in language.
☐ Given the Medical Orientation brochure in language.
☐ Given the Health Information brochures in language.
☐ Patient verbalized understanding of teaching or instruction provided.
☐ Patient was asked if he or she had any additional questions and all questions were addressed.
☐ Female ONLY: Educated and provided brochure describing female medical and mental health services related to pregnancy, terminated/miscarried pregnancies, contraception, family planning and age-appropriate gynecological health care.
☐ Other education provided:

Provider's Signature	Stamp / Printed Name	Date	Time
Reviewer's Signature	Stamp / Printed Name	Date	Time

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal

Patient was identified by (check 2 sources): □ Wrist Band, □ Picture, □ Verbally, □ ID Badge, □ Other _____
Chaperone Present? □ Yes □ No If yes, give chaperone name: _____

Communication Assessment:
What language do you speak? □ English, □ Spanish, □ Other: _____
Interpreter provided? □ Yes □ No If yes, Name or INT#:_____
Detainee speaks □ English Fluently; □ Provider fluent in patient's native language; □ No interpreter available at this time

Do you have any difficulty with □ hearing, □ speech or □ vision? Check if Yes.
If yes, what accommodations, do you need to help you read, communicate, or navigate the facility? _____

Subjective:

Current Significant Medical Problems	Date Problem began	Current Status

Current Medications including OTC and Herbal:

Name	Dose	Route	Frequency

Allergies:

Medications/Food/Environmental: List All: _____\

Pain Assessment

Are you currently in pain? □ Yes □ No If yes, pain began when?_____ Intensity: (0/10 scale)_____
Character of Pain:_____ Location:_____
Duration:_____
Has anything you have done or tried in the past relieved the pain or made it worse? □ Yes □ No
If yes, explain_____

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal (con't)

Disability

Do you have any difficulty with walking, standing, or climbing stairs? □ Yes □ No
If yes, do you use a wheelchair, walker, cane or crutches? _____

Have you ever had an injury to your head or brain which resulted in the loss of consciousness and/or recurring headaches, dizziness, confusion or memory loss? □ Yes □ No If yes, when was the injury? mm/yyyy _____
Can you read? □ Yes □ No If yes, in which language? _____Do you have difficulty reading? □ Yes □ No
Can you write? □ Yes □ No If yes, in which language? _____Do you have difficulty writing? □ Yes □ No
What was the highest grade you completed in school? _____
Do you have difficulty understanding directions? □ Yes □ No
If yes, does someone normally assist you with any regular tasks of daily living? _____

Medical History Has a medical professional ever diagnosed you with any of the following?

☐Yes ☐No Asthma	☐Yes ☐No Cardiovascular disease	☐Yes ☐No Tuberculosis	Comment: **Type
☐Yes ☐No Cancer	☐Yes ☐No Kidney Disease	☐Yes ☐No Stroke	
☐Yes ☐No HIV	☐Yes ☐No Hyperlipidemia	☐Yes ☐No Hepatitis**	
☐Yes ☐No Seizures	☐Yes ☐No Diabetes	☐Yes ☐No Sexually Transmitted Infections**	
☐Yes ☐No Hypertension	☐Yes ☐No Sickle Cell Anemia		
Varicella □ Yes □ No ☐ Admits to prior infection ☐ Admits being vaccinated ☐ History denied at physical exam			
Other			

Surgical/Hospitalization History:

Surgery or reason for hospitalization	When (mm/yyyy)

Dental

Do you have any significant dental problems? ☐No, ☐Cavity, ☐ Broken tooth, ☐Infection, ☐Broken jaw, ☐ Other_____
Do you have any dental prosthesis? ☐None, ☐Full upper denture, ☐full lower denture, ☐partial denture upper, ☐partial denture lower, ☐braces, ☐retainer

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal (con't)

Family History

Asthma □ Yes □ No Hypertension □ Yes □ No Diabetes □ Yes □ No Cardiovascular Disease □ Yes □ No
Cancer □ Yes □ No Tuberculosis □ Yes □ No Stroke □ Yes □ No Other: _____
Breast or gynecological problems □ Yes □ No

Female Only

OB History:
Have you ever been pregnant? □No □Yes #Pregnancies_____ #C-Sections_____
#Live Births _____#Full Term_____#Pre-Term_____ #Abortions____ #Miscarriages_____ #Living_____
Are you pregnant? ☐No □Yes
Are you currently receiving prenatal care? □No □Yes Where? _____
Have you ever been told that you had a 'high risk' pregnancy? If yes, what was the reason?
_____
Are you currently breast feeding? □No □Yes
If yes, how old is the nursing child? _____ When was the last time you breast fed? (mm/dd/yyyy)_____

GYN History:
When was the first day of your LMP? _____ If more than 30 days, why?
_____
Do you have a history of breast or gynecological problems? □No □Yes Explain_____
Do you use birth control? □No □Yes What type? _____ When was the last time you used it? _____
When was your last PAP smear? _____ If known, results_____

Sexual Abuse and Assault/Vulnerabilities

Have you ever been a victim of physical abuse? □No □Yes
Have you ever been a victim of sexual abuse or assault? □No □Yes
If yes, refer patient for medical evaluation in two working days or for mental health evaluation in 72 hours.

Are you gay/ lesbian, bisexual, transgender, intersex or gender non- conforming? ☐Yes ☐No
If transgender, what gender do you identify with_____

Do you believe you are vulnerable to sexual abuse or assault in ICE custody? ☐Yes ☐No If yes, why?_____
If yes, implement treatment plan.

Have you ever been involved in an incident where you sexually abused others? ☐Yes ☐No
If yes, refer patient for medical evaluation in two working days or for mental health evaluation in 72 hours.

Mental Health

Do you have a history of:
Manic episodes ☐Yes ☐No Depression ☐Yes ☐No Psychotropic medications ☐Yes ☐No
Severe anxiety ☐Yes ☐No Psychosis ☐Yes ☐No Violence towards others ☐Yes ☐No
Suicide attempts/gestures ☐Yes ☐No

Are you currently having any mental health issues? ☐Yes ☐No If yes, explain problem and date problem began _____
_____

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal (con't)

Social History

Drug Use History:

Have you used drugs other than those for medical reasons in the past 12 months? □No □Yes If yes, what?

PCP □No □Yes Ketamine □No □Yes Marijuana □No □Yes Prescription Opiates □No □Yes

LSD □No □Yes Ecstasy □No □Yes Methamphetamine □No □Yes

Heroin □No □Yes Route: Injected □No □Yes Intranasal □No □Yes Smoked □No □Yes

Cocaine □No □Yes Route: Injected □No □Yes Intranasal □No □Yes Smoked □No □Yes

When did you last use? _____ Are you having any withdrawal symptoms? □No □Yes If yes, which apply?

□Nausea □Vomiting □Diarrhea □Chills □Sweating □Insomnia □Aches & pains □ Anxiety

Have you ever gone through withdrawal from drugs? □No □Yes If yes, when? _____

Are you currently in a drug treatment program? □No □Yes If yes, Name of program? _____

Type of Program: □Detox □Methadone □Residential Treatment □Outpatient □12 Step□ Other

Alcohol Use History:

Do you drink alcohol? □ No □Yes If yes, type? □Beer □Malt liquor □Wine □Liquor

How often do you drink? □ Daily □Weekly □Monthly □Rarely

How much do you drink when you drink? _____

Do you notice over time that you need to drink more for the same effect? □No □Yes

When was your last drink? _____

Are you having any withdrawal symptoms? □No □Yes If yes, which apply? □Headache □Fever □Nausea

□Vomiting □Insomnia □Tremor □Hallucinations □Convulsions

Have you ever gone through alcohol withdrawal in the past? □No □Yes How long ago? _____

Have you ever been in treatment for alcohol use? □No □Yes If yes, when? _____

What type of program? □Outpatient □Inpatient

Have you ever been convicted for driving under the influence of alcohol? □No □Yes If yes, when? _____

Tobacco History:

Have you ever used tobacco products? □No □Yes If yes, please answer the following questions:

Do you currently use tobacco products? □No □Yes If yes, what type of products? □ Cigarettes □Cigar □Pipe □Chewing tobacco

How long have you used tobacco products? _____ How frequently did/do you use tobacco?_____

When did you last use tobacco products?_____

Are you having any withdrawal symptoms from not using tobacco? □No □Yes If yes, what symptoms are you experiencing?

□Cravings □Irritation □Anger □Increased Appetite □Weight Gain □Concentration Problems □Restlessness □Insomnia

□Anxiety

Preventative Medicine/Screening History

Have you had screening for cancer? ☐Yes ☐No When? (mm/yyyy) _____

What type screening & results if known? _____

Have you had a mammogram? ☐Yes ☐No When? (mm/yyyy)_____ Results, if known_____

Have you had a pap smear? ☐Yes ☐No When? (mm/yyyy)_____ Results, if known_____

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal (con't)

OBJECTIVE:

Vital Signs

T_____ P_____ R_____ BP_____ HT_____ WT_____
Visual Acuity (Snellen): Left_____ Right_____ Both_____
Hearing: □ Grossly intact □ Other_____

General Physical Examination

	R = Refused	NE = Not Evaluated	
General	R	NE	Findings:
ENT	R	NE	Findings:
Dental	R	NE	Findings:
Neurological	R	NE	Findings:
Cardiac	R	NE	Findings:
Pulmonary	R	NE	Findings:
Gastrointestinal	R	NE	Findings:
Genitourinary	R	NE	Findings:
Extremities	R	NE	Findings:
Skin	R	NE	Findings:
Comments/Other Findings:			

Mental Status Examination

Orientation	Alert □No □Yes Oriented to person □No □Yes Place □No □Yes Time □No □Yes
Perceptions/ Thought Content	Perceptual disturbances? □No □Yes If yes, □ Auditory hallucinations □ Visual hallucinations □ Delusions
Appearance	□ Appropriately dressed □ well groomed; □ Disheveled; □ Other
Posture	□ Erect; □ Stooped; □ Slouched; □ Other
Gait/Walk	□ Steady; □ Shuffle; □ Limp; □ Other
Movement	□ Appropriate; □ Tics; □ Repetitive; □ Rigid; □ Agitated; □ Slow; □ Other
Mood	□ Appropriate; □ Labile; □ Relaxed; □ Happy; □ Calm; □ Distressed; □ Angry; □ Agitated; □ Sad/Depressed; □ Fearful/Anxious; □Irritable, □ Other
Attitude	□ Cooperative; □ Uncooperative; □ Threatening; □ Evasive
Speech	□ Coherent; □ Incoherent; □ Pressured; □ Average speed; □ Rapid; □ Slow; □ Slurred; □ Mumbled; □ Talkative; □ Loud; □ Soft; □ Other
Intelligence	□ Appears normal; □ Appears developmentally delayed
Insight	□ Good; □ Impaired
Comments:	

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

AMERICAN OVERSIGHT

Physical Examination/Health Appraisal (con't)

Assessment:

___Physical exam/health appraisal shows no significant medical, mental health or dental issues currently.

___Physical exam/health appraisal shows the following significant issues:

Plan:

Treatment including medications: _____
_____
_____
_____

Immunizations, Injections, Imaging, Labs:

Referrals:

Other

Preventative Medicine/Patient Education:
__Given the Staying Healthy brochure in the _____ language.
__Verbally given instruction on dental hygiene.
__Provided with instruction appropriate to patient's health needs.
__Patient verbalized understanding of teaching or instructions provided.
__Patient was asked if he/she had any additional questions, and any questions were addressed.
__Patient was instructed to return to medical clinic as needed.
__Patient was instructed to return to clinic for appointment.
__Health Assessment was rescheduled until [_____] to provide sign language interpreter for health assessment.
__Health Assessment was rescheduled until [_____] to provide foreign language interpreter for health assessment.
__Other:_____

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival:	DOB:
Facility:	Sex:

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MEDICAL TRANSFER SUMMARY

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival at Sending Facility:	DOB:
Sending Facility:	Sex:

1. General Information:

Cleared for Travel by Ground Transportation: □ Yes □ No Date of Departure: _____

Cleared for Travel by Air Transportation: □ Yes □ No Final Destination, if known: _____

Reason for Transfer: □ Custody □ Medical Medical Escort required: □ Yes □ No If yes, type: □ Medical □ Psychiatric

2. Current Medical, Dental, and/or Mental Health Diagnoses/Problems: **URGENT**

_____

_____

_____

_____

3. Allergies: _____

4. Current Prescribed Medications: List All (Name, Dosage, Directions in layman's terms)

Check off Medication Required for Care en Route

Medication	Dose	# Sent	Route	Instructions for use (include proper time for administration)	Stop Date
☐					
☐					
☐					
☐					
☐					
☐					
☐					

5. TB Clearance Status for Transfer or Transportation

Screening Modality *(Check all that apply and document below)*: ☐ CXR ☐ TST ☐ IGRA ☐ Symptom Screen

CXR: Date: _____

TB Screening: ☐ Negative, not consistent w/TB ☐ Positive, consistent w/TB

TST: Administered Date: _____ **TST** Read Date: _____ Results: _____ mm induration

IGRA: Collection Date: _____ Results: ☐ Positive ☐ Negative ☐ Indeterminate

Symptom Screening Date: _____ Results: ☐ Positive ☐ Negative

Is the patient being treated for TB? ☐ No ☐ Yes, select options:

☐ Cleared for general detention population

☐ Not cleared for general detention population

☐ Being treated for TB, see attached TB Case Management documentation

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Medical Transfer Summary (con't)

6. Healthcare Follow-Up:

Recent (within 6 months) Test Results: _____

Recent (within 6 months) Hospitalizations/Surgeries: _____

Recommended Future Lab Work: _____

Pending Specialty Appointment (s):_____

Recommended Specialty Appointment (s):_____

Requires Immediate Follow Up: _____

7. Special Needs Affecting Transportation: -- Use Standard Infection Control Precautions for all patients --

Are there any medical, dental, or mental health condition that restricts the length of time the patient can be on travel status? □Yes □No

Reason(s) and maximum length of travel time: _____

Does the patient have any special needs that escorting staff should be aware of? □Yes □No

If so, what? _____

Equipment provided by: □ Medical Authority □ Other_____ Equipment owned by: □ Medical Authority □ Other_____

Patient will keep equipment upon arrival at destination? □Yes □No

Is there any medical equipment required to accompany the patient during travel? ☐ Yes ☐ No

If so, what? _____

Are any special precautions required during transport? □Yes □No

Precautions needed for the patient: _____

Precautions needed for the escorting staff: _____

8. Additional Comments (Mark through if no comments are made): Attach additional pages or medical records as needed

9. Release from custody: Attach □ Instructions for Requesting Complete Medical Records
□ Community Resource Information, if applicable

Sending Facility Point of Contact: _____

Sending Facility Contact Number: _____

_____	_____	_____	_____
Completed by Provider Printed Name	Date	Time	Provider Signature

Last Name:	First Name:
A#:	Country of Origin:
Date of Arrival at Sending Facility:	DOB:
Sending Facility:	Sex:

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IHSC Suspected and Confirmed Pulmonary Tuberculosis Medical Provider Guidance, rev. 10/23/18

The following is general guidance based on American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America 2016 practice guidelines. Please consult with clinical leadership as needed.

Initial appointment:

1) House individually in airborne infection isolation (AII).[1]
2) Recommend utilizing eCW TB template (initial and MHU admission)
3) Obtain a TB history including prior exposure and prior diagnosis/treatment.
    a. If the patient has a history of TB treated in the past several years:
        i. Advanced practice providers (APPs) should consult with a physician proficient in TB care to assess for likelihood of drug resistance/treatment failure.
        ii. If treated in the US, request records including prior smears, cultures and/or drug sensitivity testing (DST).
        iii. If treated in the US, request a CD of the end of treatment CXR and once received request the IHSC radiology vendor perform a direct comparison reading to IHSC admission CXR (See Appendix A).
4) Conduct a thorough review of systems especially respiratory and constitutional.
5) Order baseline labs – cbc, cmp, hgba1c, HIV Ab, 2-3 view CXR (PA/LAT or PA/LAT apical lordotic).
    a. Following uric acid levels is not recommended
6) Order 3 consecutive sputum specimens (AFB smear and culture x 2, AFB smear/MTB NAA (with RIF if possible)/culture x 1) by hypertonic saline induction[2], at least 8 hours apart but no more than 24 hours apart, ideally at least 1 performed before the morning meal. Recommending collecting the smear with the MTB NAA before the morning meal
7) Order TST (ppd), unless **documented** positive in the past. Document TST results in millimeters.
8) Counsel patient about possible TB diagnosis, diagnostics/confirmation pending, need for isolation to protect fellow detainees and staff. Unless CXR findings and clinical factors meet criteria to defer treatment (see Appendix B), order weight based RIPE/B6 (See Appendix C) to start after the 3rd sputum specimen is collected.[3] Your pharmacist is an excellent resource for specific dosing questions.
9) Order baseline Snellen/Ishihara
10) If all three AFB smears are negative (regardless of NAA being positive or negative), discharge the detainee to general population (GP) after 5 days of RIPE therapy, follow AFB cultures to completion and order a 6-week CXR (single view) with comparison to initial film.
11) Report patient to Compliance Officer, Infection Prevention Officer, or designee, to ensure reporting within 24-hour requirement to local health department, and CureTB enrollment is conducted.
12) Update problem list (See Appendix D).

[1]If no AII rooms are available, admission to a local hospital will be necessary. Also consider hospital admission for pleural effusion to assess for thoracentesis.
[2]If the patient is spontaneously producing copious purulent sputum, you can collect by expectoration without induction.
[3]UNLESS you have an alternate explanation for the CXR findings, you should assume they represent TB until proven otherwise and start RIPE treatment.

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At minimum weekly MHU/AII appointment (s):

1) Review all labs including smears/NAA – ensure all 3 sputum specimens have been collected and accessioned by the lab. Note: Positive smears and/or NAA should be discussed with a physician experienced with management of TB patients.
    a. If all 3 initial smears are AFB negative (even if the NAA is positive) and the patient has received 5 days of RIPE/B6, and drug resistance is not suspected, you may discharge them to GP[4].
    b. If any smear is positive, and confirmed by NAA to be MTB complex[5], order another set of 3 sputum specimens (smear/culture only, no NAA) to be performed 14 days from start of RIPE/B6, and continue AII.
        i. Order vitamin D 25-OH level and replete if deficient.
        ii. If 3 smears collected at 14 days after start of RIPE are **AFB negative** and drug resistance is not suspected (includes neg RIF on NAA test), you can discharge the patient to GP.
        iii. If 1 or more smears collected at 14 days after start of RIPE are **AFB positive**, AII should continue and sets of 3 sputum specimens should be repeated every 1-2 weeks until all 3 are negative. Once this occurs and if drug resistance is not suspected, you can discharge the patient to GP.
2) Assess for and document any possible drug reactions.
    a. Possible drug reactions should be discussed with a pharmacist and/or physician.
3) Obtain weekly weights, on the same scale, if possible.
    a. If weight has changed, assess for need to change drug doses.
4) Document TST result in millimeters.
5) If baseline labs are normal, order next cbc/lfts for 1 month from baseline labs.
    a. If abnormal, consult with a physician as to the next interval to be tested, additional testing as clinically indicated and/or any adjustments in treatment.
    b. If HIV Ab is positive, consult with a physician familiar with HIV/TB coinfection management for further guidance.
6) Review Snellen/Ishihara
    a. Order another set for 1 month from the start of RIPE/B6.
7) Counsel patient on status of diagnosis and results of diagnostics thus far.
8) Ensure enrollment in transnational referral program for continuity of care (CureTB) has been initiated; if not completed, recommend completion prior to discharge to GP.
9) Inform the patient that the local health dept. and/or transnational referral program may be visiting with or calling them to obtain information about their possible TB infection.
10) Schedule a single view CXR with comparison to initial for 6 weeks after the start of RIPE/B6.
11) Update problem list as applicable.

[4]note, clearance for GP is synonymous with clearance for travel.
[5]if probe positive for MAC and negative for MTB, can discharge to GP, defer RIPE/B6 and follow cultures. if probe fails or another species is identified, continue as if MTB and consult with a physician experienced with TB management.

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General population (monthly) visits:

1) Review all labs including AFB cultures (drug susceptibility testing (DST) if culture positive), cbc, lfts. Schedule monthly cbc/lfts while on TB treatment.
    a. Positive AFB cultures should be discussed with a physician experienced with TB management.
2) Assess for and document any possible drug reactions
    a. Possible drug reactions should be discussed with a physician and/or pharmacist well-versed in managing complications of TB treatment.
3) Review monthly Snellen/Ishihara; schedule testing to occur monthly while on ethambutol.
4) Calculate and document # days of RIPE/B6; be cognizant that **unless the patient has cultures positive for MTB and you are waiting for DST results, 4 drug therapy should not extend beyond 56 days**. If AFB cultures are positive for MTB, **do not stop** 4 drug therapy until DST is available. If DST is taking longer than 2 weeks from the time of positive culture growth, inquire directly with laboratory as to cause for delay.
5) Review 6-week CXR result, if available.
6) Monthly weight
    a. If weight has changed, assess for need to change drug doses.
7) As diagnosis is confirmed or excluded, update local health department and CureTB.
8) Counsel patient on status of diagnosis and results of diagnostics thus far.
9) Update problem list.
10) If AFB cultures have been finalized as **negative** and CXR comparison results are available, a decision should be made as to whether treatment should be continued (continuation phase) and TB Classification can be completed (Appendix E).
    a. If the cultures are negative and the CXR is unchanged, 4 drug treatment can be discontinued. Note, if LTBI (positive ppd or IGRA), consider completion of 56 days of 4 drug treatment which is sufficient treatment for LTBI.
        i. This would be your final visit w/r/t this TB assessment.
    b. If initial cultures are negative but the CXR is improved or lesions have resolved, this is a confirmed case of culture negative TB, should be classified as 3, and INH/RIF/B6 should be continued to complete a total of 16 weeks of treatment[6].
        i. Continue to see the patient monthly as above until completion of treatment
        ii. Repeat a CXR with comparison after treatment is complete. This will become the patient's new baseline should they ever be assessed for TB in the future.
        iii. Counsel the patient on the possibility of both relapse and reinfection in the future. Any signs/symptoms of TB should be assessed immediately.
11) If AFB cultures are **MTB complex positive**[7]:
    a. Co-manage this patient with a physician experienced with TB treatment. The minimum duration of treatment of drug-sensitive MTB is 26 weeks (8 weeks 4 drugs + 18 weeks of INH/RIF/B6); duration should be determined by a physician well-versed in TB management).
    b. Ensure DST has been reported within 2-3 weeks after initial positive culture report
        i. If it hasn't been reported, please contact the lab (LabCorp or local health dept) weekly to follow up.
        ii. If any drug resistance is detected, notify the National Infectious Disease Physician and PHSP Unit ASAP.
            1. If you can't reach someone immediately, place the patient back in AII/MHU until relevance of drug resistance can be assessed and determined whether or not the patient may remain in GP.

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2. The transnational referral program should be informed since second line drugs may be limited in the patient's country of nationality.

c. A single sputum for AFB smear/culture (ideally early AM, pre-prandial) should be induced monthly to assess for "culture conversion" (culture negative on treatment). Once cultures are negative, no further sputum specimens are necessary unless clinically indicated (e.g. relapse in symptoms).
d. Repeat a CXR with comparison after treatment is complete. This will become the patient's new baseline should they ever be assessed for TB in the future.
e. Counsel the patient on the possibility of both relapse and reinfection in the future. Any signs/symptoms of TB should be assessed immediately.
f. Update the local health department and CureTB as to the status of treatment.

[6]if the CXR had cavitary changes or significant fibrosis, continue treatment for a total of 26 weeks (just as if culture positive).
[7]any other species identified are likely to be non-pathogenic; please discuss with a physician knowledgeable in this area.

For further reference:
IHSC PHSP Unit guidance (b)(7)(E)
ATS/CDC/IDSA 2016 TB clinical practice guidelines: http://cid.oxfordjournals.org/content/63/7/e147

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Appendix A – Instructions on requesting a comparison chest radiograph

1) If the radiology vendor is the same (e.g., Xrad interpreted the initial CXR and follow-up CXR), order an "IH X ray: Chest, single view follow up, on TB treatment"
    a. If the report does not indicate a comparison was made, request an addendum be issued with the comparison and whether it is unchanged, overall improved or overall worse. This may be achieved by calling the Xrad toll free number (1-800-380-8296) or via site's radiology technologist.
2) If the radiology vendors are different, request a CD image from vendor 1, upload image or provide CD to vendor 2 and request "comparison with prior film dated X/Y, patient currently on TB treatment". A call directly to our vendor is recommended to alert them of the image in question (1-800-380-8296).
    a. If the report does not indicate a comparison was made, request an addendum be issued with the comparison and whether it is unchanged, overall improved or overall worse.

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Appendix B - Initial Tuberculosis Management by Symptom Screening and Radiographic Findings

Category A Patient	Category B Patient	Category C Patient
Initial management		
Airborne infection isolation + diagnostics* + empiric treatment	**Diagnostics*; Airborne infection isolation only during sputum induction; no empiric treatment**	**No further work up; clear for GP/travel**
Symptom Screening and Radiographic findings		
Any of the following:	*No **A** criteria but any of the following:*	*No **A** or **B** criteria, could include…*
Positive symptom screen (with or without abnormal CXR)	Small pleural effusion/costophrenic angle (CPA) blunting	Apical pleural thickening
Retraction and/or volume loss	Uncalcified nodule(s) of any size	Calcified lesion of any size
Infiltrate, opacity, density or mass in any location of any size	Linear scar	Bronchovascular markings
Moderate or large pleural effusion^	Hilar enlargement	Peribronchial cuffing
Cavity of any size/location		
Miliary infiltrates		

*diagnostics: induced sputum every 8 – 24 hours x 3 (including 1 early AM, fasting) for AFB smear and culture, and at least 1 with MTB NAA (preferably with RIF molecular testing); complete blood count; comprehensive metabolic panel; HIV 4th generation screen; hgba1c; ppd (TST) or QFT
^patient should also undergo diagnostic thoracentesis

1) When an initial CXR screen is "positive" and findings are confirmed by a 2-3 view study, a provider must review the findings of the report to identify any findings consistent with **Category A**. If identified, proceed with full diagnostic evaluation*, airborne infection isolation (AII) and empiric weight-based 4 drug therapy + B6. **EXCEPTION**: An upper lobe **Category A** lesion visualized on single view CXR but not on the 2-3 view should be treated with full diagnostics, isolation and empiric treatment as well.

2) If CXR findings are not consistent with **Category A**, the provider should review **Category B**. If the CXR report has any finding in **Category B**, proceed with full diagnostic evaluation*, AII only to collect the sputa, and defer empiric TB treatment. *These patients should not be reported to the local health department, referred to CureTB or have a TB-CM note entered.* If AFB smears, NAA or cultures are positive, please contact the National Infectious Disease Consultant for further advisement.

3) If symptom screen and CXR findings are not consistent with **Category A** or **Category B**, no further work up is necessary and the patient should be cleared for GP/travel. The findings would be classified as **Category C**; a non-inclusive list of "other" findings is located in the table above. If the provider is unsure, they are encouraged to discuss with clinical leadership.

4) Assessment of CXR findings in immunocompromised patients should be reviewed on an individual basis with clinical leadership.

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Appendix C – RIPE/B6 dosing

Note: All PO, once daily^, directly observed via pill line. Seek assistance from your pharmacist if you have further questions.

Isoniazid (INH): 5 mg/kg, maximum 300 mg.

Rifampin (RIF): 10 mg/kg, maximum 600 mg.

Pyridoxine (B6): 50 mg.

Pyrazinamide (PZA): 40-55 kg* = 1000 mg, 56-75 kg = 1500 mg, >75 kg = 2000 mg

Ethambutol (EMB): 40-55 kg* = 800 mg, 56-75 kg = 1200 mg, >75 kg = 1600 mg

^if patient is experiencing GI intolerance recommend ranitidine 300 mg PO QHS and/or food with TB treatment. Avoid split dosing.

*use estimated lean body weight for any patient with BMI >30. Please utilize this calculator if needed: http://medcalc.com/body.html

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Appendix D - Pertinent ICD-10 codes

Positive ppd without active TB – R76.11

Contact with and (suspected) exposure to tuberculosis – Z20.1

Personal history of tuberculosis - Z86.11

Tuberculosis of lung – A15.0 (subcodes A15.0-A15.9 exist for more specificity)

Miliary tuberculosis – A19

Tuberculosis of other organs – A18 (subcodes A18.01-A18.89 exist for more specificity)

Resistance to a single antimycobacterial drug – Z16.341

Resistance to multiple antimycobacterial drugs – Z16.342

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Appendix E – Tuberculosis Classification

Class	Type	Description
0	No exposure to TB Not infected	No history of exposure, negative reaction to the tuberculin skin test
1	Exposure to TB No evidence of infection	History of exposure, negative reaction to a tuberculin skin test (given at least 10 weeks after exposure)
2	TB infection No TB disease	Positive reaction to the tuberculin skin test, negative bacteriologic examinations (if done), no clinical or x-ray evidence of TB disease
3	Current TB disease	Meets current laboratory criteria (for example, a positive culture) **or** criteria for current clinical case definition
4	Previous TB disease (not current)	Medical history of TB disease, **or** Abnormal but stable x-ray findings for a person who has a positive reaction to the tuberculin skin test, negative bacteriologic examinations (if done), and no clinical or x-ray evidence of current TB disease
5	TB suspected	Signs and symptoms of TB disease, but evaluation not complete (diagnosis pending)

Source: Diagnostic Standards and Classification of Tuberculosis in Adults and Children. Am. J. Respir. Crit. Care Med., Volume 161, Number 4, April 2000, 1376-1395

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U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

CLINICAL PRACTICE GUIDELINES FOR CHRONIC CARE CONDITIONS

IHSC Directive: 03-04
ERO Directive Number: 11735.1
Federal Enterprise Architecture Number: 306-112-002b
Effective Date: 24 Mar 2016

By Order of the Acting Assistant Director
Stewart D. Smith, DHSc/s/

---

1. PURPOSE: This issuance sets forth the policy and procedures for designating Clinical Practice Guidelines to be used to guide treatment for chronic care conditions.

2. APPLICABILITY: This directive applies to all Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) personnel, including but not limited to, Public Health Service (PHS) officers and civil service employees supporting health care operations in ICE-owned or contracted detention facilities and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ.

3. AUTHORITIES AND REFERENCES:

3-1. Title 8, Code of Federal Regulations, Section 235.3 (8 CFR § 235.3), Inadmissible Aliens and Expedited Removal.

3-2 Section 232 of the Immigration and Nationality Act, as amended, Title 8, U.S. Code, Section 1222 (8 USC § 1222), Detention of Aliens for Physical and Mental Examination.

3-3. Title 8, Code of Federal Regulations, Section 232 (8 CFR § 232), Detention of Aliens for Physical and Mental Examination.

3-4. Section 322 of the Public Health Service Act, as amended, Title 42 U.S. Code, Section 249(a) (42 USC § 249(a)), Medical Care and Treatment of Quarantined and Detained Persons.

3-5. Title 42, U.S. Code, Section 252 (42 USC § 252), Medical Examination of Aliens.

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4. **POLICY:** The frequency and content of periodic health assessments for individuals with chronic illnesses will be in accordance with the recommendations of nationally recognized organizations and/or in accordance with IHSC personnel's medical/clinical expertise. The following resources will be used to guide treatment:

4-1. Asthma
IHSC Asthma Clinical Practice Guideline
DAD Clinical Services Shared Documents

4-2. Chemical Dependence/Intoxication/Withdrawal
Federal Bureau of Prisons Clinical Practice Guideline: Detoxification of the Chemically Dependent Inmate
http://www.bop.gov/resources/health_care_mngmt.jsp

4-3. Depression
Federal Bureau of Prisons Clinical Practice Guideline: Management of Major Depressive Disorder
http://www.bop.gov/resources/health_care_mngmt.jsp

4-4. Diabetes
Federal Bureau of Prisons Clinical Practice Guideline: Diabetes
http://www.bop.gov/resources/health_care_mngmt.jsp

4-5. Epilepsy
American Epilepsy Society
http://www.aesnet.org/go/practice/guielines

4-6. Hepatitis A, B, and C
Federal Bureau of Prisons Clinical Practice Guidelines for Hepatitis A, Hepatitis B, and Hepatitis C and Cirrhosis (three different clinical practice guidelines).
http://www.bop.gov/resources/health_care_mngmt.jsp

IHSC Hepatitis C Clinical Guidelines
DAD Clinical Services Shared Documents

4-7. HIV
Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents NIH http://www.aidsinfo.nih.gov/guidelines

4-8. Hypertension
IHSC Hypertension Clinical Practice Guideline
DAD Clinical Services Shared Documents

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4-9. Lipids

2013 American College of Cardiology/American Heart Association Blood Cholesterol Guideline

2011 American Heart Association Scientific Statement: Triglycerides and Cardiovascular Disease

https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a

https://circ.ahajournals.org/content/123/20/2292.full.pdf

4-10. Schizophrenia

Federal Bureau of Prisons Clinical Practice Guideline: Pharmacological Management of Schizophrenia

http://www.bop.gov/resources/health_care_mngmt.jsp

4-11. Sickle Cell Disease

IHSC Sickle Cell Disease Clinical Practice Guideline

DAD Clinical Services Shared Documents

4-12. Transgender Care

IHSC Clinical Guidelines for the Treatment of Gender Dysphoria

DAD Clinical Services Shared Documents

4-13. Tuberculosis

American Thoracic Society, Centers for Disease Control and Prevention, and Infectious Disease Society of America: Treatment of Tuberculosis

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm

5. PROCEDURES: N/A

6. HISTORICAL NOTES: This policy replaces subsection 8.23 of the legacy DIHS Chapter 8, Medical. It is the first issuance in the new policy format.

7. DEFINITIONS: See definitions for this policy in the IHSC Glossary located on SharePoint: GLOSSARY FOR IHSC OFFICIAL GUIDANCE

8. APPLICABLE STANDARDS:

8-1. Performance Based National Detention Standards (PBNDS) 2011:
4.3 Medical Care

8-2. ICE Family Residential Standards
4.3 Medical Care

8-3. American Correctional Association (ACA):
1-HC-1A-16 Chronic Care; 4-4359 Chronic Care;

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4-ALDF-4C-19 Chronic Care

8-4. National Commission on Correctional Health Care (NCCHC):
Standards for Health Services in Jails, 2014
J-E-12 Continuity and Coordination of Care During Incarceration

9. PRIVACY AND RECORDKEEPING. IHSC maintains records generated as provided in this policy in accordance with applicable DHS Policy and the Alien Health Records System of Records Notice, 80 Fed. Reg. 239 (January 5, 2015).

Protection of Medical Records and Sensitive Personally Identifiable Information (PII).

9-1. Medical records, whether electronic or paper, may only be disclosed to or accessed by those officers and employees of the agency which maintain the record who have a need for the record in the performance of their duties. Paper records must be secured at all times within a locked cabinet or room when not under the direct control of an officer or employee of the agency with a need for the record in the performance of his or her duties.

9-2. Staff is trained at orientation and annually on the protection of patient medical information and Sensitive PII.

9-3. Staff references the Department of Homeland Security *Handbook for Safeguarding Sensitive Personally Identifiable Information* (March 2012) at:
https://insight.ice.dhs.gov/mgt/oop/Documents/pdf/safeguarding_spii.pdf
when additional information is needed concerning safeguarding Sensitive PII.

10. NO PRIVATE RIGHT STATEMENT. This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

AMERICAN OVERSIGHT

U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics

Approved by: CAPT (b)(6); (b)(7)(C) MD

Title: Acting AD-ERO, IHSC

Date Signed: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Effective Date:

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Foreword

This *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics* supplements the following IHSC Directives:

- # 05-11 (ERO # 11786.1*), Public Health Actions for Tuberculosis Care*

This Guide explains concepts, assigns responsibilities and details procedures for public health actions for tuberculosis prevention and care.

The intended audience is IHSC-staffed medical clinics.

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I. Tuberculosis Overview

A. Epidemiology

Tuberculosis (TB) is a serious disease caused by a bacterium called *Mycobacterium tuberculosis*. The bacteria usually attack the lungs, but TB bacteria can attack any part of the body such as the kidney, spine, and brain.

Transmission

TB bacteria are transmitted through airborne particles (droplet nuclei) that are generated when persons with pulmonary or laryngeal TB cough, sneeze, shout, or sing.

TB Infection

TB bacteria can live in the body without making you sick. This is called TB infection. People with TB infection are not contagious and cannot spread TB bacteria to others. If TB bacteria become active in the body and multiply, the person will progress from TB infection to TB disease.

TB Disease

TB bacteria become active if the immune system can't stop them from growing. People with TB disease are sick and may be able to spread the bacteria to other people.

Should exposure result in transmission and new infection, a newly infected person will not quickly become contagious. TB takes a long time to progress from infection to disease, with a 5-10% lifetime risk of progressing to TB disease. Persons are considered contagious as long as viable tubercle bacilli are discharged in the sputum. Effective treatment usually eliminates contagiousness of pan-sensitive TB within 2-4 weeks, although M. *tuberculosis* can still be cultured from sputum; drug resistant, multidrug-resistant, and extensively drug-resistant TB will require longer treatment to render a patient non-contagious. Contagiousness must be assessed individually based on clinical and laboratory monitoring.

B. Risk Factors

The following risk factors increase a person's chances of developing TB disease:

- HIV infection.
- Diabetes mellitus.

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- Recently infected with TB bacteria (past 2 years).
- Other health problems or treatment regimens that affect the immune system.
- Alcohol abuse or illicit drug use.
- Inadequate treatment for TB infection.

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C. Acronyms and Terminology

Term	Definition
Acid fast bacilli (AFB) examination	A laboratory test that involves microscopic examination of a stained smear of a patient specimen (usually sputum) to determine if mycobacteria are present. A presumptive diagnosis of pulmonary tuberculosis (TB) can be made with a positive AFB sputum smear result; however, approximately 50% of patients with TB disease of the lungs have negative AFB sputum smear results. The diagnosis of TB disease is usually not confirmed until Mycobacterium tuberculosis is identified in culture or by a positive nucleic acid amplification (NAA) test result; presence of acid fast bacilli on smear microscopy indicates higher potential for contagiousness.
Airborne infection isolation (AII) precautions	The isolation of patients infected with organisms spread through airborne droplet (AII) nuclei 1–5 µm in diameter. This isolation area receives substantial air changes per hour (ACH) (≥12 ACH for new construction since 2001 and ≥6 ACH for construction before 2001) and is under negative pressure (i.e., the direction of the air flow is from the outside adjacent space [e.g., the corridor] into the room). The air in an AII room is preferably exhausted to the outside, but can be recirculated if the return air is filtered through a high efficiency particulate respirator (HEPA) filter.
Airborne infection isolation room	A room designed to maintain AII. Formerly called negative pressure isolation room, an AII room is a single-occupancy patient-care room used to isolate persons with suspected or confirmed infectious TB disease. Environmental factors are controlled in AII rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. AII rooms provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of 6–12 ACH, and direct exhaust of air from the room to the outside of the building or recirculation of air through a HEPA filter.
Bacille Calmette-Guérin (BCG) vaccine	A vaccine for TB named after the French scientists Calmette and Guérin used in most countries where TB disease is endemic. The vaccine is effective in preventing disseminated and meningeal TB disease in infants and young children. It may have approximately 50% efficacy for preventing pulmonary TB disease in adults. The vaccine is not available in the U.S. but still used in many developing countries.

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Term	Definition
Cavity (pulmonary)	A hole in the lung parenchyma, usually not involving the pleural space. Although a lung cavity can develop from multiple causes, and its appearance is similar regardless of its cause, in pulmonary TB disease, cavitation results from the destruction of pulmonary tissue by direct bacterial invasion and an immune interaction triggered by *M. tuberculosis*. A TB cavity substantial enough to see with a normal chest radiograph predicts contagiousness.
CDC	U.S. Centers for Disease Control and Prevention.
Close contact to a TB patient	A person who has shared the same air space in a cell or room, or other enclosed environment for a prolonged period (days or weeks, not minutes or a couple hours) with a person with suspected or confirmed TB disease. Close contacts are referred to as high-priority contacts because they have the highest risk for infection with *M. tuberculosis*.
Co-infection	Refers to a patient who has two infections at the same time (e.g. HIV infection and TB infection).
Contact to a TB patient	Refers to someone who was exposed to *M. tuberculosis* infection by sharing air space with a contagious TB patient.
Contagious	Describes a characteristic of a disease that can be transmitted from one living being to another through direct contact or indirect contact; communicable. The agent responsible for the contagious character of a disease is also described as being infectious; the usual culprits are microorganisms.
Culture	Growth of microorganisms in the laboratory performed for detection and identification in sputum or other body fluids and tissues. This test usually takes 2–4 weeks for mycobacteria to grow (2–4 days for most other bacteria).
CXR	Chest x-ray.
Directly observed therapy (DOT)	Adherence-enhancing strategy in which a health care worker (HCW) or other trained person watches a patient swallow each dose of medication. DOT is the standard care for all patients with TB disease.

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Term	Definition
Drug susceptibility test	A laboratory determination to assess whether an *M. tuberculosis* complex isolate is susceptible or resistant to anti-tuberculosis drugs that are added to mycobacterial growth medium or are detected genetically. The results predict whether a specific drug is likely to be effective in treating TB disease caused by that isolate.
EID/ENFORCE	ICE ERO maintains records pertaining to arrests, detentions and removals in the Immigration and Enforcement Operational Records (ENFORCE) System of Records, which includes the Enforcement Integrated Database (EID).
Exposure	The condition of being subjected to something (e.g., an infectious agent) that could have an adverse health effect. A person exposed to *M. tuberculosis* does not necessarily become infected.
Extrapulmonary TB	TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes). The presence of extrapulmonary disease does not exclude pulmonary TB disease.
Extensively drug resistant (XDR) TB	MDR-TB plus resistance to a flouroquinolone and an injectable aminoglycoside.
First line therapy	Consists of the four TB drugs (isoniazid, rifampin, ethambutol, pyrazinamide) that form the core of treatment regimens for TB disease.
Detainee Health Record	IHSC health records include all records of care including medical, dental, and behavioral health provided to ICE detainees on-site at IHSC staffed facilities. IHSC health records may also include off-site care records received by IHSC such as testing, specialized care, or records of previous medical care.
High efficiency particulate air (HEPA) filter	High efficiency particular air filtration; required for AII room exhaust. A filter that is certified to remove ≥99.97% of particles 0.3 μm in size, including *M. tuberculosis*–containing droplet nuclei; the filter can be either portable or stationary. Use of HEPA filters in building ventilation systems requires expertise in installation and maintenance.
HIV	Human immunodeficiency virus

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Term	Definition
Index patient	The first person with TB disease who is identified in a particular setting. This person might be an indicator of a potential public health problem and is not necessarily the source patient.
Infectious period	The period during which a person might have transmitted a communicable microrganism to others. In the case of tuberculosis, for patients with positive AFB sputum smear results, the infectious period begins 3 months before the collection date of the first positive smear result or the symptom onset date (whichever is earlier) and ends when the patient is placed into AII or the date of collection for the first of consistently negative smear results. For patients with negative AFB sputum smear results, the infectious period extends from 1 month before the symptom onset date and ends when the patient is placed into AII (whichever was earlier).
Isoniazid (INH)	A highly active anti-tuberculosis chemotherapeutic agent that is a cornerstone of treatment for TB disease and the cornerstone of treatment for TB infection.
Interferon Gamma Release Assay (IGRA)	A type of an ex vivo test that detects the release of interferon (an immunoprotective protein) when a patient's cells are mixed with tuberculosis proteins. A positive test may indicate tuberculosis (latent) infection or disease.
Surgical Mask	A device worn over the nose and mouth of a person with suspected or confirmed infectious TB disease to prevent infectious particles from being released into room air.
Monoresistant	TB with resistance to one first line drug only.
Mycobacterium (M.) tuberculosis	The namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis, M. africanum, M. microti, M. canetii, M. caprae,* and *M. pinnipedii*.
M. tuberculosis culture	A laboratory test in which the organism is grown from a submitted specimen (e.g., sputum) to confirm the presence of *M. tuberculosis*.
Multi-drug resistant (MDR) TB	TB with resistance to at least INH and rifampin.
N95 disposable respirator	An air-purifying, filtering-facepiece respirator that is ≥95% efficient at removing 0.3 μm particles and is not resistant to oil.

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Term	Definition
Nucleic acid amplification test (NAAT)	Laboratory method used to target and amplify a single DNA or RNA sequence usually for detecting and identifying a microorganism. The NAAT tests for *M. tuberculosis* complex are sensitive and specific and can accelerate the confirmation of pulmonary TB disease.
Pansensitive	Pathogen (in this case TB) isolates which are sensitive to all drugs tested.
Resistance	The ability of certain strains of mycobacteria, including *M. tuberculosis*, to grow and multiply in the presence of certain drugs that would ordinarily kill or suppress them. Such strains are referred to as drug-resistant strains and cause drug-resistant TB disease.
Respirator	A CDC/National Institute for Occupational Safety and Health (NIOSH)-approved device worn to prevent inhalation of airborne contaminants.
Rifampin	A highly active anti-tuberculosis chemotherapeutic agent that is a cornerstone of treatment for TB disease.
RTMCC	TB Regional Training and Medical Consultation Center.
Second line therapy	Drugs less active against TB; used if there is resistance to first line drugs; includes fluoroquinolones, aminoglycosides, capreomycin, ethionomide, cycloserine, linezolid, *p*-aminosalicylic acid PAS, bedaquiline.
Smear (AFB smear)	A laboratory technique for preparing a specimen so that bacteria can be visualized microscopically. Material from the specimen is spread onto a glass slide and usually dried and stained. Specific smear, stain, and microscopy methods for mycobacteria are designed to optimally detect members of this genus. The slide is scanned by light or fluorescent high-power microscopy. These methods require ongoing quality assurance for prompt and reliable results. The results for sputum smears usually are reported as numbers of AFB per high-powered microscopy field or as a graded result, from +1 to +4. The quantity of stained organisms predicts infectiousness.
Sputum	Mucus containing secretions coughed up from inside the lungs. Tests of sputum (e.g., smear and culture) can confirm pulmonary TB disease. Sputum is different from saliva or nasal secretions, which are unsatisfactory specimens for detecting TB disease. However, specimens suspected to be inadequate should still be processed because positive culture results can still be obtained and might be the only bacteriologic indication of disease.

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Term	Definition
Suspected TB	A tentative diagnosis of TB that will be confirmed or excluded by subsequent testing. Cases should not remain in this category for longer than 3 months.
Symptomatic	A term applied to a patient with health-related complaints (symptoms) that might indicate the presence of disease. In certain instances, the term is applied to a medical condition (e.g., symptomatic pulmonary TB).
Symptom screen	A procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).
Tuberculosis (TB) disease	Condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present [see below]) illness. The bacteria can attack any part of the body, but disease is most commonly found in the lungs (pulmonary TB). Pulmonary TB disease can be infectious, whereas extrapulmonary disease (occurring at a body site outside the lungs) is not infectious, except in rare circumstances.
Tuberculosis (TB) infection	Tuberculosis infection is a continuum that may or may not include clinical TB disease; in the absence of TB disease, TB infection is not contagious. Once infected with TB, persons are at risk of progressing to TB disease if they do not complete a preventive therapeutic regimen.
Tuberculin skin test (TST)	A diagnostic aid for finding *M. tuberculosis* infection. A small dose of tuberculin is injected just beneath the surface of the skin (in the United States by the Mantoux method), and the area is examined for induration by palpation 48–72 hours after the injection. The indurated margins should be read transverse (perpendicular) to the long axis of the forearm.

II. TB Risk Classification and Assessment

A. TB Risk Classification

Detention facilities are classified as non-minimal risk unless there is evidence of ongoing transmission; risk classifications for correctional and detention facilities are established in accordance with CDC | TB | TB Guidelines - Correctional Facilities. The ongoing transmission category should be used when there is documented

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transmission of TB within a facility and is to be used only as a temporary category while the transmission is investigated and contained.

B. TB Risk Assessment

The Health Services Administrator (HSA) or designee should evaluate each possible occurrence of TB transmission within the facility, including consideration of the following indicators:

- the number and percentage of staff, detainees, and/or residents whose tests for TB infection converted and the conditions contributing to the conversion.
- the number of TB exposure incidents (see Contact Investigation).
- evidence of person-to-person transmission.
- the timeliness with which patients with suspected TB disease are detected, isolated, and evaluated.

III. TB Screening

Health staff should screen all newly arriving detainees and residents for symptoms suggestive of TB within 12 hours of arrival and in accordance with CDC | TB | TB Guidelines by Topic.

Health staff should implement TB screening for adult detainees at detention and staging facilities with IHSC medical staffing in accordance with the Performance Based National Detention Standards (PBNDS) under which the facility that will house the detainee operates.

Health staff should conduct TB screening for family residential facilities with IHSC medical staffing in accordance with the most current Family Residential Standards.

Separate housing need not be provided pending completion of screening unless a detainee presents with clinical or radiographic evidence suggestive of TB disease.

A. TB Symptom Screening

Health staff should screen all detainees for symptoms consistent with TB disease within 12 hours of arrival to facilities with IHSC medical staffing, regardless of anticipated duration of stay. TB symptom screening includes assessment of the following:

- Cough of two weeks duration or longer.
- Chest pain.
- Hemoptysis (bloody cough).

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- Unexplained weight loss.
- Night sweats.
- Fever.
- Loss of appetite.

B. Evaluation of Persons with High Risk Conditions for TB

A medical provider should evaluate detainees at elevated risk for TB for atypical clinical presentation within 72 hours of identification; elevated risk includes, but is not limited to the following characteristics:

- Known history of tuberculosis disease.
- HIV.
- Known close contact to a person with TB disease.
- Diabetes mellitus.
- Injection or noninjection illegal drug use.
- Alcohol abuse.
- Other immunosuppressed state (e.g., lymphoma, on chronic steroid therapy).

C. Persons in Continuous Law Enforcement Custody with Recent TB Test Results

For adult detainees in continuous law enforcement custody, documented negative TB testing results within one year of arrival are acceptable as intake TB testing assuming the detainee is asymptomatic.

For adult detainees in continuous law enforcement custody with negative TB test results dated more than one year prior to arrival, health staff should test for TB within 72 hours of arrival (and if feasible, during intake medical screening) using a chest x-ray (CXR), TB skin test (TST), or interferon gamma release assay (IGRA) depending on the capabilities of the facility and within the scope of each health care staff's clinical license.

For all detainees, regardless of age, in continuous law enforcement custody who will be housed at family residential facilities, TB symptom screening and documented negative TB testing results within one year of arrival may be accepted as intake TB screening. Acceptable TB test documentation from previous facilities includes TST results in mm documented by an RN, Nurse Practitioner, Physician Assistant, or Physician, CXR findings, laboratory results of sputa for AFB smears, cultures, and/or nucleic acid amplification test (NAAT).

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D. Considerations for TB Screening of Persons Expected to be in the Facility for Less than 72 Hours

Health staff should conduct TB symptom screening for all newly arriving detainees within 12 hours of arrival. Health staff should evaluate detainees with symptoms suggestive of TB disease for possible TB disease, including appropriate testing for TB infection (TST or IGRA) and active disease (CXR). Health staff should manage detainees with clinical presentation suggestive of TB disease and document appropriately for placement in the general population, release, or removal.

E. TB Testing in Facilities with Radiography On-Site

In facilities with on-site CXR capabilities, adult detainees should have a single view, posteroanterior (PA), CXR completed as soon as possible, but no later than 72 hours. Detainees with symptoms suggestive of active pulmonary TB should be placed in an airborne infection isolation (AII) room promptly.

Health staff that perform CXRs should ensure that administering CXRs is consistent with the scope of their clinical license in the state that issued the license and in the state where the service is performed.

Health staff should obtain a two view CXR (PA and lateral) as an additional verifier for any single view CXR with an abnormal impression consistent with suspected TB disease ("positive") as soon as possible but no later than 72 hours of the initial, abnormal, single view CXR result. The two view CXR may be obtained on-site or off site, depending on the availability of appropriately licensed staff to perform this function.

Health staff should inform female detainees of their pregnancy test (urine hCG) result before a CXR is taken. Health staff should counsel female detainees with a positive pregnancy test prior to receiving a CXR. Health staff should inform female detainees with a positive pregnancy test that fetal radiation exposure after an x-ray is negligible and clinically insignificant, particularly if appropriately shielded. Health staff should offer pregnant female detainees the choice of TB testing via TST, IGRA or CXR. If a TST or IGRA is selected and the reading indicates infection, or if symptoms suggestive of TB disease are present, health staff should order or refer for a CXR.

F. TB Testing without Radiography On-Site

If the facility does not have on-site radiography capabilities, and in the absence of a prior documented positive test for TB infection, detainees with symptoms suggestive of active, pulmonary TB must be referred promptly for a CXR; if same day referral is not possible, detainees with symptoms suggestive of pulmonary TB disease should be placed in an AII room until they can be transported offsite for a CXR. For

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detainees without symptoms suggestive of active pulmonary TB, health care staff should administer a TST or blood draw for an FDA-approved IGRA within 72 hours of arrival; TSTs must be read once within 48–72 hours after it is placed. They may remain in general population during this period of time. For routine testing, it is acceptable to use IGRAs in place of, but not in addition to TSTs, with some special considerations as stated in the CDC | TB | TB Guidelines - Testing; see also TB Radiology Resource Page.

If the TST or IGRA result is newly positive, health staff should obtain a CXR to assess for possible TB disease as soon as possible, preferably within 72 hours, but not to exceed 7 days after receiving the positive TST or IGRA result. If the detainee is referred off-site for a CXR, a two-view, PA and lateral, CXR is recommended.

Health staff should refer detainees that have reliable documentation of a positive TST or IGRA and a prior negative CXR to a clinician for evaluation and assessment of TB status. Individuals with a previously negative CXR are not recommended to routinely have serial CXRs; i.e., annual CXRs are not recommended or necessary, unless there are other signs or symptoms of progression to active TB disease or the detainee has a significant underlying risk factor (e.g. HIV).

It is not necessary to house detainees separately from the general population unless there is clinical or radiographic evidence suggestive of TB disease.

For family residential facilities, refer also the section of this Guide, *TB Screening in Detainees and Residents <18 Years of Age*.

G. TB Screening in HIV Positive Individuals

A medical provider should order a CXR for all known HIV positive detainees routinely as part of their intake screening. The clinical and radiographic presentation of HIV related TB disease may be atypical and different than that of an HIV negative individual and radiographic manifestations may be subtle. Perform a TST or an IGRA on HIV positive detainees annually to exclude TB infection; this can be performed at their physical examination or chronic care appointment. If they have a baseline positive TST and/or IGRA, please perform a CXR for annual screening.

H. TB Screening in Detainees and Residents <18 Years of Age

Health care personnel should evaluate residents <18 years of age for symptoms consistent with pediatric presentations of TB disease. Health care personnel should also assess them for a history of close contact to a person known to have had TB disease. *See* Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents and Pediatrics: Targeted Testing and Treatment for TB in Children and Adolescents. Signs and symptoms of TB disease in children include the following:

- Cough;

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- Feelings of sickness or weakness, lethargy, and/or reduced playfulness;
- Weight loss or failure to thrive;
- Fever; and/or
- Night sweats.

The most common form of TB disease occurs in the lungs, but TB disease can affect other parts of the body as well. Symptoms of TB disease in other parts of the body depend on the area affected. Infants, young children and immunocompromised children (e.g., children with HIV) are at the highest risk of developing the most severe forms of TB such as TB meningitis or disseminated TB disease.

For detainees and residents <18 years of age, health care staff should perform intake TB testing according to the following algorithm:

1. For residents less than two years of age:

   a) If the resident does not have signs and symptoms suggestive of TB, no further testing is required unless required by state law.

   b) If the resident shows signs or symptoms suggestive of TB, health care staff should administer a tuberculin skin test (TST) and chest x-ray (CXR) with two views [posteroanterior (PA) or anteroposterior (AP) and a lateral view].

   c) If the resident shows signs or symptoms suggestive of TB (extrapulmonary or pulmonary), a medical provider should refer the resident to a specialist with expertise in childhood TB to obtain gastric aspirates for smear and culture.

2. For residents two through four years of age:

   a) If the resident does not have signs and symptoms suggestive of TB, health care staff should attempt to administer a TST. If a TST cannot be accomplished, or if interpretation of the TST 48–72 hours after placement cannot be accomplished, health care staff should conduct perform a CXR with two views (PA or AP and lateral views).

   b) If the resident shows signs or symptoms suggestive of TB or has a positive TST, health care staff should administer a CXR with two views (PA or AP, and a lateral view).

3. For residents five through 14 years of age:

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a) If the resident does not show signs or symptoms suggestive of TB, health care staff should administer a test for TB using a TST or FDA-approved Interferon Gamma Release Assay (IGRA). If a TST or IGRA cannot be accomplished, or if interpretation of the TST 48–72 hours after placement cannot be accomplished, health care staff should administer a CXR with two views (PA and lateral views).

b) If the resident shows signs or symptoms suggestive of TB, or has a positive TST or IGRA, health care staff should administer a CXR with two views (PA and lateral views).

4. For residents 15 through 17 years of age:

a) Health care staff should administer a CXR (PA view only). If a CXR cannot be accomplished promptly, health care staff should administer a TST or IGRA.

It is recommended that health care staff administer the same TB testing method consistently for a target age group with minimal exceptions. Reference Figure 2, *TB Screening Algorithm for Residents in ICE Custody at Family Residential Centers with IHSC Medical Staffing*.

Health care personnel that perform CXRs must have verified competency in age-appropriate technical specifications when performing CXRs on residents. *See* ACR-SPR Practice Parameter for the Performance of Chest Radiography and ACR-SPR Practice Parameter for the Performance of Portable (Mobile Unit) Chest Radiography.

I. Refusal of TB Screening

If a detainee refuses TB screening using radiography, offer screening using TST or an FDA-approved IGRA.

If a detainee refuses all methods of TB screening and testing and presents with signs or symptoms suggestive of TB, a medical provider should order that the detainee be placed in an airborne infection isolation room for 14-30 days, and health staff should provide education daily, offer TB screening daily, and observe and assess for changes in signs and symptoms. If a detainee with clinical signs or symptoms continues to refuse TB screening for longer than 14-30 days, the medical provider should consult with the Regional Clinical Director or Associate Medical Director for guidance regarding continued isolation.

If a detainee refuses all methods of TB screening and testing (including verbal symptoms screen) and presents without signs suggestive of TB, health staff should recommend that the detainee be housed in a single cell (not airborne infection isolation) for 14-30 days, provide daily education, offer TB testing daily, and observe and assess for onset of clinical signs or symptoms. If a detainee without clinical

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signs and symptoms continues to refuse TB screening for longer than 14-30 days and has not developed signs or symptoms, it is acceptable to release to general population and clear for transfer, release, or removal.

J. Tuberculin Skin Test Interpretation

For general TB screening with a TST, health staff should follow CDC: Targeted Tuberculin Testing and Treatment of Latent TB Infection. For general screening in any detainee without other known risk factors for TB, a TST reading of greater than or equal to 10 mm of induration is considered to be a positive result. Health staff should interpret the TST reaction once 48-72 hours after application by measuring the induration, not erythema, on the horizontal axis. Health staff should document results in number of mm (even if 0 mm).

For testing during contact investigations, health staff should refer to CDC | TB | TB Guidelines - Contact Investigations.

A TST reaction of greater than or equal to 5mm of induration is considered positive in the following circumstances:

- HIV-infected detainees
- Recent contacts of a detainee with infectious TB disease
- Detainees with fibrotic changes in chest radiograph consistent with prior TB
- Organ transplant recipients
- Detainees who are immunosuppressed for other reasons (e.g., taking equivalent of greater than or equal to 15 mg/day of prednisone for 1 month)

A TST reaction of greater than or equal to 10 mm induration is considered positive in the following:

- Recent immigrants (within the last 5 years) from countries where TB has a high prevalence
- Injection illegal drug users
- Residents or employees of high-risk congregate settings (e.g., prisons, jails, long-term care facilities for the elderly, health-care facilities, residential facilities for patients with HIV, and homeless shelters)
- Detainees with clinical conditions not previously mentioned
- Detainees younger than 4 years of age
- Detainees younger than 18 years of age exposed to an adult at high risk for TB disease

A TST reaction of greater than or equal to 15 mm of induration is considered positive in persons with no known risk factors for TB (not applicable in the ICE detention or resident setting).

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K. Interferon Gamma Release Assay (IGRA)

IGRAs test for TB infection; IGRAs do not identify TB disease. Health staff may use FDA-approved IGRAs for detection of TB infection in accordance with CDC guidelines and manufacturer instructions; consider the availability of laboratory resources and specific training requirements to perform testing according to specifications. For routine testing, IGRAs may be used in place of, but not in addition to TSTs, with some special considerations as stated in the CDC guidelines. Health staff should refer to CDC | 2010 Guidelines for using IGRAs to Detect M.TB infection.

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Figure 1: Intake TB Screening for Adult ICE Detainees

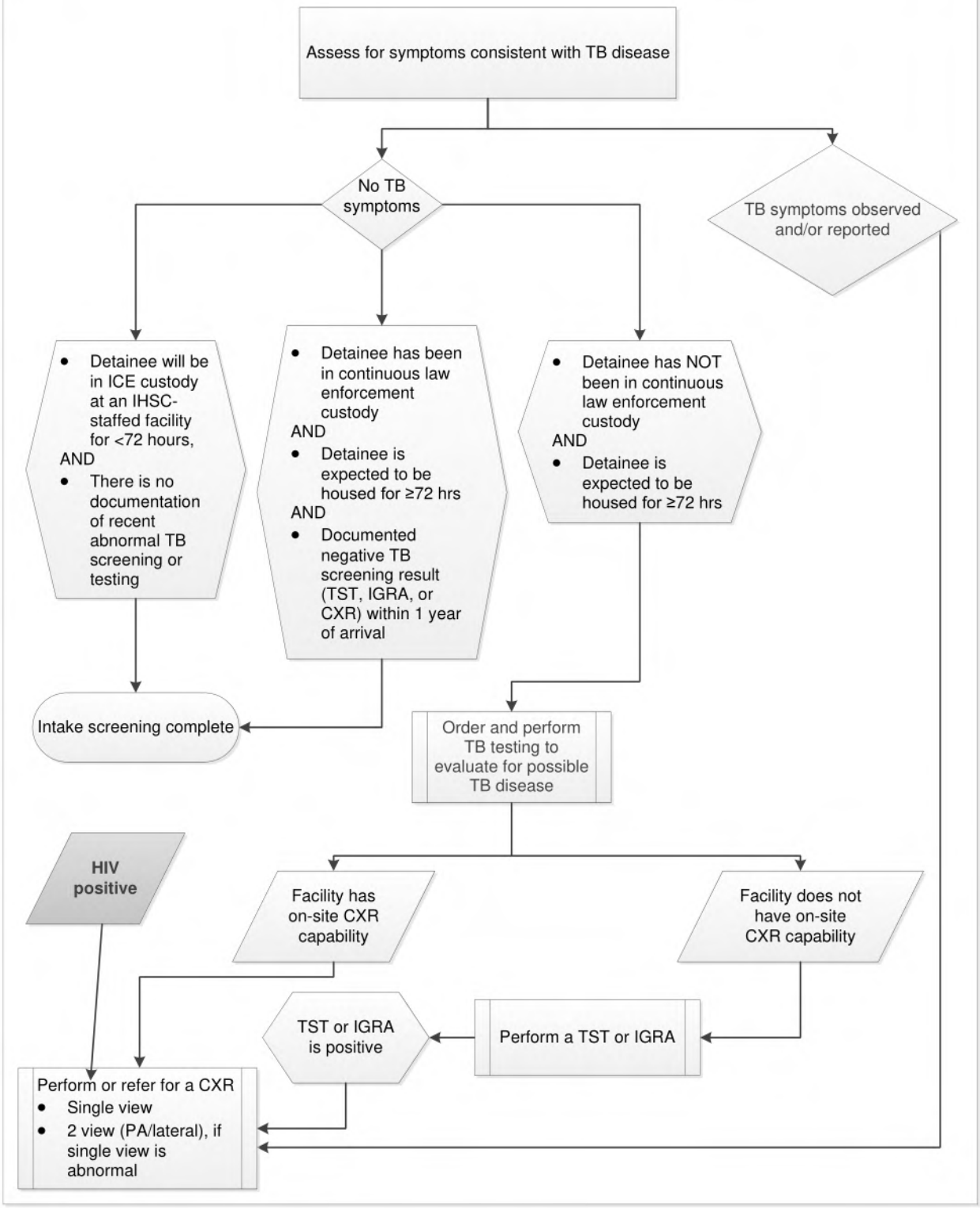

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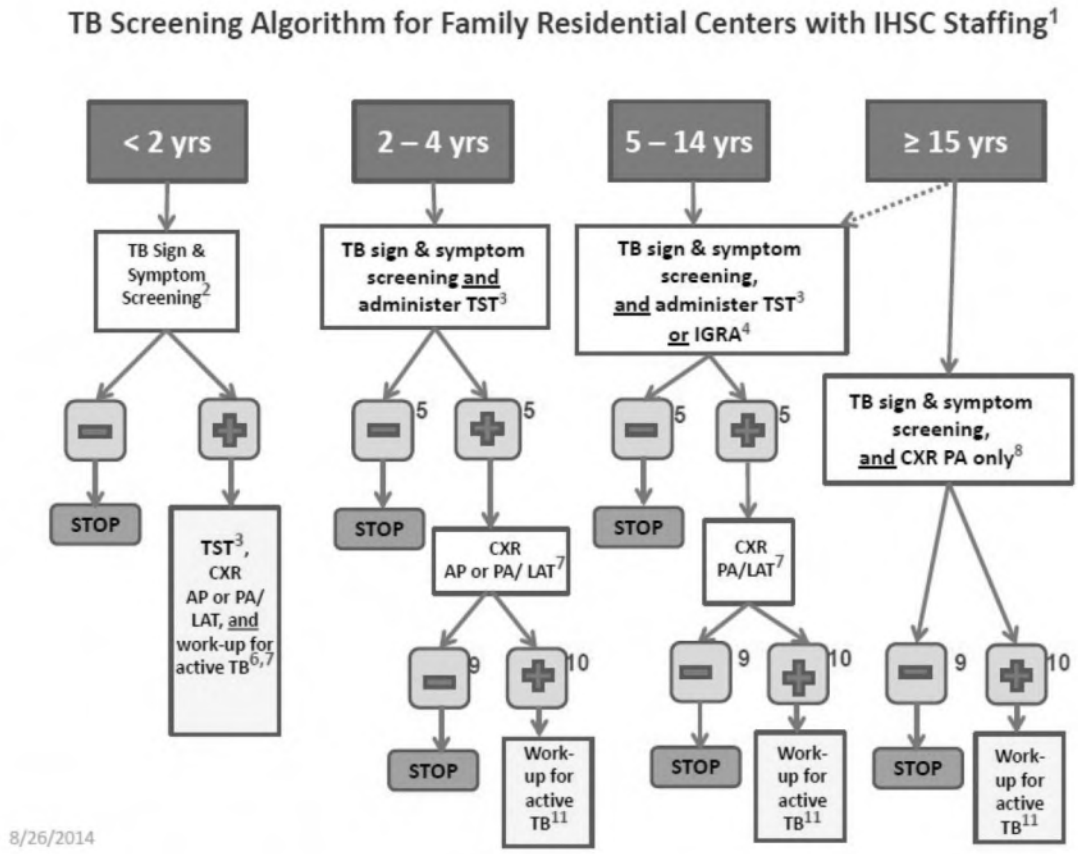
Figure 2



Footnotes for Figure 2

1. As part of the initial medical screening, each resident should be examined for signs and symptoms of TB disease by health care personnel. Signs and symptoms suggestive of TB disease include: cough of two weeks duration or longer, chest pain, hemoptysis, fever, night sweats, unexplained weight loss and loss of appetite. In pediatric residents, additional signs and symptoms include feelings of sickness or weakness; lethargy, and/or reduced playfulness; and failure to thrive. Note that TST or IGRA results can be falsely negative when patients have TB disease. A resident whose illness could be TB might need specialty medical care regardless of TST or IGRA results. Note that TB disease presents differently in younger children than it does in older children or adults. If pediatric or medically complicated TB is suspected, expert medical consultation is recommended.

2. Signs and symptoms suggestive of TB include cough of two weeks duration or longer, chest pain, hemoptysis, fever, night sweats, unexplained weight loss and loss of appetite. In children, additional signs and symptoms include feelings of sickness or weakness, lethargy, and/or reduced playfulness, and failure to thrive.

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A medical history focusing on risk factors for TB (e.g., previous history of TB, family or household contact with contagious TB) should be elicited.

3. Tuberculin skin test (TST) should be administered intradermally, "Mantoux method," with tuberculin purified protein derivative (PPD).

4. Interferon-gamma release assays (IGRA) are blood tests. QuantiFERON®-TB Gold-in-Tube (QFT) and T-SPOT® TB (T-Spot) tests are currently the two commercial IGRAs for indirectly diagnosing infection with Mycobacterium tuberculosis, the causative agent of TB. If use of IGRA is implemented, the T-Spot test is recommended in IHSC facilities due to the complex logistical requirements needed for processing Quantiferon Gold InTube. IGRA is advantageous when testing residents who have been vaccinated with Bacillus Calmette–Guérin (BCG) because the results are not influenced by cross-sensitization, as they can be for TST. The interpretation of IGRA results is not stratified by risk factors or clinical condition as it is for TST. For IGRA, laboratory results will include standard qualitative test interpretation: positive, negative, indeterminate, or invalid. T-spot test results have the additional category of "Borderline (equivocal)." If the result is indeterminate, invalid or borderline, the IGRA should be repeated, or TST should be administered. For routine testing, IGRAs may be used in place of, but not in addition to TSTs, with some special considerations as stated in the CDC guidelines. See CDC's Morbidity and Mortality Weekly Report: *Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection – United States, 2010*.

5. Negative results from either TST or IGRA must not be used to exclude a diagnosis of TB disease if a resident has symptoms suggestive of TB. For routine testing, IGRAs may be used in place of, but not in addition to TSTs, with some special considerations as stated in the CDC guidelines. See CDC's Morbidity and Mortality Weekly Report: *Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection – United States, 2010*.

6. Children less than two years of age with signs or symptoms suggestive of TB should be administered a TST and CXR with 2 views [posteroanterior (PA) or anteroposterior (AP), and a lateral view]; in addition, they should be referred to a specialist with expertise in childhood TB to obtain gastric aspirates for smear and culture. These examinations should be done in coordination with the TB control program of the local health department in most settings.

7. When radiography is indicated because of symptoms or positive TST or IGRA results: two-view CXR (AP or PA), and a lateral view, for children two through four years of age ; PA and lateral view for children five through 14 years of age. Pregnant residents should have their abdomen and pelvis protected with double wrap-around lead shields.

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8. CXR with only a PA view should be used for residents 15 years of age and older. Pregnant residents should have their abdomen and pelvis protected with double wrap-around lead shields. CXR is preferred, with options for TST or IGRA if CXR cannot be accomplished.

9. CXR is negative for active TB disease: If the TST or IGRA is positive but CXR is negative and the resident does not have findings suggestive of extrapulmonary TB.

10. CXR is positive if it demonstrates abnormalities suggestive of TB disease (e.g., infiltrate or consolidation, cavities, nodules) as reported by the radiologist, regardless of symptoms.

11. Pediatric residents with suspected TB disease (extrapulmonary or pulmonary) should be referred to a specialist with expertise in childhood TB to obtain gastric aspirates for smear and culture and for case management guidance.

L. Post Screening Evaluation

Detainees with Symptoms or Abnormal CXR Results

Health care staff should refer detainees that have any symptom suggestive of TB disease, or any detainee with an abnormal CXR suggestive of pulmonary TB disease to a medical provider for medical consultation. If no medical provider is on duty at time of intake screening, health staff should place the detainee with suspected TB to an AII room pending prompt evaluation by a medical provider. If no AII room is available on site, health staff should refer the detainee to the nearest tertiary care facility for isolation and evaluation in consultation with the Clinical Director, staff physician, or designee.

Health care staff should fit the detainee with a tight-fitting surgical mask (not an N-95 respirator) when not in an AII room until determined by a medical provider to be noncontagious.

For all detainees with single view or two view abnormal/positive CXR results (if two CXR studies were ordered, labs/studies below must be ordered even if the second test was negative) , a medical provider should order a TST, and laboratory tests, including the following:

- three consecutive induced sputum specimens, collected 8–24 hours apart (at least one collected in the early morning) tested for acid fast bacilli (AFB) smear and culture plus nucleic acid amplification test (NAAT) on one sputum; and
- HIV serology; and
- baseline complete blood count; and
- complex metabolic panel

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It the two-view CXR is negative; the detainee is asymptomatic; and AFB smears, NAAT, and HIV serology are negative, the detainee is clear for general population and transportation and does not require empiric four drug TB treatment. However, medical providers should continue to follow AFB culture results and if culture results are positive, re-assess management needs and initiate public health notifications and actions to ensure that results are communicated to public health authorities and subsequent detention facility medical staff.

All patients with two view confirmation of the single view abnormal CXR findings will be managed for suspected, pulmonary TB disease, with full labs and empiric four drug TB treatment until culture results and 6–8 week comparison CXR can be assessed.

Adult Detainees with Positive TST or IGRA Results

For detainees that have a positive TST or IGRA result, health staff should perform or refer the detainee for a CXR to detect possible pulmonary TB disease, if the detainee does not have a recent documented CXR result. Health staff should ensure that the CXR is completed as soon as possible following medical evaluation and positive test result for TB infection, preferably within 72 hours from time of positive TST or IGR, but not to exceed 7 days. If the detainee is referred off-site for a CXR, a two-view, PA and lateral, CXR is recommended. Health staff that perform CXRs should ensure that administering CXRs is consistent with the scope of their clinical license in the state that issued the license and in the state where the service is performed.

It is not necessary to house detainees separately from the general population unless there is clinical or radiographic evidence suggestive of TB disease.

Persons Transferred Prior to Interpretation of TST or IGRA

If a detainee is transferred after the TST is placed and before the TST is interpreted, or after blood is drawn for IGRA and before the result is reported, health staff should document the date and time of TST placement or blood draw on the medical transfer summary, as well as dated assessment of TB symptoms.

Residents <18 Years of Age with a Positive TST, IGRA or CXR

- A medical provider should perform a directed physical examination for all children and adolescents with a positive TST, IGRA or CXR to assess for pulmonary or extrapulmonary TB disease or risks for TB-drug toxicity. *See* Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis Infection in Children and Adolescents.

- A medical provider should refer pediatric residents with suspected TB disease (extrapulmonary or pulmonary) to a specialist with expertise in childhood TB to obtain gastric aspirates for smear and culture.

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- A medical provider should consult with a pediatric TB expert for the treatment of pediatric residents with TB and for the management of infants, young children and immunocompromised children that are known to have been exposed to someone with infectious TB disease.

- A medical provider should seek expert medical consultation as needed through one of the Regional TB Training and Medical Consultation Centers. See U.S. Centers for Disease Control and Prevention (CDC) Regional Training and Medical Consultation Centers.

- Health staff should notify the Regional Clinical Director, Associate Medical Director-Field, Infectious Disease Consultant, and the Public Health Safety and Preparedness Unit of any pediatric resident with suspected or confirmed TB disease.

- Note that confirming the diagnosis of TB disease in children with a laboratory test can be challenging because it is difficult to collect sputum specimens from infants and young children. The laboratory tests used to find TB in sputum are less likely to have a positive result in children, due to the fact that children are more likely to have TB disease caused by a smaller number of bacteria (paucibacillary disease). For these reasons, the diagnosis of TB disease in children is often made without laboratory confirmation and instead based on a combination of the following factors:

    - Clinical signs and symptoms typically associated with TB disease;
    - Positive TST or positive TB blood test (IGRA);
    - CXR that has patterns typically associated with TB disease; and
    - History of contact with a person with infectious TB disease.

M. Annual TB Evaluation for Detainees in Continuous Law Enforcement Custody

Evaluate detainees in continuous law enforcement custody for symptoms consistent with TB within one year of the previously documented TB evaluation. Routine annual CXR is not recommended.

In HIV positive detainees, health staff should perform a TST or an IGRA annually to exclude recent TB infection.

Evaluate detainees with known recent exposure to contagious TB in accordance with CDC | TB | TB Guidelines - Contact Investigations.

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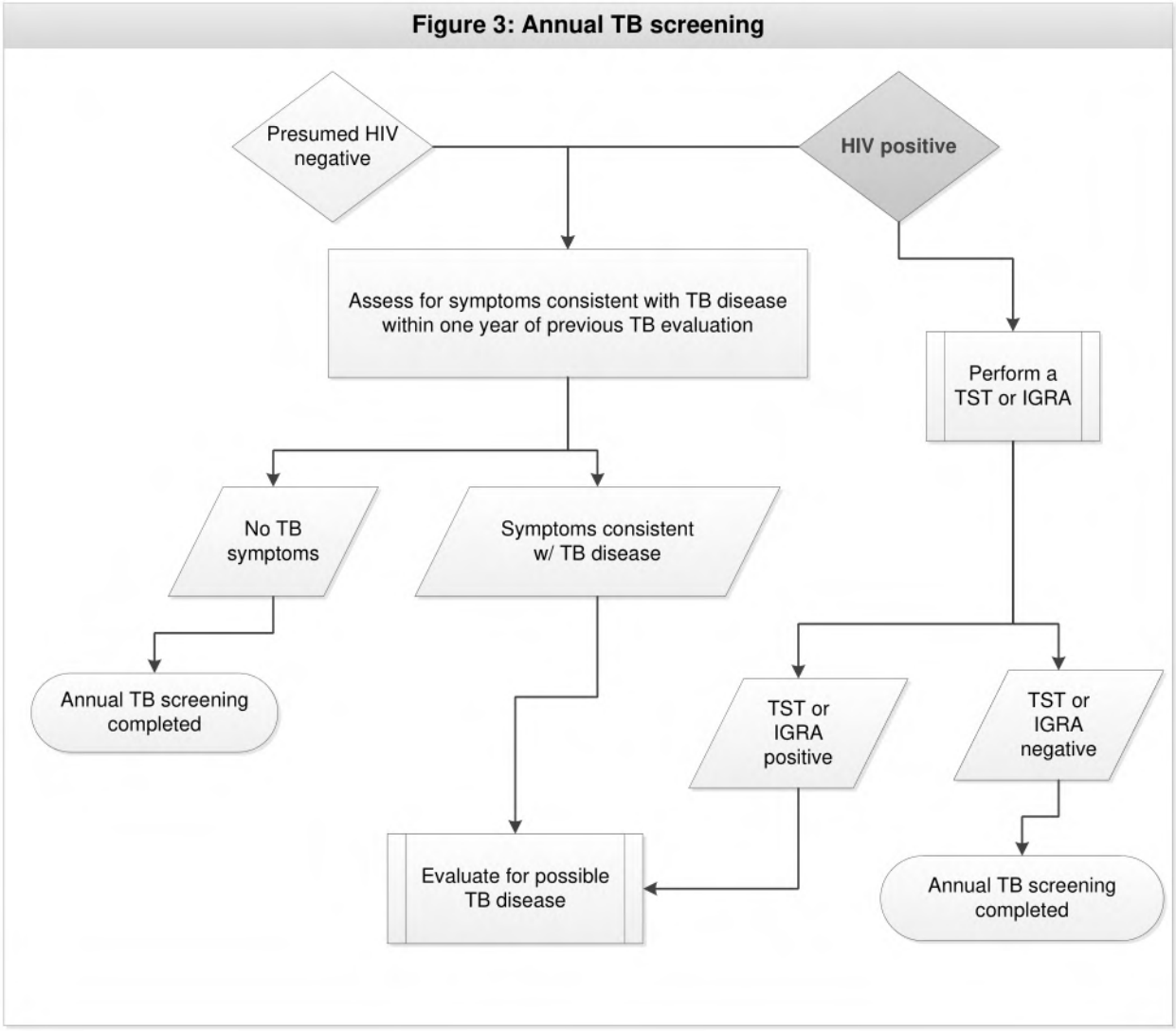
Figure 3: Annual TB screening



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IV. TB Disease Management

A. Diagnostic Testing

Health staff should refer to Table 1 for summary guidance on initial evaluation for suspected TB disease in adults, and to CDC | TB | TB Guidelines by Topic.

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Table 1
Guidelines for the evaluation of pulmonary tuberculosis (TB) in adults in five clinical scenarios

Patient characteristics	Recommended clinical evaluation
☐ Any patient with a cough of ≥ 2 weeks duration, with at least one additional symptom, including fever, night sweats, weight loss, or hemoptysis OR ☐ Any patient at high risk for TB‡ with an unexplained illness, including respiratory symptoms, of ≥ 2 weeks duration	Chest radiograph: if suggestive of TB,* • Collect three respiratory specimens for acid-fast bacilli (AFB) smear microscopy and culture collected 8–24 hours apart, including 1 early morning specimen; respiratory specimens include ○ 3 sputa(preferably induced), OR ○ 2 sputa (preferably induced) and 1 bronchoalveolar lavage (BAL); at least 1 sputum should be collected after BAL • Process at least one respiratory specimen for nucleic acid amplification test (NAAT)
☐ Any patient with HIV infection and unexplained cough and fever OR ☐ Any patient at high risk for TB‡ with a diagnosis of community-acquired pneumonia who has not improved after 7 days of treatment	• Chest radiograph* • Collect three respiratory specimens for acid-fast bacilli (AFB) smear microscopy and culture collected 8–24 hours apart, including 1 early morning specimen; respiratory specimens include ○ 3 sputa(preferably induced), OR ○ 2 sputa (preferably induced) and 1 BAL; at least 1 sputum should be collected after BAL • Process at least one respiratory specimen for nucleic acid amplification test (NAAT)
☐ Any patient at high risk for TB‡ with equivocal findings on chest radiograph (performed for any reason) suggestive of TB even if symptoms are minimal or absent	• Review of previous chest radiographs* if available • Collect three respiratory specimens for acid-fast bacilli (AFB) smear microscopy and culture collected 8–24 hours apart, including 1 early morning specimen; respiratory specimens include ○ 3 sputa(preferably induced), OR ○ 2 sputa (preferably induced) and 1 BAL; at least 1 sputum should be collected after BAL • Process at least one respiratory specimen for nucleic acid amplification test (NAAT)

*See TB Radiology Resource Page.

‡ Includes: recent exposure to a person with infectious TB; history of a positive test result for M.*tb* infection; HIV infection; injection or noninjection drug use; foreign birth and immigration in <5 years from a region in which incidence is high; residents and employees of high-risk congregate settings; membership in a medically underserved, low-income population; or a medical risk factor for TB (including diabetes mellitus, conditions requiring prolonged corticosteroid and other immunosuppressive therapy, chronic renal failure, certain hematological malignancies and carcinomas, weight >10% below ideal body weight, silicosis, gastrectomy, or jejunoileal bypass).

Source:

- Controlling Tuberculosis in the United States Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America, *MMWR* 2005; 54 (No. RR-12).
- Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis, *MMWR* 2009; 58 (01); 7-10.
- CDPH/CTCA. Guidelines for the Assessment of Tuberculosis Patient Infectiousness and Placement into High and Lower Risk Settings, 2009.

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B. Treatment

Health staff should manage detainees with suspected or confirmed TB disease in accordance with CDC | TB | TB Guidelines - Treatment.

Clinical decision making authority

A medical provider should make treatment decisions for detainees with suspected or confirmed TB disease and in consultation with the IHSC Infectious Disease Consultant or other medical provider experienced with TB clinical management, and in consultation with the respective local or state health department as needed. Health staff should refer to CDC | TB | TB Guidelines - Treatment and resources available through the CDC | TB | Regional Training and Medical Consultation Centers (RTMCC).

Directly Observed Therapy

Health staff should administer medications for suspected or confirmed TB disease using directly observed therapy (DOT). DOT involves a health care provider observing the detainee swallowing each dose of anti-TB medication. Health staff should document each observed dose of anti-TB medication on a medication administration record, and maintained as part of the health record.

Multidrug-Resistant (MDR) and Extensively Drug-Resistant (XDR) TB

A medical provider must treat MDR and XDR TB in consultation with the IHSC Infectious Disease Consultant and the local or state health department and/or the TB Regional Training and Medical Consultation Center and/or a CDC MDR/XDR TB, medical expert; see CDC | TB | Regional Training and Medical Consultation Centers (RTMCC).

Empiric Treatment Initiation

A medical provider should manage detainees suspected of having TB disease (symptoms or radiographic findings) empirically after the three initial sputa specimen are collected and before sputum or tissue culture results are known unless another explanation for clinical findings exclude TB disease.

C. TB Case Definition

See CDC TB case definition at NNDSS TB Case Definition.

Clinical Description

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lungs, but other organs might be infected.

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Clinical Case Definition

All criteria must be met to meet the clinical case definition. Medical providers should refer also to Table 2 and Figure 4.

1. A positive tuberculin skin test or positive interferon gamma release assay for *M. tuberculosis*, and
2. Other signs and symptoms compatible with TB (e.g., abnormal chest radiograph, abnormal chest computerized tomography scan or other chest imaging study, or clinical evidence of current disease), and
3. Treatment with two or more anti-TB medications, and
4. A completed diagnostic evaluation

Laboratory Criteria for Diagnosis

1. Isolation of *M. tuberculosis* from a clinical specimen; or
2. Demonstration of *M. tuberculosis* complex from a clinic specimen by nucleic acid amplification test; or
3. Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated

Case Classification

Confirmed – a case meets the clinical case definition or is laboratory confirmed. TB case classification should be documented after final cultures result and are reported, and if culture negative, after a 6-8 week comparison chest x-ray is administered (if the detainee is remains in ICE custody) to assess radiographic response to treatment.

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Table 2
American Thoracic Society Classification System for Tuberculosis

Class	Type	Description
0	No TB exposure; not infected	Persons in this class have no history of exposure and a negative reaction to the TST (if tested).
1	TB exposure; no evidence of infection	Persons in class 1 do have a history of exposure but have a negative reaction to the TST or a negative IGRA
2	TB infection; no disease	Persons in class 2 have a positive reaction to the TST (indicate mm in duration) or a positive IGRA, negative bacteriologic studies (if done), and no clinical, bacteriological, or radiographic evidence of active tuberculosis.
3	TB, clinically active	Clinical, bacteriologic, or radiographic evidence of current TB disease; Class 3 includes all patients with clinically active tuberculosis whose diagnostic procedures are complete.
4	TB; not clinically active	This classification is defined by a history of previous episode(s) of TB disease or abnormal stable radiographic findings in a person with a positive reaction to a TST (indicate mm induration) or a positive IGRA, negative bacteriologic studies (if done), and no clinical and/or radiographic evidence of current disease.
5	Suspected TB disease; diagnosis pending	Persons should be so classified when a diagnosis of tuberculosis is being considered, whether or not treatment has been started, until diagnostic procedures have been completed. Persons should not remain in this class for more than 3 months. When diagnostic procedures have been completed, the person should be placed in one of the preceding classes.

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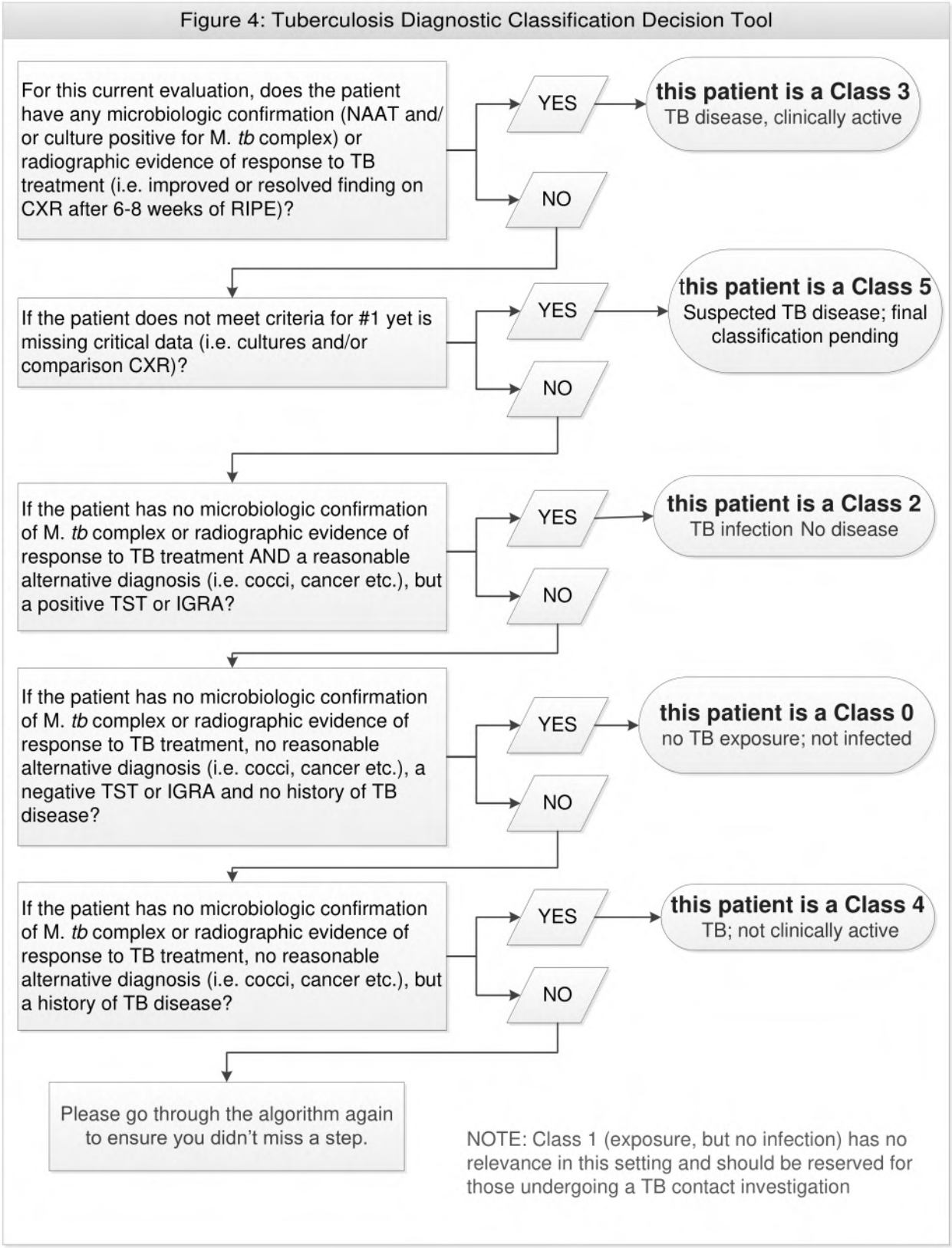
Figure 4: Tuberculosis Diagnostic Classification Decision Tool



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V. Considerations for Contagiousness

A. Airborne Precautions

Health staff should fit detainees with suspected or confirmed TB disease and detainees being evaluated for TB disease with a tight fitting surgical mask until they are moved to an area with environmental controls for airborne precautions. Health staff should immediately place detainees with suspected or confirmed TB disease and detainees being evaluated for TB disease under airborne precautions including placement in an airborne infection isolation (AII) room.

The HSA or designee should have a plan for referring detainees with suspected or confirmed TB to an appropriate facility with AII capabilities if AII rooms on-site are not available. The HSA or designee should establish arrangements or agreements with medical facilities in the local community to accept detainees for TB evaluation and AII.

A medical provider should determine when detainee suspected of having TB disease is non-contagious may be released from airborne precautions based on a clinical assessment of contagiousness in accordance with CDC guidelines and/or expert consultation.

Health staff should don a fit-tested, FDA-approved N95 respirator when entering an occupied AII room.

Additional Considerations for Family Residential Facilities

Family members living and traveling together are considered already exposed to their family member that has, or is suspected of having, active TB disease. In family residential facilities, parents may be placed in an AII room with a child requiring AII, and children may be placed in an AII room with a parent requiring AII, if the room can accommodate co-habitation and the non-ill family member is not at high risk for complications.

B. Assessment of Contagiousness

Contagiousness is related to the number of viable tubercle bacilli expelled in the air. For information to determine contagiousness, health staff should refer to the following:

- CDC | TB | TB Guidelines - Infection Control & Prevention
- CDC | TB | TB Guidelines - Correctional Facilities
- Controlling Tuberculosis in the United States

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A medical provider should evaluate detainees that have or are suspected of having pulmonary, laryngeal, or pleural TB disease for contagiousness based on the following characteristics:

- Respiratory tract disease with involvement of the lung, or airways including larynx, and
- Presence, frequency, and strength of cough, and
- Extent of cavitary pulmonary disease, and
- Sputa positive for AFB on smear microscopy, and
- Undergoing cough-inducing or aerosol-generating procedures (e.g., sputum induction, bronchoscopy, airway suction), and
- No receipt of anti-TB therapy, just started therapy, poor compliance with therapy or poor clinical or bacteriologic response to therapy.

C. Criteria for Assessing Contagiousness and Response to Treatment for Placement in General Population

Health staff should maintain detainees suspected of having TB disease in an AII room until TB disease is excluded by a medical provider based on history, physical examination, CXR, and bacteriology, and either an alternate diagnosis is made that explains the clinical syndrome or the detainee is determined to be noncontagious in accordance with CDC guidelines and/or expert consultation.

A medical provider should order that sputa specimens are collected for AFB using sputum induction. Sputa should be induced with hypertonic saline unless the detainee is spontaneously producing copious amounts of sputum. Where available, request that laboratories assess for and report on specimen quality. A medical provider should order nucleic acid testing (NAAT, or *M. tuberculosis* DNA probe) on at least one of the initial three sputum specimens collected. A medical provider should order sputa specimens at least monthly for AFB smear and culture to monitor for effectiveness of treatment. A medical provider may discontinue monthly sputa monitoring once three consecutive cultures are negative, unless clinical presentation dictates otherwise.

Health staff should ensure that detainees believed or known to have drug susceptible TB remain in an AII room at a detention facility or in the hospital while receiving TB evaluation and treatment and not be housed in the general detention population until the individual is determined by a medical provider to be noncontagious by meeting the criteria for placement in general population (see Table 3, Figure 5, and Figure 6).

A medical provider should apply more restrictive criteria for discontinuing isolation if the detainee is suspected or confirmed to have MDR-TB disease (i.e., TB that is resistant to both isoniazid and rifampin), Persons with MDR-TB are more difficult to

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render noncontagious and are more likely to have poor response to treatment and become contagious again. Since the consequences of MDR-TB transmission are greater than for drug-sensitive disease, a longer period of isolation is recommended to prevent TB transmission to others. Maintain detainees with or suspected of having MDR-TB in an AII room in a detention facility or hospital while receiving effective anti-TB therapy until the detainee is determined by a physician to be noncontagious by meeting the following criteria for placement in general population (see Table 3, Figure 5, and Figure 6).

Criteria for placement in general population are applicable regardless of whether the patient was evaluated in a detention facility or in a hospital.

A medical provider should evaluate clinical and radiographic improvement based on assessment of improvement of clinical signs and symptoms and of comparative radiographic findings. A medical provider should assess effective multidrug treatment based on molecular and phenotypic drug sensitivity testing and, if MDR or XDR TB, with expert consultation. Persons at increased risk of MDR-TB include the following:

- Known contact to an MDR-TB case.
- Current TB treatment with evidence of treatment failure.
- Prior incomplete or interrupted treatment for TB disease.
- Prior TB treatment since 1970 (exception: relapse of disease following completion of adequate therapy by Directly Observed Therapy (DOT) for an episode of pansusceptible disease).

Foreign birth in a country identified in the most current WHO | Global Tuberculosis Report as having high rates of MDR TB.

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Table 3: Criteria for Assessing Contagiousness and Response to Treatment for Placement in General Population

Category	Criteria
• **No symptoms suggestive of pulmonary TB disease, and** • **Initial respiratory specimens AFB smear negative x3, and** • **Negligible likelihood of MDR TB** (no known exposure to MDR TB, no history of prior episodes of TB with poor compliance during treatment), and not from a country or region with high incidence of MDR and XDR TB‡	1. Has produced 3 consecutive respiratory specimens NEGATIVE for AFB on smear microscopy, each obtained 8-24 hours apart with at least one collected in the morning* ○ Respiratory specimens include: • 3 sputa (preferably induced), **OR** • 2 sputa (preferably induced) and 1 bronchoalveolar lavage (BAL); at least 1 sputum should be collected after BAL **AND** 2. Has completed 5–7 days of standard multidrug anti-TB treatment* ***Treatment should be initiated after the initial 3 respiratory specimens have been collected**
• **Symptoms suggestive of pulmonary TB disease, and/or** • **One or more initial three respiratory specimens positive for AFB on smear microscopy, and** • **Negligible likelihood of MDR TB** (no known exposure to MDR TB, no history of prior episodes of TB with poor compliance during treatment), and not from a country or region with high incidence of MDR and XDR TB‡	1. Exhibits clinical improvement **AND** 2. Has completed at least 2 weeks of standard multidrug anti-TB treatment* **AND** 3. Has produced 3 consecutive respiratory specimens NEGATIVE for AFB on smear microscopy, each obtained 8-24 hours apart with at least one collected in the morning* ○ Respiratory specimens include: • 3 sputa (preferably induced), **OR** • 2 sputa (preferably induced) and 1 bronchoalveolar lavage (BAL); at least 1 sputum should be collected after BAL ***Treatment should be initiated after the initial 3 respiratory specimens have been collected**

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Category	Criteria
• **Suspected or confirmed to have MDR-TB disease** (i.e., TB that is resistant to both isoniazid and rifampin)	1. Notify the Regional Medical Director, Associate Medical Director, Deputy Assistant Director for Clinical Services, and the PHSP Unit of any detainee with or suspected of having MDR or XDR TB for awareness and placement on the HQ Significant Detainee Illness (SDI) list **AND** 2. Has produced 3 consecutive sputum specimens negative for AFB on smear microscopy and culture, each obtained 8-24 hours apart with at least two collected in the morning ○ more frequent AFB smears may be useful to assess the early response to treatment and to provide an indication of infectiousness ○ during treatment of patients with suspected MDR-TB pulmonary tuberculosis, a sputum specimen for microscopic examination and culture should be obtained at a minimum of monthly intervals until two consecutive early morning specimens are negative on culture **AND** 3. Has completed at least 2 weeks of effective multidrug anti-TB treatment **AND** 4. Exhibits clinical improvement

Extrapulmonary TB	Detainees with extrapulmonary TB are usually not contagious and do not require placement in AII (except for laryngeal TB); however, TB can be transmitted from a draining skin or tissue abscess, or post-operative incisions, containing *M. tuberculosis*. Follow established treatment guidelines in consultation with applicable subspecialties which include infectious disease and possibly other depending on the organ(s) involved.

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Figure 5
Criteria for placing detainees in general population following evaluation for TB disease
with respiratory specimens negative for AFB

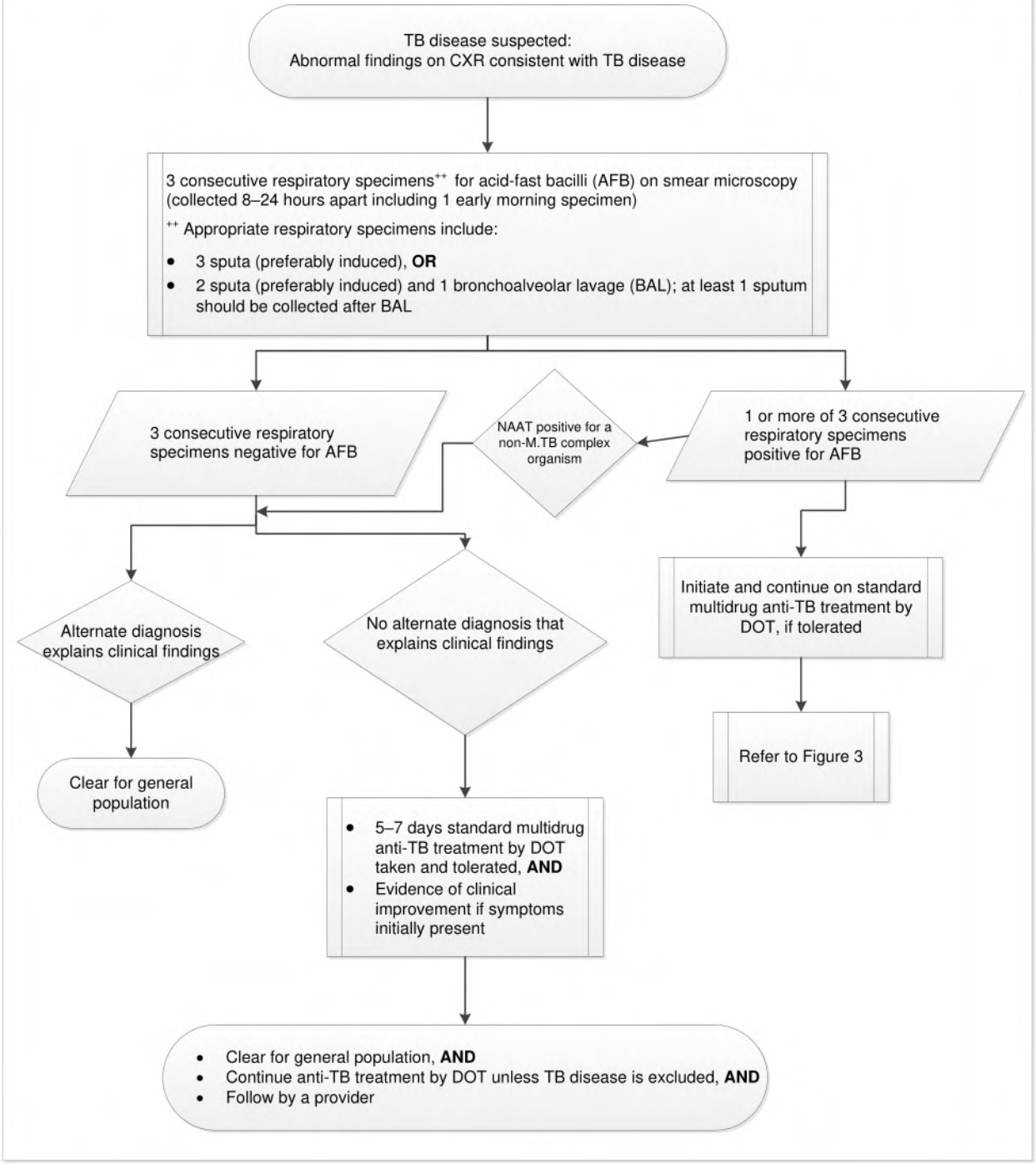

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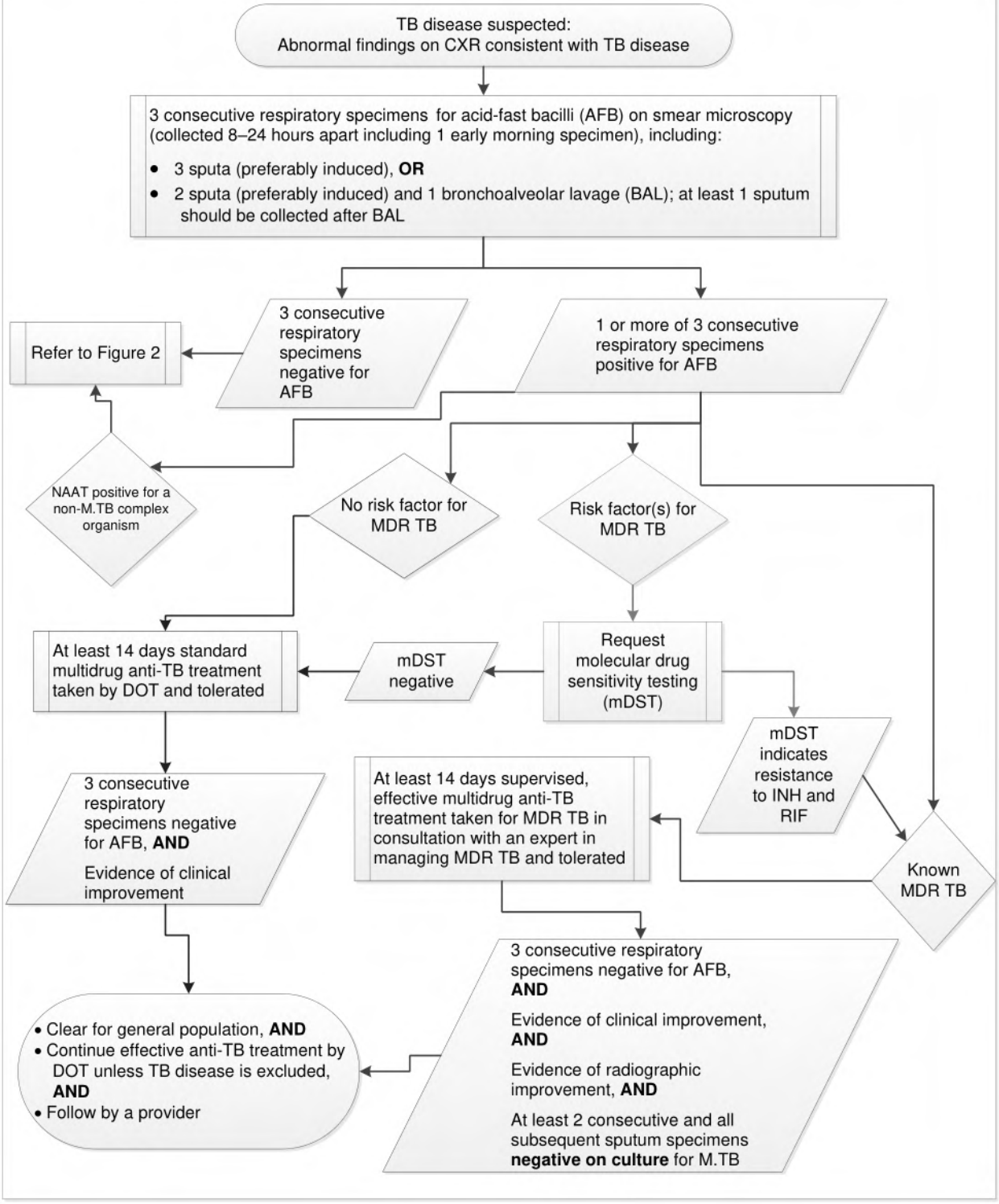
Figure 6
Criteria for placing detainees in general population following evaluation for TB disease with respiratory specimen(s) positive for AFB



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VI. Management of TB Infection After TB disease Has Been Excluded

Consider treatment for TB infection using the following guiding principles:

- TB disease has been excluded by culture; and
- the detainee has uncomplicated TB infection (e.g., not known to have recent exposure to MDR or XDR TB); and
- the detainee is at high risk for developing TB disease; and
- there is a reasonable likelihood of completing a course of treatment as directed

Continue treatment for TB infection if started prior to ICE custody. It is not recommended that treatment for TB infection be initiated for ICE detainees unless it is likely that the regimen will be continued following release or removal. Seek consultation from the IHSC Regional Medical Director, Associate Medical Director, or Deputy Assistant Director for Clinical Services prior to continuing or initiating a 12 dose regimen for TB infection using isoniazid and rifapentine; note that this regimen is not available in developing countries nor is it approved for HIV positive patients. For detainees with known recent exposure to multidrug-resistant or extensively drug resistant TB, seek expert consultation prior to initiating any treatment regimen.

VII. Surveillance and Reporting

For tuberculosis (TB) reporting, the Compliance Officer or other designated health care staff must enter case reporting information in the TB Case Management (TB-CM) template in the electronic health record (eHR). Health staff should refer to the *Infectious Disease Public Health Actions Guide: Surveillance and Reporting* and the *IHSC eCW User Guide: TB Case Management* for detailed guidance on reporting of suspected and verified tuberculosis using the TB-CM template in eCW.

- The TB-CM template must only used for TB case management reporting and it should not be used for documenting any other encounters, transfer summaries, or templates.
- Structured data fields in the TB-CM template must be used where available
    - Structured data are required for generated reports to reflect all of the information required by health departments for reporting a *Verified Case of Tuberculosis*.

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- The initial TB-CM report should be documented within one working day of the detainee meeting the criteria for reporting (Box 1) and the note assigned to the PHSP Unit Infection Control Lead for review.
- The TB-CM template should only be used for documenting and reporting detainees with diagnostic evidence of TB disease that meet the criteria specified in Box 1.

Box 1

Criteria for Reporting TB using the TB-CM Template in eCW

1) All detainees with culture-positive, confirmed M.*tb* complex
2) Detainees with suspected TB disease that have at least one of the following:
   a. Started or continued multidrug treatment for suspected TB disease
   b. Smear positive
   c. NAAT positive
   d. Cavitary lesions on CXR
   e. Symptoms consistent with adult or pediatric TB disease

Note: an abnormal chest x-ray alone does not need to be reported unless the above criteria are met.

The Compliance Officer or designated health care staff must continue documenting updated case information using the eCW TB-CM template and maintain accountability until final culture, drug sensitivity results, and case classification are available, regardless of whether the detainee is still in custody at the time final results are received.

The Compliance Officer of other designated health care staff should merge the TB-CM templates into a single progress note and print it for reporting to the local or state health department, if the health department agrees to accept the case report in this format. The Compliance Officer of other designated health care staff should report all detainees with suspected or verified TB disease to the local or state TB programs in accordance with local and state regulations. Most states will require this to be completed within one working day after meeting criteria for reporting. Refer also to the *Infectious Disease*

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Public Health Actions Guide: Surveillance and Reporting and the *IHSC eCW User Guide: TB Case Management* for detailed guidance on reporting of suspected and verified tuberculosis using the TB-CM template in eCW.

VIII. Medical Holds and Medical Alerts

Health staff should utilize medical holds as a tool to communicate the need for a requested action for medical or public health reasons, such as recommended movement restrictions while the detainee is contagious and until the transnational referral process is complete, or to request notification prior to transfer, release, or removal. Refer to IHSC Directive: 05-06, *Infectious Disease Public Health Actions* and *Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*.

IX. Release Planning and Continuity of Care

Health staff should facilitate domestic or transnational referrals for continuity of care for all detainees with confirmed or suspected TB disease requiring anti-TB therapy.

A. Collaboration with Public Health Authorities

Health staff should collaborate with local or state health departments on the identification, case management, treatment continuity of care, and contact investigations.

Health staff should coordinate case management with local, state, and federal public health agencies to plan for appropriate treatment during and following custody, and to plan for any outcome to immigration proceedings. For detainees with significant medical complications (e.g., MDR, XDR, poor tolerance to therapy), the medical provider, Compliance Officer, or designee should utilize expert medical consultation for TB when coordinating continuity of care and include in communications the Clinical Director; the IHSC Infectious Disease Consultant; the Public Health, Safety, and Preparedness Unit; the Regional Clinical Director; and the Associate Medical Director-Field, and the Deputy Assistant Director for Clinical Services.

B. Considerations for Detainees Released from Custody in the U.S.

The Compliance Officer or designee should notify local or state health departments in the jurisdiction where the facility is located as soon as it is known that a detainee with verified or suspected TB will be or has been released from custody to a U.S. community, to include the following information prior to release, if possible: the intended destination, address, telephone numbers, cell phone

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numbers, and e-mail address. When possible, the Compliance Officer or designee should arrange for the public health program staff to interview the detainee prior to release. Health care personnel should educate the detainee regarding the continuity of care and the importance of supervised treatment. Detainees may require a transnational referral if final resolution of their proceedings are pending.

If a detainee must be released from custody while contagious, health staff must notify public health authorities in advance of release, to coordinate care in a manner that maintains airborne precautions.

C. Transnational Referrals

Without coordinated continuity of care, TB patients are more likely to interrupt or stop treatment, become contagious and infect others, acquire drug resistance, have undetected medical complications, and die from TB disease.

The Compliance Officer or designee should facilitate transnational referrals for detainees with suspected or confirmed TB disease requiring anti-TB therapy through the Centers for Disease Control and Prevention (CDC), CureTB Program (Box 2).

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Box 2
Transnational Referrals for TB Continuity of Care



Centers for Disease Control and Prevention (CDC)/ CureTB Program

- Provides transnational TB referral services regardless of nationality.
- Transnational continuity of care program operated by the CDC, Division of Global Migration and Quarantine, U.S.-Mexico Unit, in partnership with San Diego County TB Branch.
- You can submit a CureTB referral in 3 ways:
  1. Fax: 404-471-8905
  2. E-mail: CureTB@cdc.gov (type the name of the detention facility in subject)
  3. Call: 619-542-4013 (main)
- Toll free patient line:
  International: 001-800-789-1751
  From US: 1-800-789-1751
- Website: www.CureTB.org

How to refer a patient to CureTB:

- Provide education to the patient on the continuity of care and referral process
- The referral should be made as soon as a diagnosis of TB is suspected and treatment is initiated or planned.
- No written consent is required.
- Fax or secure email the most current TB-CM progress note (merged to include all prior TB-CM notes), inclusive following info, as well as laboratory reports as attachments:
  1) Patient's name, A#, and DOB
  3) Patient's country of nationality
  4) Chest X-Ray report(s) and digital image(s)
  5) Pulmonary cases: sputum smear results & culture/drug susceptibilities (as available)
  6) Extra-pulmonary cases: specimen type with smear and culture/drug susceptibilities, path report
  7) Other known co-morbidities
  8) Treatment regimen (medications, dosages, start dates)
  9) Adverse TB medication reactions
  10) Name of the detention facility and site contact person for medical information/clarification

Next Steps:

- CureTB staff will respond to your request and provide dates and times available to conduct the telephone interview with the patient. Ideally, the interviews should be done within 24 hours after CureTB receives all the needed information. Interviews are conducted on business days except by special arrangement.
- CureTB staff will conduct patient interviews by phone to obtain and provide information to assist patient in connecting to TB care upon release.
- CureTB will send a Referral Verification Notice Form to the referring entity. The bottom half of form is formatted to be given to patient upon release.

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D. Coordinated Removals and International Notifications

If it is anticipated that the detainee with verified or suspected TB will require special attention upon removal, the Compliance Officer or designee, or medical provider, should notify PHSP Unit staff with advance notice to request assistance for a coordinated removal or international notification to the National TB Program in the country of nationality, including, but not limited to the following:

- Detainees with exceptional medical and/or social considerations, e.g., MDR-TB, XDR-TB, other medically-complicated TB, HIV coinfection, concomitant medical and/or mental health conditions, substance abuse, social service needs, and
- Detainees that do not cooperate with the transnational referral process

Health staff at IHSC-staffed facilities in Arizona routinely coordinate removals to of detainees with TB to Mexico in collaboration with the Arizona Department of Health Services (ADHS) and the ERO Field Office. Health staff in Arizona should follow protocols established by ADHS.

X. TB Clearance for Transportation

Document that detainees meet the criteria for general population or the criteria specified in Table 4 prior to air or ground transportation without environmental controls (including time in non-moving vehicles). Health staff may note that ICE Air will reference a *Tuberculosis (TB) Clearance for Air Transport for ICE Detainees: Reference Sheet* to guide their decisions for TB clearance to board aircraft.

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Table 4: TB Clearance for Transportation

ICE Custody <72 Hours	ICE Custody ≥72 Hours
No symptoms suggestive of TB assessed and documented within one year prior to transport; **AND**	No symptoms suggestive of TB assessed and documented within one year prior to transport, **AND**
Prior positive TST or IGRA and prior normal CXR (not suggestive of TB disease); **OR**	No documented indication of contagious pulmonary TB disease
Negative TST or IGRA within one year of scheduled transport; **OR**	
CXR not suggestive of TB disease; **OR**	
Three consecutive respiratory specimen^{++} microscopy results smear negative for AFB and no clinical suspicion of TB disease; **OR**	
Suspected or confirmed drug-susceptible TB disease; ***AND*** three consecutive respiratory specimen^{++} microscopy results smear negative for AFB; ***AND*** taking and tolerating multidrug, anti-TB therapy; ***AND*** evidence of clinical improvement; **OR**	
Suspected or confirmed MDR- or XDR-TB disease; ***AND*** three consecutive respiratory specimen^{++} microscopy results smear negative for AFB; ***AND*** taking and tolerating an effective, multidrug, anti-TB regimen; ***AND*** evidence of clinical improvement; ***AND*** at least two early morning sputum specimens of good quality, collected on consecutive days, that are all negative for MTB on culture; **OR**	
Reliable documentation of recent, successful completion of effective TB therapy	
++ Respiratory specimens include: • 3 sputa (preferably induced), **OR** • 2 sputa (preferably induced) and 1 bronchoalveolar lavage (BAL); at least 1 sputum should be collected after BAL	

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XI. Contact Investigations

A TB contact investigation is the process of identifying, evaluating, and treating all persons (contacts) who have sustained a significant exposure to a person with suspected or confirmed contagious TB disease of the lungs (pulmonary or pleural) or larynx. Contacts are at increased risk of acquiring TB infection and developing TB disease.

For more information on the decisions to initiate a TB contact investigation, scope, determination of significant exposures, and contact investigation steps, refer to CDC | TB | TB Guidelines - Contact Investigations.

A. Purpose

- Identify additional cases.
- Initiate appropriate medical treatment.
- Prevent the development of TB disease among recently infected contacts.
- Halt TB transmission.

B. Initiating Contact Investigations

TB contact investigations are generally initiated when the index patient is confirmed to have pulmonary or laryngeal TB disease by sputum culture (results available in 4-8 weeks) or nucleic acid amplification (NAAT), if done. Health staff should consider initiating a contact investigation as soon as a detainee is identified with high suspicion of TB disease and contagiousness based on symptoms consistent with TB, sputa positive for AFB on smear microscopy, or cavitary pulmonary disease.

C. Collaborating Partners and Responsibilities

Health staff should collaborate with local or state health departments to conduct the contact investigation for detainees with suspected or confirmed contagious TB disease of the lungs or larynx. Health staff should determine the scope of the contact investigation in consultation with the local or state health department. The contact interview will generally require interviewing the detainee who is the index patient to obtain information regarding their close contacts. . The HSA or designee should recommend to facility staff that they accommodate local, state, or federal public health program requests to interview detainees and staff as necessary to support the public health investigation.

The HSA or designee should provide the local, state, or federal public health program with information to support the public health investigation to the extent permissible under the Privacy Act and other applicable law and regulations, and ICE and DHS policies.

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Once the scope of the contact investigation is established, health staff should provide or recommend testing for TB infection and medical evaluations to these detainees identified with significant exposure, and recommend or offer treatment, as indicated. IHSC is not responsible for establishing nor implementing protocols implemented outside of the medical clinic area, however, health staff should coordinate with the facility to mitigate risks. The local health department has the responsibility for the entirety of the contact investigation, including investigation of possible contacts in the community and coordinating with other detention facilities and jurisdictions, if applicable.

Health staff must seek expert consultation on the management of contacts if the index patient is suspected or known to have MDR or XDR TB; TB expert consultation is available through the IHSC Infectious Disease Consultant, the local or state health department (State/City/Territory - National Tuberculosis Controllers Association), CDC | TB | Regional Training and Medical Consultation Centers (RTMCC), the CDC.

D. Exposure Incident Definition

A TB exposure incident is defined as a situation in which a person or persons have had significant exposure to an individual with suspected or confirmed pleural, laryngeal, or pulmonary TB disease (or to air containing TB bacteria) during the determined contagious period without the benefit of appropriate exposure control measures.

E. Significant Exposure Factors

Factors that will be used to determine if an exposure incident has occurred include but are not limited to the following:

- Physical proximity of contacts to the person with suspected or confirmed contagious TB disease.
- Volume of air shared between the contagious patient and contacts (the greater the volume of air, decreased change for infection).
- Duration of exposure to the person with TB disease, including exposure through a shared ventilation system.
- Use of exposure control measures that are functioning appropriately at the time of contact.
- Likelihood of contagiousness of the person with confirmed or suspected TB disease.
- Susceptibility or risk of progression to TB disease for the exposed contact
    - HIV
    - Diabetes mellitus
    - Silicosis

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- Injection or noninjection illegal drug use
- Alcohol abuse
- Cancer treatment
- Other immunosuppressed state (e.g., lymphoma, on chronic steroid therapy)
- Greater than 10 percent underweight

Health care and public health personnel should prioritize significant exposures that may lead to transmission based on proximity and duration of exposure and ventilation, with close proximity for 8 hours or longer being given the highest priority, including household contacts, bunkmates, cellmates, transport in an enclosed vehicle or airplane (especially within 3 rows). Health care personnel should evaluate the highest priority contacts (with most significant exposures and/or highest risk of progression) first. Health care and public health personnel should use the results of testing among higher priority contacts to guide decisions to expand the contact investigation to lesser priority contact tiers.

XII. References and Resources

A. CDC | TB | Fact Sheets

B. CDC | TB | TB Guidelines by Topic

C. CDC | TB | State TB Control Offices

D. National Tuberculosis Controllers Association

E. National Tuberculosis Controllers Association | State-City-Territory

F. TB Radiology Resource Page

G. CDC | TB | Regional Training and Medical Consultation Centers (RTMCC)

- Heartland National TB Center (serves Arizona, Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas).
- Global TB Institute| RTMCC (serves Connecticut, Delaware, District of Columbia, Indiana, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont and West Virginia and the cities of Baltimore, Detroit, New York City and Philadelphia).
- Southeastern National Tuberculosis Center (serves Florida, Mississippi, Alabama, Georgia, South Carolina, North Carolina, Tennessee, Kentucky, Virginia, West Virginia, Puerto Rico and the U.S. Virgin Islands).

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- Curry International TB Center [serves Alaska, California (including Los Angeles, San Diego, and San Francisco), Colorado, Hawaii, Idaho, Nevada, Oregon, Utah, Washington and the U.S. Pacific Island Territories].
- Mayo Clinic Center for Tuberculosis (serves Illinois, Indiana, Iowa, Michigan, Minnesota, Montana, North Dakota, Ohio, South Dakota, Wisconsin and Wyoming).

H. ACR-SPR | Practice Parameter for the Performance of Chest Radiography.

I. ACR-SPR | Practice Parameter for the Performance of Portable (Mobile Unit) Chest Radiography

J. Quality & Safety - American College of Radiology

K. WHO | Global Tuberculosis Report

L. CDC | CureTB Referral Program

M. CDC | TB in Children

N. Pediatrics: Targeted Tuberculin Skin Testing and Treatment of Latent Tuberculosis in Children and Adolescents

O. Curry International TB Center | Pediatric TB.

P. Southeastern National Tuberculosis Center, Pediatric TB for the Private Provider.

Q. Find TB Resources - TB Education & Training

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U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

PUBLIC HEALTH ACTIONS FOR TUBERCULOSIS CARE

IHSC Directive: 05-11
ERO Directive Number: 11786.1
Federal Enterprise Architecture Number: 306-112-002b
Effective Date: 29 APR 2014
Latest Update: 30 JUN 2017

By Order of the Acting Assistant Director	(b)(6); (b)(7)(C)	(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **MD**		

1. **PURPOSE:** The purpose of this issuance is to set forth the policies for public health actions for tuberculosis (TB) care.

2. **APPLICABILITY:** This directive applies to all U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) personnel, including but not limited to, Public Health Service (PHS) officers, civil service employees and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned or contracted detention facilities, and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES:**

3-1. Title 8, Code of Federal Regulations, section 235.3 (8 CFR 235.3), Inadmissible Aliens and Expedited Removal;

3-2. Section 232 of the Immigration and Nationality Act (8 USC 1222), Detention of aliens for physical and mental examination;

3-3. Title 8, Code of Federal Regulations, section 232 (8 CFR 232), Detention of Aliens for Physical and Mental Examination;

3-4. Section 322 of the Public Health Service Act (42 USC 249(a)), Medical Care and Treatment of Quarantined and Detained Persons;

3-5. Title 42, U.S. Code, Public Health Service Act, Section 252 (42 USC 252); Medical Examination of Aliens.

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3-6. Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement—013 Alien Health Records System of Records. 80 FR 239.

3-7. Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement-- 011 Criminal Arrest Records and Immigration Enforcement Records (CARIER). 81 FR 72085.

3-8. Continuity of Care Requirements for Adult Detainees Diagnosed with Active Tuberculosis, ICE Policy No. 11014.1, May 14, 2004.

4. **POLICY:** IHSC staff implements public health actions for TB care. Public health actions include a broad range of public health activities and interventions to promote and protect health, and prevent or mitigate infectious disease transmission.

4-1. Facility TB Risk Classification and Assessment.

a. Detention facilities are classified as non-minimal risk unless there is evidence of ongoing transmission; risk classifications for correctional and detention facilities are established in accordance with CDC | TB | TB Guidelines - Correctional Facilities.

b. Health staff must assess possible TB transmission within the facility, including consideration of the following relevant indicators:

(1) Conversions in tests for TB infection among staff and detainees.

(2) TB exposure incidents.

(3) Evidence of person-to-person transmission.

(4) Timeliness with which patients with suspected TB disease are detected, isolated, and evaluated.

4-2. TB Screening.

a. General application to all detainees

(1) Health care personnel perform TB screening in accordance with the scope of their licenses and usual protocols for intake screening and ordering of diagnostic tests.

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(2) Health care personnel screen all newly arriving detainees and residents for symptoms suggestive of TB disease within 12 hours of arrival during medical intake screening; see also CDC guidelines, available at CDC | TB | TB Guidelines by Topic and *the Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics*.

(3) Health care personnel screen all newly arriving detainees for TB at intake consistent with the applicable ICE detention or family residential standards under which the facility housing the person operates.

(4) If a detainee presents with clinical or radiographic evidence suggestive of TB disease, the detainee should be promptly placed in an airborne infection isolation (AII) room until determined to be noncontagious.

(5) Health care personnel should evaluate detainees with symptoms consistent with pulmonary TB disease, including appropriate testing for TB infection and active disease.

(6) Health care personnel manage detainees with clinical presentation suggestive of TB disease and document appropriately for release to the general detention population or transport per the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics.*

b. TB screening for adult detention and staging facilities

(1) Health care personnel should test adult detainees not in continuous law enforcement custody for TB within 72 hours of arrival (and if feasible, during intake medical screening) using a chest x-ray (CXR), TB Skin Test (TST), or FDA-approved Interferon Gamma Release Assay (IGRA), depending on the capabilities of the facility and within the scope of each health care staff's clinical license.

(2) Documented negative TB testing results within one year of arrival are acceptable as intake TB testing for adult detainees in continuous law enforcement custody without symptoms suggestive of pulmonary TB disease.

(3) For adult detainees in continuous law enforcement custody with negative TB test results dated longer than one year prior to arrival, IHSC health care personnel should test for TB within 72 hours of arrival using a CXR, TST, or IGRA, depending on the

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capabilities of the facility and within the scope of each health care staff's clinical license.

(4) An IHSC medical provider should evaluate detainees at high risk of TB infection for atypical presentation within 72 hours of identification of the high risk condition.

c. TB screening for family residential facilities

(1) Health staff must conduct TB screening for IHSC-staffed family residential facilities in accordance with the most current Family Residential Standards.

(2) TB symptom screening during intake and documented negative TB screening results within one year of arrival are acceptable as intake TB screening for adult and juvenile residents in continuous law enforcement custody in family residential facilities.

d. TB screening of detainees and residents less than 18 years of age

(1) IHSC health care personnel evaluate detainees aged less than18 years old for symptoms consistent with pediatric presentation of TB disease, and assess them for a history of close contact to a person known to have had TB disease. Health care personnel should refer to the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics* for pediatric TB testing recommendations.

e. Detainee refusal of TB testing

(1) If a detainee refuses TB testing using radiography, health staff should offer testing using TST or an FDA-approved IGRA.

(2) If a detainee refuses all methods of TB testing, IHSC staff will follow guidance provided in the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics*

f. Detainee annual TB evaluation

(1) Health care personnel should evaluate detainees in continuous law enforcement custody for symptoms consistent with TB within one year of the previously documented TB evaluation.

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(2) IHSC does not recommend routine annual CXRs in accordance with CDC | TB | TB Guidelines - Correctional Facilities.

(3) Health staff should administer an annual TST or IGRA to detainees with HIV, or are immunocompromised with another condition that presents high risk for progression to TB disease if infected with TB. For detainees with HIV and a prior positive TST or IGRA, health staff should administer a CXR for annual TB screening.

(4) Health care personnel should evaluate detainees with known recent exposure to contagious TB in accordance with guidance for contact investigations, see CDC | TB | TB Guidelines - Contact Investigations

4-3. Management of TB Disease.

a. An IHSC medical provider is responsible for clinical management of detainees with verified or suspected TB disease.

b. Diagnostic testing

(1) A medical provider should actively follow up with laboratories to facilitate timely notification of abnormal results.

(2) A medical provider should obtain and document final laboratory results in a timely manner, including culture and drug sensitivity results, including for specimens collected prior to detention at the current facility, and including results that become available after the detainee is transferred, released, or removed.

(3) A medical provider should ensure that all diagnostic results are communicated to the Compliance Officer or other staff responsible for TB care, reporting, and transnational referrals.

c. Treatment

(1) A medical provider experienced in TB care should make TB treatment decisions in consultation with the IHSC National Infectious Disease Consultant

(2) A medical provider should order TB treatment to be administered using directly observed therapy (DOT).

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(3) A medical provider should treat detainees with suspected or confirmed TB disease according to CDC | TB | TB Guidelines - Treatment.

(4) A medical provider must consult with the IHSC National Infectious Disease Consultant for treatment of detainees with suspected or known drug-resistant TB, multidrug-resistant TB, extensively drug-resistant TB, HIV co-infection, adverse reaction to anti-TB drugs, or other complications.

4-4. Management of TB infection after TB disease has been excluded.

a. See definition of Tuberculosis Infection in the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics.*

b. A medical provider should consider initiating treatment for TB infection using the following guiding principles:

(1) TB disease has been fully excluded by provider evaluation, radiographic studies and culture.

(2) The detainee is not known to have recent exposure to multidrug resistant or extensively drug-resistant TB.

(3) The detainee is at high risk for developing TB disease.

(4) There is a reasonable likelihood of completing a course of treatment as directed following release or removal.

c. A medical provider should continue treatment for TB infection if started prior to ICE custody.

d. A medical provider should consult with the IHSC National Infectious Disease Consultant before initiating any short course regimen for TB infection (e.g., isoniazid and rifapentine or rifampin only).

e. For detainees with known recent exposure to multidrug-resistant or extensively drug resistant TB, a medical provider should consult with the IHSC National Infectious Disease Consultant prior to initiating any treatment regimen.

4-5. Airborne precautions.

a. Health staff should manage detainees with suspected or confirmed TB until determined to be non-contagious using airborne precautions.

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b. The Health Services Administrator or designee should have a plan for referring detainees with suspected or confirmed TB to a hospital or other detention facility with AII capabilities if AII rooms on-site are not available.

c. Health staff must ensure that the detainee is non-contagious, or an alternate clinical diagnosis is provided that explains the clinical syndrome, before clearing him or her for placement in the general detention population. Health staff should refer to the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics* for guidance on determination of non-contagiousness and placement in general population.

4-8. Medical Holds and Medical Alerts.

a. Health staff should utilize medical holds as a tool to communicate the need for a requested action for medical or public health reasons, such as recommended movement restrictions while the detainee is contagious and until the transnational referral process is complete or a reasonable effort to accomplish the transnational referral is made, or to request notification prior to transfer, release, or removal. Refer to IHSC Directive: 05-06, *Infectious Disease Public Health Actions* and *Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*

4-9. Release Planning and Continuity of Care.

a. Coordination with Public Health Authorities:

(1) Health staff must report all detainees with confirmed or suspected TB disease to the local or state TB control programs in accordance with local and state regulations.

a) Health staff must continue reporting updated TB care information inclusive of final culture results, complete drug sensitivity results (if culture positive), and diagnostic classification, and including information that result after a detainee leaves the facility.

(2) Detainees with confirmed or suspected TB disease that meet reporting criteria specified in the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics* are reportable to the Public Health, Safety, and Preparedness (PHSP) Unit using the Tuberculosis Reporting – Adult or Pediatric Template in the electronic health record (eHR).

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(3) For detainees that meet the TB reporting criteria, the Compliance Officer or other designated health staff must enter TB care information in the template titled "Tuberculosis Reporting – Adult" or "Tuberculosis Reporting – Pediatric" in the eHR, which serves as a TB case report. The TB Reporting Adult/Pediatric Template is only used for TB case management reporting and it should not be used for documenting any other patient or telephone encounters, or transfer summaries, Health staff should merge the templates into a single progress note and print it for reporting to the local or state health department, if the health department agrees to accept the case report in this format. See *IHSC eCW User Guide: TB Case Management* for detailed instructions. Refer also to *Infectious Disease Public Health Actions Guide: Surveillance and Reporting.*

a) The Compliance Officer or other designated health staff must continue reporting updated TB care information, inclusive of final culture results, complete drug sensitivity results (if culture positive), diagnostic TB classification, and final patient disposition, which includes information that results after a detainee completes treatment or leaves the facility.

(4) The Compliance Officer or other designated health staff must facilitate continuity of care for detainees confirmed or suspected of having active TB disease and on anti-TB therapy through the local health department in the jurisdiction where the facility is located. Health staff should notify the local health department in advance (to the extent feasible) of transfer or release, including identifying information, telephone numbers for the detainee or resident, and addresses in the intended destination.

(5) The Compliance Officer or other designated health staff must facilitate transnational referrals for all detainees confirmed or suspected of having active TB disease and on anti-TB therapy through the Centers for Disease Control and Prevention, CureTB Program. *Refer to Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics.*

(6) The Compliance Officer or other designated health staff should promptly notify PHSP Unit staff of detainees anticipated to be removed and requiring a coordinated removal with additional assistance immediately upon arrival in the country of nationality.

4-10. Contact Investigations.

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a. Health staff should collaborate with the local or state health department to conduct contact investigations. Refer to the *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics* and *IHSC Public Health Actions for Contact and Outbreak Investigations Guide.*

b. Health staff should conduct all contact investigations in accordance with CDC | TB | TB Guidelines - Contact Investigations.

c. Health staff must follow all applicable ICE and DHS policies addressing privacy and disclosure of law enforcement sensitive information.

d. Health staff must not disclose information regarding an individual's legal claims or proceedings to non-DHS entities.

4-11. TB Clearance Requirements for Transportation.

a. A health care provider should screen detainees without documentation of results of recent TB testing for symptoms consistent with TB disease prior to scheduled domestic or international air transportation or ground transportation without environmental controls.

b. Health staff should ensure that detainees with confirmed or suspected TB disease have no clinical findings suggestive of current contagiousness prior to scheduled domestic or international air transportation or ground transportation without environmental controls. Refer to *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics*.

4-12. Orientation and Training. IHSC health staff receives initial orientation and annual training inclusive of topics addressing management and control of tuberculosis.

5. PROCEDURES: Detailed procedures related to this directive are found in the following guides:

a. *Public Health Actions for TB Care Guide: IHSC-Staffed Medical Clinics*

b. *Public Health Actions for TB Care Guide: IHSC Headquarters*

c. *IHSC Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*

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d. *IHSC Infectious Disease Public Health Actions Guide: Surveillance and Reporting*

e. *IHSC Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations*

6. **HISTORICAL NOTES:** This is an annual review. Key changes include the following: 1) the Directive title was changed from *Tuberculosis Management and Control* to *Public Health Actions for Tuberculosis Care, 2) this Directive incorporates specific considerations for family residential facilities and for residents <18 years of age, and supersedes and eliminates the need for a separate OM 15-011, Tuberculosis Management and Control for Family Residential Centers, which will be archived. 3) references were updated throughout the document, 4) process guidance was deleted and will be placed in appropriate Guides, 5) editorial and formatting changes to improve clarity, and 6) the CDC Cure TB Program is identified as the primary transnational TB referral program and references to TBNet were deleted.*

7. **DEFINITIONS:** See the *IHSC Glossary and Public Health Actions for TB Care Guide: IHSC Staffed Medical Clinics.*

8. **APPLICABLE STANDARDS:**

8-1. 2011 Performance Based National Detention Standards (PBNDS):

a. 4.3 Medical Care.

8-2. ICE Family Residential Standards

a. 4.3 Medical Care.

8-3. American Correctional Association (ACA):

ACA, Performance-Based Standards for Correctional Health Care in Adult Correctional Institutions (ACI), 2002; and ACA, 2014 Standards Supplement

a. 1-HC-1A-04 Continuity of care

b. 1-HC-1A-05 Referrals

c. 1-HC-1A-11 Management of communicable and infectious diseases

d. 1-HC-1A-12 Management of tuberculosis

e. 1-HC-1A-19 Intake medical screening

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8-4. National Commission on Correctional Health Care (NCCHC):

Standards for Health Services in Jails, 2014.

a. J-B-01 Infection Control Program

b. J-D-05 Hospital and Specialty Care

c. J-E-12 Continuity of Care During Incarceration

9. PRIVACY AND RECORDKEEPING. IHSC maintains detainee health records in accordance with the Privacy Act and as provided in the DHS/ICE-013 Alien Health Records System of Records Notice, 80 Federal Register 239 (Jan. 5, 2015). The records in the electronic health records (eHR)/eClinicalWorks (eCW) are destroyed ten (10) years from the date the detainee leaves ICE custody. Retention periods for records of minors may differ. Paper records are scanned into eHR and destroyed after upload is complete.

10. Protection of Medical Records and Sensitive Personally Identifiable Information.

10-1. Staff must keep all medical records, whether electronic or paper, secure with access limited only to those with a need to know. Staff should lock paper records in a secure cabinet or room when not in use or not otherwise under the control of a person with a need to know.

10-2. Staff are trained at orientation and annually on the protection of a patient's medical information and Sensitive PII.

10-3. Only authorized individuals with a need to know are permitted to access medical records and Sensitive PII.

10-4. Staff should reference the Department of Homeland Security *Handbook for Safeguarding Sensitive PII* (Handbook) at (b)(7)(E) (b)(7)(E) when additional information is needed concerning safeguard sensitive PII.

11. NO PRIVATE RIGHT STATEMENT. This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

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U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

PEDIATRIC IMMUNIZATIONS

IHSC Directive: 06-05
ERO Directive Number: 11799.2
Federal Enterprise Architecture Number: 306-112-002b
03 Jun 2014
Annual Review: 21 Mar 2016 No Changes

By Order of the Acting Assistant Director
(b)(6); (b)(7)(C) **DHSc/s/**

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1. **PURPOSE:** The purpose of this issuance is to set forth the policies and procedures for immunization of detainees under the age of 18 years.

2. **APPLICABILITY:** This directive applies to all IHSC personnel, including but not limited to, Public Health Service (PHS) officers and civil service employees supporting health care operations at ICE Family Residential Facilities (ICE FRF). This directive applies to contract personnel when supporting IHSC at ICE FRF. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES:** The relevant laws and regulations pertaining to the medical care of persons detained by the U.S. Immigration and Customs Enforcement (ICE) provide the authority to establish policy and management practices for this issuance.

   3-1. Title 8, Code of Federal Regulations, section 235.3 (8 CFR 235.3), Inadmissible Aliens and Expedited Removal;

   3-2. Section 232 of the Immigration and Nationality Act (8 USC 1222), Detention of aliens for physical and mental examination;

   3-3. Title 8, Code of Federal Regulations, section 232 (8 CFR 232), Detention of Aliens for Physical and Mental Examination;

   3-4. Section 322 of the Public Health Service Act (42 USC 249(a)), Medical Care and Treatment of Quarantined and Detained Persons;

   3-5. Title 42, U.S. Code, Public Health Service Act, Section 252 (42 USC 252); Medical Examination of Aliens.

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4. **POLICY:** IHSC staff does not provide routine immunizations to unaccompanied alien children (UAC) in ICE custody pending their transfer to the Health and Human Services' Office of Refugee Resettlement, or removal. Accompanied children in ICE custody, meaning children accompanied by a parent or legal guardian, are immunized in accordance with Centers for Disease Control (CDC), American Academy of Pediatrics (AAP), and Advisory Committee on Immunization Practices (ACIP) recommendations and guidelines. All children are considered not to have been immunized unless there is written documentation to the contrary. Health staff documents the child's immunizations in the health record.

   4-1. **Documentation of Immunizations.** IHSC staff document IHSC-provided immunizations on the transfer summary. A copy of the form is sent to the receiving institution and the original is maintained in the child's health record.

5. **PROCEDURES:** IHSC personnel follow immunization guidelines published by community medical authorities, including the CDC, AAP, and ACIP.

6. **HISTORICAL NOTES:** This is an annual review with no changes.

7. **DEFINITIONS:** See definitions for this policy at IHSC Glossary.

8. **APPLICABLE STANDARDS:**

   8-1. **Family Residential Standards, ICE-DRO Residential Standard 2008** Medical Care, V. Expected Practices, sections: 2. "Communicable Disease and Infection Control", 20. "Special Provisions for Care of Children", 22. "Transfer and Release of Residents."

   8-2. **American Correctional Association (ACA):** Standards for Juvenile Residential Facilities, 3rd edition, Section C, Health Care.

   8-3. **National Commission on Correctional Health Care (NCCHC):** Standards for Health Services in Juvenile Detention and Confinement Facilities (2011), Sections: Y-B-01"Infection Control Program", Y-E-04 "Health Assessment", Y-E-11 "Nursing Assessment Protocols", Y-F-01 "Healthy Lifestyle", Y-H-01 "Health Record Format and Contents", and Y-H-04 "Management of Health Records."

   8-4. **Pennsylvania Department of Public Healthcare:** 55 Pa. Code § 3800.141, Child health and safety assessment; 55 Pa. Code § 3800.143, Child health examination.

9. **RECORDKEEPING.** IHSC maintains detainee health records as provided in

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the Alien Medical Records System of Records Notice, 74 Fed. Reg. 57688 (Nov 9, 2009)

Protection of Medical Records and Sensitive Personally Identifiable Information.

9-1. Staff keeps all medical records, whether electronic or paper, secure with access limited only to those with a need to know. Staff locks paper records in a secure cabinet or room when not in use or not otherwise under the control of a person with a need to know.

9-2. Staff is trained at orientation and annually on the protection of a patient's medical information and Sensitive PII.

9-3. Only authorized individuals with a need to know are permitted to access medical records and Sensitive PII.

9-4. Staff references the Department of Homeland Security *Handbook for Safeguarding Sensitive PII* (Handbook) at:

(b)(7)(E)

when additional information is needed concerning safeguard sensitive PII.

10. **NO PRIVATE RIGHT STATEMENT.** This directive in an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

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ICE HEALTH SERVICE CORPS **OPERATIONS MEMORANDUM**

ADULT INFLUENZA VACCINE PROTOCOL

OM: 17-005
Effective Date: January 9, 2018

By Order of the Assistant Director
Dr. (b)(6); (b)(7)(C) **DHSc, MPH** (b)(6); (b)(7)(C) b)(6); (b)(7)(C)

TO: IHSC U.S. Public Health Service (PHS) Commissioned Corps officers, civilian federal employees, and contract personnel

SUBJECT: Adult Influenza Vaccination Protocol

1. **PURPOSE:** The purpose of this directive is to standardize influenza immunization administration practices to facilitate the safe administration of influenza vaccination for adult detainees in IHSC-staffed detention facilities. Immunizing patients with the influenza vaccine helps to reduce morbidity and mortality caused by the influenza virus.

   The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices provides recommendations regarding which patients should receive the influenza vaccine. Where permitted by state licensure, this protocol enables registered nurses, pharmacists, advanced practice providers, and physicians to assess the need for influenza vaccination, screen for contraindications and precautions, and to administer inactivated influenza vaccine (IIV) to adult patients without a separate medication order.

2. **APPLICABILITY:** This directive is applicable to all U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) personnel, including but not limited to PHS Commissioned Corps officers, federal employees, and contract support staff. It is applicable to IHSC personnel supporting health care operations in both ICE-owned and contracted detention facilities, and to IHSC Headquarters staff.

3. **AUTHORITIES AND REFERENCES:**

   3-1. Centers for Disease Control and Prevention (CDC). Information for Health Professionals. "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices." The vaccine advisory document is located on the CDC's website at: https://www.cdc.gov/flu/professionals/index.htm.

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3-2. Immunization Action Coalition (IAC). Diseases and Vaccines; Vaccine Information Statements. Influenza (IIV) and (LAIV) VIS. The vaccine advisory documents are located located on IAC's website at: http://www.immunize.org/influenza/.

4. PROCEDURE:

4-1. Timing of Vaccination. Annual influenza vaccine should be provided to detainees as soon as the vaccine is available. Receiving the vaccine prior to the start of influenza season should help to protect patients. Vaccination efforts should be continued until the end of the influenza season in the local area. Information about local influenza activity can be obtained through the local, or the state's, department of health websites, or through the CDC's weekly influenza tracking website.

4-2. Assessing the Need for Vaccination.

4-2.1 All adults are recommended to receive influenza vaccination each year unless contraindicated.

4-2.2 Detainees at high risk of complication from influenza are priority candidates for vaccination, especially if influenza vaccine supplies are limited. The CDC provides materials and advice for clinicians on people at risk for developing flu-related complications on their website titled "CDC: People at High Risk of Developing Flu-Related Complications."

4-2.3 If a detainee at high risk of complication from influenza refuses vaccination, a refusal form must be completed to document counseling.

4-2.4 High risk detainee conditions include:

4-2.4.a Age 65 years and older;

4-2.4.b Pregnant women;

4-2.4.c Asthma;

4-2.4.d Neurological and neurodevelopmental conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy, stroke, intellectual disability, moderate to severe developmental delay, muscular dystrophy, or spinal cord injury);

4-2.4.e Chronic lung diseases (such as chronic obstructive pulmonary disease and cystic fibrosis);

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4-2.4.f Heart disease (such as congenital heart disease, congestive heart failure, and coronary artery disease);

4-2.4.g Blood disorders (such as sickle cell disease);

4-2.4.h Endocrine disorders (such as diabetes mellitus);

4-2.4.i Kidney disorders;

4-2.4.j Liver disorders;

4-2.4.k Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders);

4-2.4.l Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids);

4-2.4.m People younger than 19 years of age who are receiving long-term aspirin therapy; and

4-2.4.n People with extreme obesity (body-mass index of 40 or more).

4-2.5 Pregnant women are recommended to receive the influenza vaccination each year. Administer any recommended, age-appropriate inactivated influenza vaccine to pregnant women in any trimester.

4-2.6 All adults who do not recall whether they have received influenza vaccine this year should be vaccinated.

4-3. Screening for Vaccine Contraindications and Precautions.

4-3.1 For influenza vaccination contraindication and precaution screening questions (to be documented in the health record), refer to the eClinicalWorks (eCW) template, titled “Immunization Influenza Adult.” For additional information regarding immunization documentation, refer to section 4-7 in the eCW template.

4-3.2 The influenza vaccine is contraindicated for any person who has :

4-3.2.a Experienced a serious systemic, or anaphylactic reaction, to a prior dose of the vaccine or to any of its components. (For a list of vaccine components, refer to the manufacturer’s package insert (www.immunize.org/packageinserts) or go to

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www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf); and

4-3.2.b A history of severe allergic reaction to eggs involving any symptom other than hives (e.g., angioedema, respiratory distress, lightheadedness, recurrent emesis), or who required epinephrine or another emergency medical intervention.

4-3.3 Precautions for use of all influenza vaccines include:

4-3.3.a A moderate or severe acute illness with or without fever; and

4-3.3.b A history of Guillain-Barré syndrome within six weeks of a previous influenza vaccination.

4-3.4 Consult a medical provider for further guidance if a patient reports a contraindication or precaution to receiving the influenza vaccine.

4-4. Providing Vaccine Information Statements (VIS).

4-4.1 A health care staff member should provide all patients with a copy of the most current federal VIS.

4-4.2 A health care staff member should provide non-English speaking patients with a copy of the VIS in their native language (where available). A translated VIS may be printed from http://www.immunize.org/vis/vis_flu_inactive.asp.

4-4.3 If a patient is unable to read, a health care staff member must read the VIS to the patient, using appropriate translation services as needed, and document this in the health record.

4-4.4 A signed consent form for the influenza vaccine is no longer required. The IHSC 141 Form, "Seasonal Influenza Vaccination Consent Form", has been archived and should no longer be used.

4-5. Preparing to Administer Vaccine.

4-5.1 A medical provider must administer the IIV intramuscularly using a 22-25 gauge needle. A medical provider should select a needle length based on the chart below. The needle length may be adjusted as body habitus dictates.

PATIENT GENDER	PATIENT WEIGHT	NEEDLE LENGTH
FEMALE	< 200 LB	1"

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PATIENT GENDER	PATIENT WEIGHT	NEEDLE LENGTH
FEMALE	≥ 200 LB	1½"
MALE	< 260 LB	1"
MALE	≥ 260 LB	1½"

4-6. Administering the Influenza Vaccine.

4-6.1 Where permitted by state licensure and training, a registered nurse, pharmacist, nurse practitioner, physician assistant, or physician may administer inactivated influenza vaccine to adult patients without a separate medication order as a 0.5mL intramuscular injection in the deltoid muscle of the arm. The detainee should be seated or lying when the vaccine is administered to help prevent injury should the detainee become lightheaded or faint.

4-6.2 A specific period of patient observation post-vaccination is generally not required.

4-7. Documenting Vaccination.

4-7.1 The vaccinating staff person must utilize an immunization encounter, labeled "IMM" in eCW, to document immunization encounters.

4-7.2 The vaccinating staff person must document influenza vaccination screening using the eCW template labeled "Immunization Influenza—Adult".

4-7.3 The vaccinating staff person must document the education provided to the detainee, as well as any post-vaccination clinical concerns, in the electronic health record in accordance with the IHSC eCW User Guide: Immunizations Documentation.

4-8. Reporting Vaccine Adverse Event. A medical provider should report clinically important adverse events that occur after influenza vaccination to the Vaccine Adverse Event Reporting System (VAERS), even if they are unsure if the vaccine caused the adverse event. VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur after vaccination. VAERS accepts all reports, including reports of vaccination errors.

5. **HISTORICAL NOTES:** This directive supersedes those elements of IHSC directive 05-06, Infectious Disease Public Health Actions, and its accompanying guide, 05-06 G-05, Public Health Actions for the Management of Influenza, by limiting the provision of influenza vaccine to high risk patients and influenza outbreak events

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only. General vaccination of all willing and appropriate detainees should be pursued by IHSC.

6. APPLICABLE STANDARDS:

6-1. ICE Performance-Based National Detention Standards (PBNDS):

6-1.1 PBNDS 2011: 4.3: Medical Care. Communicable Disease and Infection Control.

6-2. Family Residential Standards (FRS):

6-2.1 4.3: Medical Care. Communicable Disease and Infection Control.

6-3. National Commission on Correctional Health Care (NCCHC):

6-3.1 J-B-01. Infection Prevention and Control (essential).

6-4. American Correctional Association (ACA): Performance-Based Standards for Correctional Health Care in Adult Correctional Institutions.

6-4.1 1-HC-1A-11. Communicable Disease and Infection Control Program.

6-5. American Correctional Association (ACA): Performance-Based Standards for Adult Local Detention Facilities (4th Edition).

6-5.1 4-ALDF-4C-14. Communicable Disease and Infection Control Program.

7. NO PRIVATE RIGHT STATEMENT: This directive is an internal statement of IHSC. It is not intended to, and does not create, any rights, privileges, or benefits, substantive or procedural, enforceable against the United States, its departments, agencies, or other entities; its officers or employees; or any other person.

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ICE HEALTH SERVICE CORPS

National Formulary

FY 2019

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General Information

Important Information

The IHSC formulary is a listing of medications approved for use in IHSC facilities. A variety of provider restrictions on medication utilization apply. Medications described in various clinical practice guidelines and not listed in IHSC formulary are non-formulary.

Brand names are indicated for illustrative purposes. This is not meant to imply an endorsement of any trademarked product. If "A" rated generics are available, their use is normally required over brand name products.

This formulary was lasted updated on September 1, 2018.

General Prescribing Information

Physician Use Only

A restriction placed on certain medications that require a physician's approval for both initiation and renewal. If the detainee arrives with medications, an Advanced Practice Provider (APP) may continue until an IHSC physician reviews the order and makes a judgment regarding the appropriateness of continuing the detainee on medications in this category.

Physician Initiation Only

A restriction placed on certain medications and requires a physician's approval for initiation. An APP may continue this medication without obtaining the physician's approval. If the detainee arrives with medications, an APP may continue until an IHSC physician reviews the order and makes a judgment regarding the appropriateness of continuing the detainee on medications in this category.

IHSC Psychiatric Mental Health Nurse Practitioners (PMHNP)

PMHNP are authorized to prescribe any IHSC approved psychotropic medication (including controlled substances for psychiatric purposes) as indicated in the PMHNP's scope of practice document.

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Abacavir	Ziagen	Antiretrovirals	Physician Initiation Only.	•			MedGuide	Pregnancy
Abacavir/ Dolutegravir/ Lamivudine	Triumeq	Antiretrovirals	Physician Initiation Only.	•			MedGuide	Pregnancy
Abacavir/ Lamivudine	Epzicom	Antiretrovirals	Physician Initiation Only.	•			MedGuide	Pregnancy
Abacavir/ Lamivudine/ Zidovudine	Trizivir	Antiretrovirals	Physician Initiation Only.	•			MedGuide	Pregnancy
Acetaminophen	Tylenol	Miscellaneous Analgesics and Antipyretics	Suppositories need to be refrigerated.			•		Pregnancy
Acetaminophen/ Aspirin/ Caffeine	Excedrin	Nonsteroidal Anti-inflammatory Agents Miscellaneous Analgesics and Antipyretics Respiratory and CNS Stimulants Antimigraine Agents - Miscellaneous						Pregnancy
Acetaminophen/ Codeine	Tylenol No. 3	Opiate Agonist Miscellaneous Analgesics and Antipyretics	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet. Immediate release and non-enteric coated are to be crushed prior to administration.	•	•			Pregnancy
Acetaminophen/ Hydrocodone	Vicodin	Opiate Agonist Miscellaneous Analgesics and Antipyretics	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Useful for patient allergic to codeine although cross allergenicity potential may exist. Keep in locked cabinet. Immediate release and non-enteric coated are to be crushed prior to administration.	•	•			Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Acetaminophen/ Oxycodone	Percocet	Opiate Agonist Miscellaneous Analgesics and Antipyretics	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Immediate-release and non-enteric coated tablets are to be crushed prior to administration. Keep in locked cabinet.	•	•			Pregnancy
Acetazolamide	Diamox	Carbonic Anhydrase Inhibitors	Not 1st line therapy - reserved for treatment resistant glaucoma					Pregnancy
Acetic Acid Otic		EENT Anti-Infectives, Miscellaneous						Pregnancy
Aclidinium	Tudorza	Antimuscarinics/ Antispasmodics	Not 1st line therapy; 2nd line treatment for COPD. Restricted to patients who cannot tolerate long-acting beta-agonists.					Pregnancy
Acyclovir	Zovirax	Nucleosides and Nucleotides	Topical not approved.					Pregnancy
Adapalene	Differin	Miscellaneous Skin and Mucous Membrane Agents	"Pediatric Use Only"					Pregnancy
Adefovir	Hepsera	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Albendazole	Albenza	Anthelmintics						Pregnancy
Albuterol	Ventolin, Proventil, Proair HFA	β-Adrenergic Agonist	Ventolin has a counter, and it is in a foil pack with a 2-month expiration date after opening it. Recommended for regular users. ER tablet not approved. The Pro-Air has no counter, but it doesn't have the foil pack or 2-month expiration. Recommended for occasional users.					Pregnancy
Alcohol, Isopropyl	Rubbing Alcohol	Miscellaneous Local Anti-Infectives	For in clinic use only. For external use only.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Alendronate	Fosamax	Bone Resorption Inhibitors	Medication should be taken 30 minutes before the first food of the day. Stay upright for at least 30 minutes after taking medication.				MedGuide	Pregnancy
Allopurinol	Zyloprim	Antigout Agents						Pregnancy
Aluminum Acetate/ Acetic Acid Otic	Domeboro Otic	EENT Anti-Infectives, Miscellaneous						Pregnancy
Aluminum Acetate Topical	Burow's Solution	Miscellaneous Skin and Mucous Membrane Agents	For external use only.					Pregnancy
Aluminum Hydroxide/ Magnesium Trisilicate	Gaviscon	Antacids and Adsorbents	Used for gastric reflux only.					Pregnancy
Aluminum Hydroxide/ Magnesium Hydroxide/ Simethicone	Mylanta, Maalox	Antacids and Adsorbents	See also Simethicone.			•		Pregnancy
Amantadine	Symmetrel	Adamantanes (CNS)						Pregnancy
Aminosalicylic Acid	Paser	Antituberculosis	Physician Initiation Only. Not available via VA Prime Vendor. May obtain from contracted Mail Order Pharmacy. Clinic use only.	•				Pregnancy
Amiodarone	Pacerone	Antiarrhythmic Agent Class III					MedGuide	Pregnancy
Amitriptyline	Elavil	Antidepressants	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be reordered/renewed by APPs. APPs may initiate/renew to treat neuropathic pain only. Crush immediate release prior to administration	•	•			Pregnancy
Amlodipine	Norvasc	Dihydropyridines						Pregnancy
Ammonium lactate	Lac-Hydrin	Basic Lotions and Liniments	For severe xerosis/ichthyosis.					Pregnancy
Amoxicillin	Amoxil	Penicillins						Pregnancy
Amoxicillin/ Potassium Clavulanate	Augmentin	Penicillins	875mg/125mg tablets are only available via Script Care as of 8/2018					Pregnancy
Amprenavir	Agenerase	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Antipyrine/ Benzocaine	Auralgan	Local Anesthetics (EENT)	For external use only.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Apixaban	Eliquis	Anticoagulants	May not use for valve replacement. Consider continuity of care if medication not available in patient's country of origin. Physician Initiation Only.	•			MedGuide	Pregnancy
Aripiprazole	Abilify	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•			MedGuide	Pregnancy
Ascorbic Acid	Vitamin C	Vitamin C						Pregnancy
Aspirin	Ecotrin, Chewable Aspirin	Nonsteroidal Anti-inflammatory Agents	All formulations are approved. RN use for urgent care			•		Pregnancy
Atazanavir	Reyataz	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Atazanavir/ Cobicistat	Evotaz	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Atenolol	Tenormin	β-Adrenergic Blocking Agents						Pregnancy
Atorvastatin	Lipitor	HMG-CoA Reductase Inhibitors						Pregnancy
Atovaquone	Mepron	Antiprotozoals, Miscellaneous	Not available via VA Prime Vendor. May obtain from contracted Mail Order Pharmacy. Clinic use only	•				Pregnancy
Atropine Ophthalmic	Atropisol (Ophthalmic)	Mydriatics	Injection not approved.					Pregnancy
Azathioprine	Imuran	Immunosuppressive agents						Pregnancy
Azithromycin	Zithromax	Macrolides						Pregnancy
B vitamins/ vitamin C/ folic acid	Nephrocaps Capsules	Vitamin B Complex	Use for renal failure patients.					Pregnancy
Bacitracin	Baciguent	Antibacterials (Skin and Mucous Membrane)						Pregnancy
Baclofen	Lioresal	Skeletal Muscle Relaxant	Script duration limited to 30-day supplies; extended duration on case-by-case basis	•				Pregnancy
Barium Sulfate		Roentgenography	Diagnostic agent for computed tomography or x-ray examinations					Pregnancy
Benzocaine	Orabase-B and Toothache Gel	Local Anesthetics (EENT) Dental Agents Antipruritic and Local Anesthetics	Benzocaine oral gel is restricted to dental use only, in clinic, in patients greater than 2 years of age.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Benzonatate	Tessalon	Antitussives	Limited to five-day therapy.					Pregnancy
Benzoyl Peroxide	Desquam-X	Keratolytic Agent	For external use only.					Pregnancy
Benztropine Mesylate	Cogentin	Anticholinergic Agents (CNS)		•				Pregnancy
Bethanechol	Urecholine	Parasympathomimetic (Cholinergic) Agent						Pregnancy
Bisacodyl	Dulcolax	Cathartics and Laxatives				•		Pregnancy
Bismuth Subsalicylate	Pepto-Bismol	Antidiarrhea Agents				•		Pregnancy
Borate/ Boric Acid/ H2O/ NaCl	Collyrium for Fresh Eyes Eye Wash	EENT Drugs, Miscellaneous	Eye irrigation for in clinic use only – do not dispense to patients.					Pregnancy
Brimonidine Tartrate	Alphagan P	A-Adrenergic Agonists (EENT)						Pregnancy
Bromocriptine	Parlodel	Dopamine Receptor Agonists						Pregnancy
Budesonide/ Formoterol	Symbicort	Corticosteroids (Respiratory) β-Adrenergic Agonist					MedGuide	Pregnancy
Bupivacaine Hydrochloride/ Epinephrine	Marcaine	Local Anesthetics (Parenteral)						Pregnancy
Buprenorphine/ Naloxone	Suboxone	Opiate Partial Agonist	Maximum duration of therapy is 15 days. Physician Initiation Only.	•			MedGuide	Pregnancy
Bupropion	Wellbutrin	Antidepressants	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs. Not authorized for smoking cessation. XL form is a once daily formulation and NOT equivalent to the SR formulation for twice daily dosing. Must crush immediate release formulation	•	•		MedGuide	Pregnancy
Buspirone	BuSpar	Miscellaneous Anxiolytics, Sedatives and Hypnotics		•				Pregnancy
Cabergoline	Cabergoline	Dopamine Receptor Agonists	For hyperprolactinemia					Pregnancy
Calamine	Calamine Lotion	Basic Lotions and Liniments				•		Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Calcipotriene	Dovonex	Miscellaneous Skin and Mucous Membrane Agents	Use after Failure to "Very High Potency Steroids." Physician Initiation Only.					Pregnancy
Calcitriol	Racaltrol	Vitamin D						Pregnancy
Calcium Acetate	Phos-Lo	Phosphate removing agents	Restricted to use in renal dialysis patients.					Pregnancy
Calcium Carbonate	Titralac	Replacement Preparations Antacids and Adsorbents						Pregnancy
Calcium Carbonate/ Vitamin D	Os-Cal 500 + D	Replacement Preparations						Pregnancy
Calcium Polycarbophil	Fiber-Tabs, Fibercon	Cathartics and Laxatives						Pregnancy
Camphor/ Menthol	Vaporub	Basic Lotions and Liniments	Pediatric Use Only					Pregnancy
Capreomycin		Antituberculosis	Physician Initiation Only. The second-line regimen for MDR/XDR TB	•				Pregnancy
Captopril	Capoten	Angiotensin-converting Enzyme Inhibitors						Pregnancy
Carbamazepine	Tegretol	Anticonvulsants, Miscellaneous		•			MedGuide	Pregnancy
Carbamide Peroxide	Debrox Otic	EENT Anti-Infectives, Miscellaneous						Pregnancy
Carbidopa/ Levodopa	Sinemet	Dopamine Precursors	Medication should be taken 1 hour before or 2 hours after meals.					Pregnancy
Carvedilol	Coreg	β-Adrenergic Blocking Agents						Pregnancy
Cefazolin	Kefzol	Cephalosporins	Physician Initiation Only.					Pregnancy
Cefdinir	Omnicef (brand name discontinued)	Cephalosporins						Pregnancy
Ceftriaxone	Rocephin	Cephalosporins	Medication can be reconstituted with 1.0% lidocaine to reduce pain at injection site.					Pregnancy
Cephalexin	Keflex	Cephalosporins						Pregnancy
Cetirizine	Zyrtec	Second Generation Antihistamines						Pregnancy
Charcoal, Activated	Actidose	Antacids and Adsorbents						Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Chlorhexidine Gluconate	Peridex	EENT Anti-Infectives, Miscellaneous	If the product containing alcohol is used, it must be used in clinic or given via pill line. If the alcohol-free product is used, it can be given self-carry (KOP). Topical liquid formulation (4% Scrub) is approved for clinic use.	•				Pregnancy
Chloroquine Phosphate	Aralen	Antimalarials						Pregnancy
Chlorpheniramine Maleate	Chlor-Trimeton	First Generation Antihistamines				•		Pregnancy
Chlorpromazine Hydrochloride	Thorazine	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Chlorthalidone		Thiazide-like Diuretics						Pregnancy
Cinacalcet	Sensipar	Antiparathyroid Agents	Dialysis Patient Use Only.					Pregnancy
Ciprofloxacin/ Dexamethasone	CiproDex	Antibiotic Corticosteroid	Pediatric Use Only - Authorized for use only in children < 8 years of age.					Pregnancy
Ciprofloxacin Hydrochloride	Cipro	Quinolones					MedGuide	Pregnancy
Citalopram	Celexa	Antidepressants		•			MedGuide	Pregnancy
Clarithromycin	Biaxin	Macrolides						Pregnancy
Clindamycin	Cleocin	Miscellaneous Antibiotics						Pregnancy
Clobetasol	Clobex	Anti-inflammatory Agents (Skin and Mucous Membrane)	Not recommended for application to face or groin.					Pregnancy
Clonazepam	Klonopin	Benzodiazepines	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet.	•			MedGuide	Pregnancy
Clonidine Hydrochloride	Catapres	Central α-Agonists	< 30 days; opioid withdrawal; Tourette syndrome; clozapine induced hypersalivation; not for blood pressure management (acute or chronic)	•				Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Clopidogrel Bisulfate	Plavix	Platelet-Aggregation Inhibitors	Use in aspirin intolerance or failure as antiplatelet alternative.				MedGuide	Pregnancy
Clotrimazole	Lotrimin	Antifungals (Skin and Mucous Membrane)	Topical solution is restricted for ear infections use; prohibit use for onychomycosis			•		Pregnancy
Colchicine	Colcrys	Antigout Agents					MedGuide	Pregnancy
Collagenase	Santyl	Miscellaneous Skin and Mucous Membrane Agents	Nurse application during dressing changes to avoid over-use and waste. Should not be used with Silver Sulfadiazine dressings	•				Pregnancy
Crotamiton	Eurax	Scabicides and Pediculicides	For external use only.					Pregnancy
Cyanocobalamin	Vitamin B-12	Vitamin B Complex	IM or deep SC are preferred routes of administration.					Pregnancy
Cyclobenzaprine	Flexeril	Skeletal Muscle Relaxants	Script duration limited to 30-day supplies; extended duration on case-by-case basis	•				Pregnancy
Cyclopentolate	Cyclogyl	Mydriatics	Diagnostic ophthalmic aid					Pregnancy
Cycloserine	Seromycin	Antituberculosis	Physician Initiation Only. Not first line for MDR/XDR TB. Should be administered with pyridoxine daily to mitigate neurotoxic effect. Not available via VA Prime Vendor					Pregnancy
Cyclosporine	Gengraf, Neoral	Immunosuppressive Agents	Ophthalmic preparation not approved.					Pregnancy
Cyproheptadine		First Generation Antihistamines, Derivative						Pregnancy
Dapsone	Dapsone	Miscellaneous Antimycobacterials	Physician Initiation Only.					Pregnancy
Darunavir	Prezista	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Darunavir/ Cobicistat	Prezcobix	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Delavirdine	Rescriptor	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Desipramine	Norpramin	Antidepressants	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•			MedGuide	Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Dexamethasone	Maxidex	Corticosteroids (EENT) Adrenals						Pregnancy
Dextrose/ Sodium Chloride	D5NS	Caloric Agents, Intravenous						Pregnancy
Dextrose in Sterile Water	D5W	Caloric Agents, Intravenous						Pregnancy
Dextrose Instant	Insta-Glucose, Glucose Gel, Glucose Tabs	Caloric Agents	Gel or tablets can be given either KOP or PL per provider's discretion.					Pregnancy
Diazepam	Valium	Benzodiazepines	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet.	•			MedGuide	Pregnancy
Dibucaine	Nupercainal	Antipruritics and Local Anesthetics						Pregnancy
Diclofenac (Topical)	Diclo Gel	Nonsteroidal Anti-inflammatory Agents	Restricted for use by patients with localized chronic pain refractory to oral therapy when comorbidity limits use of oral NSAIDS					Pregnancy
Diclofenac ER	Voltaren XR	Nonsteroidal Anti-inflammatory Agents						Pregnancy
Dicloxacillin	Dynapen	Penicillins	Every effort should be made to avoid the suspension in children since it has a rather offensive taste and is difficult for children to swallow.					Pregnancy
Dicyclomine Hydrochloride	Bentyl	Antimuscarinics/ Antispasmodics						Pregnancy
Didanosine	Videx	Antiretrovirals	Physician Initiation Only. Medication must be taken on an empty stomach.	•			MedGuide	Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Dietary Supplement, Oral	Ensure, Resource, Boost	Caloric Agents	Physician/Dentist Initiation Only. Indicated for broken jaw or other temporary dental issue that limits proper nutritional intake, hunger strike, wasting syndrome, malabsorption, and malnutrition. Pregnancy, HIV infection without wasting, older age, and minor weight loss are usually not indications for nutritional/dietary supplements. For such situations or others not named, a NF request should be submitted. Special diets should generally be utilized to provide additional calories if necessary. MUST CONSUME AT PILL LINE.	•				Pregnancy
Digoxin	Lanoxin	Cardiotonic agents	Oral Tablets Only					Pregnancy
Diltiazem	Cardizem	Calcium Channel Blocking Agents						Pregnancy
Dimethyl Fumarate	Tecfidera	Immunomodulatory Agents						Pregnancy
Diphenhydramine Hydrochloride	Benadryl	First Generation Antihistamines				•		Pregnancy
Diphtheria/ Tetanus Toxoid (DT)	Tenivac	Toxoids	According to CDC guidelines.					Pregnancy
Diphtheria/ Tetanus Toxoid/ Acellular Pertussis Vaccine (TDap, DPT)	Adacel, Boostrix, Daptacel, Infanrix	Toxoids	According to CDC guidelines.					Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Divalproex Sodium	Depakote	Anticonvulsants, Miscellaneous	There are currently two oral formulations of divalproex sodium available. The first agent on the market (1983) was an enteric coated tablet (Divalproex-EC), which results in a delayed-release pharmacokinetic profile and requires multiple daily doses. In 2002, a sustained release formulation (Divalproex ER), allowing once daily administration, was approved	•			MedGuide	Pregnancy
Docusate Sodium	Colace	Cathartics and Laxatives				•		Pregnancy
Dolutegravir	Tivicay	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Dorzolamide Hydrochloride	Trusopt	Carbonic Anhydrase Inhibitors						Pregnancy
Dorzolamide Hydrochloride/ Timolol	Cosopt	Carbonic Anhydrase Inhibitors EENT Preparations - β-Adrenergic Blocking Agents						Pregnancy
Doxazosin	Cardura	α-Adrenergic Blocking Agents						Pregnancy
Doxepin	Sinequan	Antidepressants	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs. Crush immediate release prior to administration	•	•		MedGuide	Pregnancy
Doxycycline	Vibramycin	Tetracyclines						Pregnancy
Drospirenone/ Ethinyl Estradiol	Gianvi	Contraceptives						Pregnancy
Duloxetine	Cymbalta	Antidepressants		•			MedGuide	Pregnancy
Efavirenz	Sustiva	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Efavirenz/ Emtricitabine/ Tenofovir	Atripla	Antiretrovirals	Physician Initiation Only.	•				Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Electrolyte Solution	Pedialyte	Replacement Preparations	Note: The use of this product should be limited to 24 hours in infants and children. After 24 hours this rehydration formula can cause diarrhea worsening gastroenteritis.			•		
Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir	Stribild, Genvoya	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Emtricitabine	Emtriva	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Emtricitabine/ Rilpivirine/ Tenofovir	Complera	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Emtricitabine/ Tenofovir	Truvada	Antiretrovirals	Physician Initiation Only. Pre-exposure prophylaxis (PrEP) is prohibited. Do not reinitiate PrEP prior to release	•			MedGuide	Pregnancy
Enalapril	Vasotec	Angiotensin-Converting Enzyme Inhibitors						Pregnancy
Enfuvirtide	Fuzeon	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Enoxaparin	Lovenox	Anticoagulants						Pregnancy
Entecavir	Baraclude	Nucleosides and Nucleotides	Physician Initiation Only.	•				Pregnancy
Epinephrine	Adrenaline	α & β Adrenergic Agonists	RN use for urgent care			•		Pregnancy
Epoetin Alfa	Epogen, Procrit	Hematopoietic Agents	Physician Initiation Only	•				Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Ergotamine/Caffeine	Cafergot	α-Adrenergic Blocking Agent (Sympath)	[US Boxed Warning]: Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of ergotamine with potent CYP 3A4 inhibitors, including protease inhibitors and macrolide antibiotics. Because CYP3A4 inhibition elevates the serum levels of ergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Therefore, concomitant use of these medications is contraindicated.					Pregnancy
Erythromycin Topical 2%	Erygel	Antibacterials (Skin and Mucous Membrane)	Utilize the most cost-effective topical formulation					Pregnancy
Erythromycin, Ophthalmic	Ilotycin	Antibacterials (EENT)						Pregnancy
Escitalopram	Lexapro	Antidepressants		•			MedGuide	Pregnancy
Estradiol	Delestrogen	Estrogens	Estradiol is preferred over Estrogen conjugated (Premarin) *Conversion (PO) Estradiol vs Premarin 2mg 1.8mg 4 mg 2.7 mg 6mg 3.75 mg 8mg 5mg Use serum estradiol to adjust accordingly	•				Pregnancy
Estradiol Cypionate	Depo-Estradiol	Estrogens						Pregnancy
Ethambutol	Myambutol	Antituberculosis	Presumptive tuberculosis requires physician review within 30 days of initiation	•				Pregnancy
Ethionamide	Trecator	Antituberculosis	Physician Initiation Only.	•				Pregnancy
Etravirine	Intelence	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Famciclovir	Famvir	Nucleosides and Nucleotides	Physician Initiation Only to HIV Patients.					Pregnancy
Fenofibrate	Lofibra	Fibric Acid Derivatives						Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Ferrous Sulfate	Fer-In-Sol	Iron Preparations	Note: When prescribing in children be sure to advise caregivers to keep this medication out of reach of children. Iron overdose is a common cause of death.					Pregnancy
Filgrastim	Neupogen	Hematopoietic Agents	Physician Initiation Only. If patient's weight is greater than or equal to 75kg, then use 480mcg dose. Restricted to Physician Initiation Only or secondary to Infectious Disease.	•				Pregnancy
Finasteride	Proscar	5 Alpha-Reductase Inhibitor						Pregnancy
Fingolimod	Gilenya	Immunomodulatory Agents					MedGuide	Pregnancy
Fluconazole	Diflucan	Azoles						Pregnancy
Fludrocortisone		Adrenals	Restricted for treatment of Addison Disease or Salt-losing adrenogenital syndrome (or congenital adrenal hyperplasia)					Pregnancy
Flunisolide (Nasal)	Nasalide	Corticosteroids (EENT)						Pregnancy
Fluocinonide	Lidex	Anti-Inflammatory Agents (Skin and Mucous Membrane)	Medication should never be used for longer than a two-week period of time without a discontinuation prior to re-starting. This and other fluorinated compounds should never be used on the face unless instructed by a dermatologist.					Pregnancy
Fluoxetine	Prozac	Antidepressants		•			MedGuide	Pregnancy
Fluphenazine	Prolixin	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Fluphenazine Decanoate	Prolixin Decanoate	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Fluticasone (Nasal)	Flonase	Corticosteroids (EENT)		•				Pregnancy
Fluticasone Propionate Oral Inhaler	Flovent	Corticosteroids (Respiratory)						Pregnancy
Folic Acid	Folvite	Vitamin B Complex						Pregnancy
Fosamprenavir	Lexiva	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Furosemide	Lasix	Loop Diuretics						Pregnancy
Gabapentin	Neurontin	Anticonvulsants, Miscellaneous	Restricted to use as anticonvulsant and for pain control. All other indications require approval via the non-formulary process.	•			MedGuide	Pregnancy
Gemfibrozil	Lopid	Fibric Acid Derivatives	Contraindication to use with simvastatin.					Pregnancy
Gentamicin Sulfate	Garamycin	Aminoglycoside Antibacterials (EENT)	Injectable-Physician Initiation Only.					Pregnancy
Gentian Violet		Antifungals (Skin and Mucous Membrane)	Not available via VA Prime Vendor. May obtain from contracted Mail Order Pharmacy. Clinic use only.					Pregnancy
Glatiramer Acetate	Copaxone, Glatopa	Immunomodulatory Agents						Pregnancy
Glipizide	Glucotrol	Sulfonylureas	The immediate release tablets are administered 30 minutes before a meal and divided doses for dosing equal or greater than 15 mg/day.					Pregnancy
Glucagon, Human Recombinant	Glucagen Hypokit	Glycogenolytic Agents						Pregnancy
Glyburide	Micronase, Diabeta	Antidiabetic Agents						Pregnancy
Glycerin suppository		Cathartics and Laxatives				•		Pregnancy
Griseofulvin Suspension	Grifulvin	Antifungals	"Pediatric Use Only." Suspension Only					Pregnancy
Guaifenesin	Robitussin	Expectorants	Recommend alcohol-free formulation.			•		Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Haloperidol	Haldol	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Haloperidol Decanoate	Haloperidol Decanoate	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs. The maximum volume per injection site should not exceed 3ml. Not to be administered IV.	•				Pregnancy
Heparin Sodium	Heparin Lock Flush Solution	Anticoagulants	Physician Initiation Only.					Pregnancy
Hepatitis A Vaccine	Havrix	Vaccines						Pregnancy
Hepatitis B Vaccine	Engerix	Vaccines						Pregnancy
Hepatitis B Vaccine, adjuvanted recombinant	Heplisav-B	Vaccines	For use in high risk patients with a CD4 greater than 500					Pregnancy
Hydralazine	Apresoline	Direct Vasodilators						Pregnancy
Hydrochlorothiazide	Microzide	Thiazide Diuretics						Pregnancy
Hydrocortisone Suppository	Anucort-HC, Anusol-HC	Anti-Inflammatory Agents (Skin and Mucous Membrane)						Pregnancy
Hydrocortisone, Topical	Cortizone	Anti-inflammatory Agents (Skin and Mucous Membrane)	Hydrocortisone 1% for RN Use			•		Pregnancy
Hydrogen Peroxide		Mouthwashes and Gargles	Main clinic and dental clinic use.			•		Pregnancy
Hydroxychloroquine	Plaquenil	Antimalarials						Pregnancy
Hydroxyurea	Hydrea	Antineoplastic Agents					MedGuide	Pregnancy
Hydroxyzine	Atarax; Vistaril	Miscellaneous Anxiolytics, Sedatives, and Hypnotics	Atarax is the Hydrochloride salt. Vistaril is the Pamoate salt. May be KOP for pruritis; Pill Line Only for all other uses. Use of hydroxyzine early in pregnancy is contraindicated	•				Pregnancy
Ibuprofen	Motrin	Nonsteroidal Anti-Inflammatory Agents				•	MedGuide	Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Imipramine	Tofranil	Antidepressants	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs. Crush immediate release prior to administration	•	•		MedGuide	Pregnancy
Immune Globulin	Gamimune	Serums	Physician Initiation Only. MUST BE REFRIGERATED					Pregnancy
Indinavir	Crixivan	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Indomethacin	Indocin	Nonsteroidal Anti-Inflammatory Agents					MedGuide	Pregnancy
Influenza Virus Vaccine	Fluzone	Vaccines						Pregnancy
Insulin	Humulin, Novolin, Lantus Regular, NPH, 70/30, Glargine	Insulins	Human insulin only. Insulin lispro, insulin aspartate not approved.	•				Pregnancy
Ipratropium	Atrovent	Antimuscarinics/ Antispasmodics						Pregnancy
Ipratropium/ Albuterol Oral Inhaler	Combivent Respimate	Antimuscarinics/ Antispasmodics β-Adrenergic Agonist		•				Pregnancy
Isoniazid	INH	Antituberculosis	Presumptive tuberculosis requires physician review within 30 days of initiation	•				Pregnancy
Isosorbide Dinitrate	Isordil	Nitrates and Nitrites	APP: Angina pectoris in adults.					Pregnancy
Isosorbide Mononitrate	ISMO, Monoket, Imdur	Nitrates and Nitrites						Pregnancy
Ivermectin	Stromectol	Anthelmintics						Pregnancy
Ketoconazole	Nizoral	Azoles					MedGuide	Pregnancy
Ketorolac Injection	Toradol	Nonsteroidal Anti-Inflammatory Agents	Do not use for greater than five continuous days. Oral formulation not approved.				MedGuide	Pregnancy
Ketorolac Ophthalmic	Acular, Acular LS	EENT Nonsteroidal Anti-Inflammatory Agents	Restricted to use only after surgery.					Pregnancy
Ketotifen	Zaditor	Antiallergic Agents						Pregnancy
Labetalol	Trandate	β-Adrenergic Blocking Agents						Pregnancy
Lactated Ringers	Ringer's Lactate	Replacement Preparations						Pregnancy
Lactobacillus	Acidophilus	Antidiarrhea Agents						Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Lactulose	Kristalose	Ammonia Detoxicants						Pregnancy
Lamivudine	Epivir	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Lamotrigine	Lamictal	Anticonvulsants, Miscellaneous	Physician Initiation Only. Lamotrigine should be discontinued at the first sign of rash, unless the rash is clearly not drug-related.	•			MedGuide	Pregnancy
Lanthanum Carbonate	Fosrenol	Phosphate removing agents	Physician Initiation Only.				MedGuide	Pregnancy
Latanoprost	Xalatan	Prostaglandin Analogs						Pregnancy
Leflunomide	Arava	Disease-Modifying Antirheumatic Agents	2nd line treatment for RA.					Pregnancy
Leucovorin Calcium	Leucovorin	Antidotes	Concomitant use with pyrimethamine to prevent hematologic toxicity.					Pregnancy
Levetiracetam	Keppra	Anticonvulsants, Miscellaneous		•			MedGuide	Pregnancy
Levofloxacin Oral Solution	Levaquin	Quinolones	Pediatric Use Only				MedGuide	Pregnancy
Levonorgestrel	Plan B One-Step	Contraceptives						Pregnancy
Levonorgestrel IUD	Liletta only	Contraceptives	If facility providers are uncomfortable with implanting IUD's, most OB-GYN offices will implant IUD's and bill only for their service if the patient/facility is able to provide them. Note: Liletta only (Mirena System and Skyla not approved). Recommend STI testing and counseling prior to implantation.					Pregnancy
Levonorgestrel/ Ethinyl Estradiol	Aviane, Levora, Trivora	Contraceptives						Pregnancy
Levothyroxine	Synthroid	Thyroid Agents						Pregnancy
Lidocaine/ Epinephrine	Xylocaine with Epinephrine	Local Anesthetics						Pregnancy
Lidocaine Hydrochloride	Xylocaine, Lidoderm Patch	Cardiac Drugs Local Anesthetics Antipruritic and Anesthetics	Patches restricted to neuropathic pain only					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Lisinopril	Zestril, Prinivil	Angiotensin-Converting Enzyme Inhibitors						Pregnancy
Lisinopril/ Hydrochlorothiazide	Prinzide, Zestoretic	Angiotensin-Converting Enzyme Inhibitors Thiazide Diuretics						Pregnancy
Lithium Carbonate	Eskalith	Antimanic Agents	Physician/Psychiatrist Initiation Only.	•				Pregnancy
Loperamide Hydrochloride	Imodium	Antidiarrhea Agents				•		Pregnancy
Lopinavir/Ritonavir	Kaletra	Antiretrovirals	Physician Initiation Only. Use oral solution within two months if patient stores at room temperature. Oral solution contains alcohol.	•			MedGuide	Pregnancy
Loratadine	Claritin	Second Generation Antihistamines						Pregnancy
Lorazepam	Ativan	Benzodiazepines	Lorazepam injectable needs to be refrigerated. APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet/refrigerator compartment.	•			MedGuide	Pregnancy
Losartan	Cozaar	Angiotensin II Receptor Antagonists	Intolerance to ACE inhibitors and/or failure to control Rennin-Angiotensin-Aldosterone System.					Pregnancy
Losartan/ Hydrochlorothiazide	Hyzaar	Angiotensin II Receptor Antagonists Thiazide Diuretics	Intolerance to ACE inhibitors and/or failure to control Rennin-Angiotensin-Aldosterone System.					Pregnancy
Lurasidone	Latuda	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•			MedGuide	Pregnancy
Magnesium Citrate		Cathartics and Laxatives	Restricted to bowel prep only	•				Pregnancy
Magnesium Hydroxide	MOM, Milk of Magnesia	Cathartics and Laxatives				•		Pregnancy
Magnesium Oxide	Mag-Ox	Antacids and adsorbents						Pregnancy
Magnesium Sulfate	Magnesium Sulfate	Anticonvulsants, Miscellaneous	Injectable-Physician Initiation Only.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Maraviroc	Selzentry	Antiretrovirals	Physician Initiation Only	•			MedGuide	Pregnancy
Measles/ Mumps/ Rubella Vaccine	MMR	Vaccines	According to CDC guidelines.					Pregnancy
Measles/ Mumps/ Rubella/ Varicella Vaccine	MMR	Vaccines	According to CDC guidelines.					Pregnancy
Meclizine	Antivert	Antihistamines (GI Drugs)						Pregnancy
Medroxy-progesterone	Provera, Depo-Provera, Depo-Subq	Progestins	All formulations are approved.					Pregnancy
Megestrol Acetate	Megace	Progestins	Appetite stimulation for patients with HIV or cachexia.					Pregnancy
Meloxicam	Mobic	Nonsteroidal Anti-Inflammatory Agents					MedGuide	Pregnancy
Meningococcal Conjugate Vaccine	Menactra, Menveo	Vaccines	According to CDC guidelines.					Pregnancy
Mepivacaine	Carbocaine	Local Anesthetics						Pregnancy
Mercaptopurine		Antineoplastic Agents	Physician Initiation Only. Recommend genetic testing for safety					Pregnancy
Mesalamine	Asacol, Lialda	Anti-Inflammatory Agents (GI Drugs)						Pregnancy
Metformin	Glucophage	Biguanides						Pregnancy
Methimazole	Tapazole	Antithyroid Agents						Pregnancy
Methocarbamol	Robaxin	Skeletal Muscle Relaxants	Script duration limited to 30-day supplies; extended duration on case-by-case basis	•				Pregnancy
Methotrexate	Rhematrex	Antineoplastic Agents		•				Pregnancy
Methyl Salicylate/ Menthol	BenGay, Icy Hot	Nonsteroidal Anti-Inflammatory Agents	Topical analgesics an alternative to oral therapy					Pregnancy
Methyldopa	Aldomet	Central α-Agonists	Preferred alternative for the treatment of hypertension in pregnancy.					Pregnancy
Methylprednisolone	Solu-Medrol, Medrol	Adrenals						Pregnancy
Metoclopramide Hydrochloride	Reglan	Prokinetic Agents					MedGuide	Pregnancy
Metoprolol	Lopressor	β-Adrenergic Blocking Agents	All tablet formulations are approved. Limited availability for metoprolol tartrate tablets, consider changing to metoprolol succinate if no contraindications exist.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Metronidazole	Flagyl and Metrogel	Antiprotozoals, Miscellaneous						Pregnancy
Miconazole	Micatin, Monistat 7	Antifungals (Skin and Mucous Membrane)						Pregnancy
Minoxidil	Loniten	Direct Vasodilators						Pregnancy
Mirtazapine	Remeron	Antidepressants		•			MedGuide	Pregnancy
Montelukast	Singulair	Leukotriene Modifiers						Pregnancy
Morphine Sulfate	Duramorph	Opiate Agonists	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet. Immediate Release, non-enteric coated are to be crushed prior to administration.	•	•			Pregnancy
Moxifloxacin HCl	Avelox	Quinolones					MedGuide	Pregnancy
Multivitamin	One-A-Day	Multivitamin Preparation	Alcoholic, dialysis, pregnant, malnutrition, and wasting syndrome patients only.					Pregnancy
Multivitamin, Children's	Chewable Multivitamin	Multivitamin Preparation	Pediatric Use Only					Pregnancy
Multivitamin/ Mineral/Folic Acid	Prenatal Vitamin	Multivitamin Preparation						Pregnancy
Mupirocin	Bactroban	Antibacterials (Skin and Mucous Membrane)	MRSA and Impetigo Use Only.					Pregnancy
Mycophenolate	CellCept, Myfortic	Immunosuppressive Agents						Pregnancy
Naloxone	Narcan	Opiate Antagonists						Pregnancy
Naproxen	Naprosyn	Nonsteroidal Anti-inflammatory Agents					MedGuide	Pregnancy
Nelfinavir	Viracept	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Neomycin/ Polymyxin B Sulfate/ Dexamethasone Ophthalmic Drop	Maxitrol	Antibacterials (EENT)						Pregnancy
Neomycin/ Polymyxin B/ Hydrocortisone	Cortisporin Otic	Antibacterials (EENT)						Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Nevirapine	Viramune	Antiretrovirals	Physician Initiation Only. [US Boxed Warning]: Severe, life-threatening hepatotoxicity, sometimes fatal, may occur; risk is greatest in the first 6 weeks of therapy. Female gender and higher CD4+ cell counts at treatment initiation increase risk of hepatotoxicity; women with CD4+ cell counts >250 cells/mm3, including pregnant women, are at greatest risk, although pregnancy itself does not appear to increase this risk.	•			MedGuide	Pregnancy
Niacin	Niacin	Antilipemic Agents, Miscellaneous						Pregnancy
Nifedipine	Procardia XL	Dihydropyridines	Immediate Release not approved.					Pregnancy
Nitrofurantoin	Macrodantin	Urinary Anti-Infectives	Contraindicated in pregnant patients at term (≥ 38 weeks)					Pregnancy
Nitroglycerin	Nitrostat, Transderm-Nitro	Nitrates and Nitrites	Nitrostat-keep the tablets in the original container.					Pregnancy
Norethindrone	Nora-BE	Contraceptives						Pregnancy
Norethindrone/ Ethinyl Estradiol	Loestrin, Microgestin	Contraceptives						Pregnancy
Norgestimate/Ethinyl Estradiol	MonoNessa, Trinessa	Contraceptives						Pregnancy
Nystatin	Mycostatin	Polyenes						Pregnancy
Ofloxacin Ophthalmic Drop	Ocuflox	Antibacterials (EENT)						Pregnancy
Ofloxacin Otic	Floxin	Antibacterials (EENT)					MedGuide	Pregnancy
Olanzapine	Zyprexa	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs. IM is NF: Use for Special Operation Only.	•			MedGuide	Pregnancy
Omeprazole	Prilosec	Proton Pump Inibitors					MedGuide	Pregnancy
Ondansetron	Zofran	5-HT3 Receptor Antagonists						Pregnancy

AMERICAN OVERSIGHT

Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Oseltamivir	Tamiflu	Neuraminidase Inhibitor	Therapy preferably initiated within 48 hours of symptom onset.	•				Pregnancy
Oxacillin	Bactocill	Penicillins	Physician Initiation Only.					Pregnancy
Oxcarbazepine	Trileptal	Anticonvulsants, Miscellaneous		•			MedGuide	Pregnancy
Oxybutynin	Ditropan	Antimuscarinics						Pregnancy
Oxymetazoline	Afrin	Vasoconstrictors (EENT)	Clinic use only for severe nosebleed.					Pregnancy
Pancrelipase	Zenpep	Digestants	Due to expected price fluctuations, product choice may change for most cost-effective option				MedGuide	Pregnancy
Pantoprazole	Protonix	Proton Pump Inibitors					MedGuide	Pregnancy
Papillomavirus (HPV Vaccines)	Gardasil, Gardasil 9	Vaccines	Pediatric Use Only. Gardasil 9-Not available via VA Prime Vendor. May obtain from contracted Mail Order Pharmacy.					Pregnancy
Paroxetine	Paxil	Antidepressants		•			MedGuide	Pregnancy
PEG (Polyethylene Glycol 3350 + Electrolytes Solution)	Golytely	Cathartics and Laxatives					MedGuide	Pregnancy
Penicillin G Benzathine	Bicillin Long-Acting	Penicillins	Medication must be refrigerated.					Pregnancy
Penicillin G Procaine	Penicillin G Procaine	Penicillins	Medication must be refrigerated.					Pregnancy
Penicillin V Potassium	Penicillin VK	Penicillins						Pregnancy
Pentamidine Isethionate	NebuPent, Pentam 300	Antiprotozoals, Miscellaneous						Pregnancy
Permethrin	Acticin, Nix	Scabicides and Pediculicides	RN Use 1% Permethrin Per RN Guidelines.			•		Pregnancy
Perphenazine	Trilafon	Antipsychotic Agents	Physician/Psychiatrist Initiation Only-Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Petrolatum	Vaseline	Emollients, Demulcents and Protectants				•		Pregnancy
Phenazopyridine	Pyridium	Antipruritics and Anesthetics						Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Phenobarbital	Phenobarbital	Barbiturates	Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Keep in locked cabinet.	•				Pregnancy
Phenylephrine	Anu-Med Suppository, oral tablets	Miscellaneous Skin and Mucous Membrane Agents α-adrenergic agonists	Suppositories and oral tablets only					Pregnancy
Phenylephrine/ Mineral Oil/ Petrolatum	Preparation H	Miscellaneous Skin and Mucous Membrane Agents	Ointment					Pregnancy
Phenytoin	Dilantin	Hydantoins	Injectable-Physician Initiation Only.	•			MedGuide	Pregnancy
Phytonadione	Vitamin K	Vitamin K	Physician Initiation Only.					Pregnancy
Pioglitazone	Actos	Thiazolidinediones	Contraindicated for Congestive Heart Failure patients				MedGuide	Pregnancy
Piperonyl Butoxide/ Pyrethrins	RID	Scabicides and Pediculicides	For external use only.			•		Pregnancy
Pneumococcal Vaccine	Pneumovax 13 & 23	Vaccines	Only to be administered to patients meeting criteria per CDC guideline.					Pregnancy
Podofilox	Condylox	Miscellaneous Skin and Mucous Membrane Agents	Clinic use only.	•				Pregnancy
Podophyllin	Podocon 25	Miscellaneous Skin and Mucous Membrane Agents	For use in condyloma acuminata in adults-to be used in clinic only. Medication is not to be dispensed to patients. For external use only. Use is contraindicated in women who are or may become pregnant. Reports in pregnant women have shown evidence of fetal abnormalities, fetal death, and stillbirth.	•				Pregnancy
Poliovirus Vaccine	IPOL	Vaccines	According to CDC guidelines.					Pregnancy
Polyethylene Glycol 3350	MiraLax	Cathartics and Laxatives						Pregnancy
Polymyxin B/ Neomycin/ Bacitracin	Neosporin Topical Ointment	Antibacterials (Skin and Mucous Membrane)				•		Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Polymyxin B/ Neomycin/ Gramicidin Ophthalmic	Neosporin Ophthalmic Solution	Antibacterials (EENT)						Pregnancy
Polymyxin B/ Trimethoprim Ophthalmic	Polytrim	Antibacterials (EENT)						Pregnancy
Potassium Chloride	Klor-Con	Replacement Preparations						Pregnancy
Pramipexole	Mirapex	Dopamine Receptor Agonists	Extended release formulations are non-formulary					Pregnancy
Pravastatin	Pravachol	HMG CoA Reductase Inhibitors						Pregnancy
Prazosin	Minipress	α-Adrenergic Blocking Agents						Pregnancy
Prednisolone Ophthalmic	Pred Forte	Corticosteroids (EENT)						Pregnancy
Prednisone	Deltasone	Adrenals	If oral steroids are to be used for greater than 5 days, they should be tapered and not abruptly stopped.					Pregnancy
Primaquine	Primaquine	Antimalarials	G6PD-deficient patients may be treated with lower doses over a longer period of time.					Pregnancy
Primidone	Mysoline	Barbiturates (Anticonvulsants)		•			MedGuide	Pregnancy
Probenecid	Benemid	Uricosuric Agents						Pregnancy
Prochlorperazine	Compazine	Antihistamines (GI Drugs)						Pregnancy
Promethazine	Phenergan	Miscellaneous Anxiolytics, Sedatives, and Hypnotics	[US Boxed Warning]: Respiratory depression - Pediatrics: Promethazine should not be used in pediatric patients younger than 2 years because of the potential for fatal respiratory depression. [US Boxed Warning]: Severe tissue injury, including gangrene (injection): Promethazine can cause severe chemical irritation and damage to tissues regardless of the route of administration.					Pregnancy
Proparacaine Hydrochloride	Alcaine	Local Anesthetics (EENT)						Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Propranolol Hydrochloride	Inderal	β-Adrenergic Blocking Agents						Pregnancy
Propylthiouracil	PTU	Antithyroid Agents						Pregnancy
Psyllium	Metamucil	Cathartics and Laxatives	Sugar free products only.					Pregnancy
Pyrazinamide	PZA	Antituberculosis	Presumptive tuberculosis requires physician review within 30 days of initiation	•				Pregnancy
Pyridostigmine	Mestinon, Regonol	Parasympatho-mimetic (Cholinergic) Agent						Pregnancy
Pyridoxine	Vitamin B-6	Vitamin B Complex						Pregnancy
Pyrimethamine	Daraprim, Fansidar	Antimalarials						Pregnancy
Quinidine Sulfate	Quinidine Sulfate	Cardiac Drugs						Pregnancy
Quinine	Qualaquin	Antimalarials	When treating uncomplicated malaria medication should be given in combination with either tetracycline or doxycycline.				MedGuide	Pregnancy
Raltegravir Potassium	Isentress	Antiretrovirals	Physician Initiation Only	•				Pregnancy
Ranitidine Hydrochloride	Zantac	Gastrointestinal Agents - Antiulcer Agents and Acid Suppressants						Pregnancy
Rifampin	Rifadin	Antituberculosis	Presumptive tuberculosis requires physician review within 30 days of initiation	•				Pregnancy
Rilpivirine	Edurant	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Risperidone	Risperdal	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Ritonavir	Norvir	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Rosuvastatin	Crestor	HMG CoA Reductase Inhibitors	The 40 mg dose should be reserved for patients who have not achieved goal cholesterol levels on a dose of 20 mg daily, including patients switched from another HMG-CoA reductase inhibitor.					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Rotavirus	Rotarix, Rota Teq	Vaccines	Live Vaccine					Pregnancy
Salicylic Acid		Keratolytic Agents	Clinic use only.	●				Pregnancy
Salmeterol	Serevent Discus	Sympathomimetic (Adrenergic) Agents	Physician Initiation Only. Use after failure with steroid inhaler and current short acting B-agonist.					Pregnancy
Saquinavir	Invirase	Antiretrovirals	Physician Initiation Only. Saquinavir should always be used with concomitant ritonavir; cobicistat is not interchangeable with ritonavir to increase systemic exposure.	●			MedGuide	Pregnancy
Selenium Sulfide	Selsun	Miscellaneous Local Anti-Infectives	OTC version-RN Use Per RN Guidelines. For external use only.			●		Pregnancy
Sertraline Hydrochloride	Zoloft	Antidepressants		●			MedGuide	Pregnancy
Sevelamer	Renagel	Ion-Removing Agent	Tablets must be swallowed intact.					Pregnancy
Silver Nitrate Applicator		Keratolytic Agents	Not available via VA Prime Vendor. May obtain from contracted Mail Order Pharmacy. Clinic use only.					Pregnancy
Silver Sulfadiazine	Silvadene	Miscellaneous Local Anti-Infectives	RN use with wound care order			●		Pregnancy
Simethicone	Mylicon	Antiflatulents	See also Maalox and Mylanta (aluminum hydroxide, magnesium hydroxide and simethicone).					Pregnancy
Simvastatin	Zocor	HMG CoA Reductase Inhibitors	Maximum recommended dose is 40mg. Contraindicated with protease inhibitors (HIV) and gemfibrozil. See pravastatin or atorvastatin for alternative. Use of simvastatin is contraindicated in pregnancy.					Pregnancy
Sodium Bicarbonate	Neut	Antacids and Adsorbents						Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Sodium Chloride		Replacement Preparations Miscellaneous Therapeutic Agents EENT Drugs, Miscellaneous	RN use with provider orders, all formulations approved except "salt packets". Not approved for oral rinse/gargle.					Pregnancy
Sodium Phosphate, Rectal	Fleet Enema	Cathartics and Laxatives						Pregnancy
Sotalol	Betapace	β-Adrenergic Blocking Agents						Pregnancy
Spironolactone	Aldactone	Diuretics-Potassium Sparing						Pregnancy
Stavudine	Zerit	Antiretrovirals	Physician Initiation Only.	•			MedGuide	Pregnancy
Streptomycin	Streptomycin	Aminoglycoside	Physician Initiation Only.	•				Pregnancy
Sucralfate	Carafate	Gastrointestinal Agents - Antiulcer Agents and Acid Suppressants						Pregnancy
Sulfacetamide	Sulamyd	Antibacterials (EENT)						Pregnancy
Sulfacetamide/ Prednisolone Ophthalmic	Blephamide	EENT Anti-Infectives, Miscellaneous						Pregnancy
Sulfamethoxazole/ Trimethoprim	Bactrim, Septra	Sulfonamides						Pregnancy
Sulfasalazine	Azulfidine	Sulfonamides						Pregnancy
Sulfur/ Salicylic Acid	Sebex	Keratolytic Agents	For external use only.					Pregnancy
Sumatriptan Succinate	Imitrex	Antimigraine Agents - Selective Serotonin Agonists						Pregnancy
Tacrolimus	Prograf	Immunosuppressive Agents		•				Pregnancy
Tamoxifen	Soltamox	Estrogen Agonist-Antagonists	Physician Initiation only. Female patients only				MedGuide	Pregnancy
Tamsulosin	Flomax	α-Adrenergic Blocking Agent (Sympath)						Pregnancy
Tar Shampoo	Ionil T	Keratinoplastic Agents	OTC versions-RN Use Per RN Guidelines. For external use only.			•		Pregnancy
Tears, Artificial	Artificial Tears, many brands	EENT Drugs, Miscellaneous				•		Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Telbivudine	Tyzeka	Antiretrovirals	Physician Initiation Only. [US Boxed Warning]: Chronic hepatitis: Severe, acute exacerbations of hepatitis B have been reported in patients who have discontinued anti–hepatitis B therapy, including telbivudine. Hepatic function should be closely monitored with both clinical and laboratory follow-up for at least several months in patients who discontinue antihepatitis B therapy. If appropriate, resumption of antihepatitis B therapy may be warranted.	•			MedGuide	Pregnancy
Tenofovir Disoproxil Fumarate	Viread	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Terazosin	Hytrin	α-Adrenergic Blocking Agents						Pregnancy
Terbinafine	Lamisil	Allylamines	Not to be used for onychomycosis. Use for tinea capitis or tinea pedis.				MedGuide	Pregnancy
Testosterone (Depo Injection)	Depo-Testosterone	Androgen	Depo Injectable Only. Physician Initiation Only.	•				Pregnancy
Tetanus and Diphtheria	Td	Toxoids	According to CDC guidelines.					Pregnancy
Tetanus Toxoid	TT	Toxoids	According to CDC guidelines.					Pregnancy
Tetrahydrozoline Ophthalmic	Visine	Vasoconstrictors (EENT)						Pregnancy
Thiamine	Vitamin B-1, Betalin S	Vitamin B Complex						Pregnancy
Thiothixene	Navane	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy
Timolol Maleate	Timoptic	EENT Preparations - β-Adrenergic Blocking Agents						Pregnancy
Tipranavir	Aptivus	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Titanium Dioxide	Vanicream	Sunscreen Agents	Topical Cream					Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Tizanidine	Zanaflex	Skeletal Muscle Relaxants	Script duration limited to 30-day supplies; extended duration on case-by-case basis	•				Pregnancy
Tobramycin Ophthalmic	Tobrex	Antibacterials (EENT)						Pregnancy
Tolnaftate	Tinactin	Antifungal Agent						Pregnancy
Topiramate	Topamax	Anticonvulsants, Miscellaneous	Used for epilepsy as monotherapy or adjunctive therapy; migraine prophylaxis	•			MedGuide	Pregnancy
Tramadol	Ultram	Opiate Agonists	APP: Requires physician consultation, APPs may be privileged to initiate and/or modify treatment based on his/her CPA/PAA. Only after documented NSAID failure or unless other NSAIDS are contraindicated. Keep in locked cabinet. Immediate release and non-enteric coated are to be crushed prior to administration.	•	•		MedGuide	Pregnancy
Trazodone	Desyrel	Antidepressants		•			MedGuide	Pregnancy
Tretinoin Topical	Retin-A	Cell Stimulants and Proliferants	Used for acne vulgaris only. Topical only.					Pregnancy
Triamcinolone Acetonide	Kenalog	Anti-Inflammatory Agents (Skin and Mucous Membranes)	In general topical corticosteroids should only be used on the involved areas of the skin and when treating chronic dermatitis should only be used when skin is inflamed.					Pregnancy
Triamcinolone Dental Paste	Kenalog in Orabase	Anti-Inflammatory Agents (Skin and Mucous Membranes)	See also Dental Agents					Pregnancy
Triamcinolone Hexacetonide	Aristospan	Adrenals						Pregnancy
Triamterene/ Hydrochlorothiazide	Maxzide	Diuretics-potassium sparing Thiazide Diuretics						Pregnancy
Trihexyphenidyl	Artane	Anticholinergic Agents (CNS)		•				Pregnancy

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Generic Name	Trade Name	Therapeutic Class	Comments	Pill Line	Crush	RN Use	FDA MedGuide	Pregnancy Information
Trimethobenzamide Hydrochloride	Tigan	Antiemetics						Pregnancy
Tropicamide	Mydriacyl	Mydriatics	For diagnostic use only.					Pregnancy
Tuberculin Purified Protein Derivative	Tubersol	Tuberculosis (Diagnostic)	Product must be refrigerated.					Pregnancy
Ulipristal	Ella	Contraceptives						Pregnancy
Umeclidinium/ Vilanterol	Anoro Ellipta	Antimuscarinics/ Antispasmodics	Long Acting Anticholinergic for COPD.				MedGuide	Pregnancy
Valproic Acid		Anticonvulsants, Miscellaneous		•				Pregnancy
Valsartan	Diovan	Angiotensin II Receptor						Pregnancy
Vancomycin	Vancocin	Miscellaneous Antibiotics	Physician Initiation Only. ADD-Vantage Vials.					Pregnancy
Varicella Vaccine	Varivax	Vaccines	According to CDC guidelines.					Pregnancy
Venlafaxine	Effexor	Antidepressants		•			MedGuide	Pregnancy
Verapamil	Calan	Calcium Channel Blocking Agents	Injectable-Physician Initiation Only.					Pregnancy
Vitamin A	Aquasol A	Vitamin A						Pregnancy
Vitamin A&D Ointment		Basic Ointments and protectants	RN use with wound care order			•		Pregnancy
Vitamin D2 & D3	Ergocalciferol Cholecalciferol	Vitamin D						Pregnancy
Warfarin	Coumadin	Anticoagulants	Physician Initiation Only. See Anticoagulation Protocol.	•			MedGuide	Pregnancy
Zalcitabine	Hivid	Antiretrovirals	Physician Initiation Only.	•				Pregnancy
Zidovudine	Retrovir	Antiretrovirals	Physician Initiation Only. Zidovudine has been associated with hematologic toxicity.	•				Pregnancy
Zidovudine/ Lamivudine	Combivir	Antiretrovirals	Physician Initiation Only. Zidovudine has been associated with hematologic toxicity.	•				Pregnancy
Zinc Oxide	Desitin	Emollient, Demulcents and Protectants	RN use with wound care order			•		Pregnancy
Ziprasidone	Geodon	Antipsychotic Agents	Physician/Psychiatrist Initiation Only- Physician/Psychiatrist can initiate and can be re-ordered/renewed by APPs.	•				Pregnancy

AMERICAN OVERSIGHT

IHSC National Formulary – Dental Products

For dental products and supplies not available via VA PPV, please consult local dental department

Generic	Trade Name	Indication	Pill Line	Clinic Use Only
Acidulated Phosphate Fluoride (APF) 1.23%	Topex 60 Second APF Foam or Gel	Children, orthodontic, and xerostomia from medical treatment.		
Articaine 4% with epinephrine	Septocaine	Local anesthetics.		•
Biotene Mouthwash (alcohol free)	Biotene Mouthwash (alcohol free)	Treatment of xerostomia due to medical treatment such as chemotherapy, radiation therapy and salivary gland disorders. “Physician/Dentist Initiation Only”.		
Biotene Oral Balance Moisturizer	Biotene Oral Balance Moisturizer	Treatment of xerostomia due to medical treatment such as chemotherapy, radiation therapy and salivary gland disorders. “Physician/Dentist Initiation Only”.		
Biotene Toothpaste	Biotene Toothpaste	Treatment of xerostomia due to medical treatment such as chemotherapy, radiation therapy and salivary gland disorders. “Physician/Dentist Initiation Only”.		
Dexamethasone elixir 0.5 mg/ 5ml	Decadron	Treatment of steroid responsive disorders of the oral mucosa, including inflammatory and ulcerative lesions. "Physician/Dentist Initiation Only" 7 days Use Only. Available from VA Prime Vendor.	•	
Denture Adhesive Cream	Fixodent	Zinc free only. "Dentist Initiation Only"		
Minocycline HCL 1mg syringes	Arestin	Locally administered antibiotic for use in scaling and root planning procedures for the reduction of pocket depth in patients with adult periodontitis. Dental use only.		•
Neutral Sodium Fluoride 2%	Topex Neutral Foam or Gel	Children, orthodontic, and xerostomia from medical treatment.		
Penciclovir cream 1%	Denavir	Treatment of oral herpes simplex. “Physician/Dentist Initiation Only”. Available from VA Prime Vendor.		
Sodium Fluoride 1.1 %	PreviDent 5000	Xerostomia from medical treatment (i.e. Radiation treatment). Available from VA Prime Vendor.		
Sodium Fluoride 2.7% Prophylaxis Paste (Fluoride Ion 1.23%)		Used for normal dental cleanings, polishing and plaque/ stain removal.		•
Sodium Fluoride Varnish 5%	Duraphat, Sultan DuraShield	Prevention of carious lesions and tooth sensitivity.		•
Sulfonated Phenolics and Sulfuric Acid	Debacterol			•

AMERICAN OVERSIGHT

IHSC National Formulary – Approved Over-The-Counter Nurse (RN) Use

Generic	Trade Name	Therapeutic Class	Comments
Acetaminophen	Tylenol	Miscellaneous Analgesics and Antipyretics	Suppositories need to be refrigerated.
Aluminum Hydroxide/ Magnesium Hydroxide/ Simethicone	Mylanta, Maalox	Antacids and Adsorbents	
Aspirin	Ecotrin, Chewable Aspirin	Nonsteroidal Anti-inflammatory Agents	All formulations are approved. RN use for urgent care
Bisacodyl	Dulcolax	Cathartics and Laxatives	
Bismuth Subsalicylate	Pepto-Bismol	Antidiarrhea Agents	
Calamine	Calamine Lotion	Basic Lotions and Liniments	
Chlorpheniramine Maleate	Chlor-Trimeton	First Generation Antihistamines	
Clotrimazole	Lotrimin	Antifungals (Skin and Mucous Membrane)	Topical
Diphenhydramine Hydrochloride	Benadryl	First Generation Antihistamines	
Docusate Sodium	Colace	Cathartics and Laxatives	
Electrolyte Solution	Pedialyte	Replacement Preparations	Note: The use of this product should be limited to 24 hours in infants and children. After 24 hours this rehydration formula can cause diarrhea worsening gastroenteritis.
Epinephrine	Adrenaline	α & β adrenergic agonists	RN use for urgent care
Glycerin suppository		Cathartics and Laxatives	
Guaifenesin	Robitussin	Expectorants	Recommend alcohol-free formulation.
Hydrocortisone, Topical	Cortizone	Anti-inflammatory Agents (Skin and Mucous Membrane)	Hydrocortisone 1% for RN Use
Hydrogen Peroxide		Mouthwashes and Gargles	Main clinic and dental clinic use.
Ibuprofen	Motrin	Nonsteroidal Anti-Inflammatory Agents	
Loperamide Hydrochloride	Imodium	Antidiarrhea Agents	
Magnesium Hydroxide	MOM, Milk of Magnesia	Cathartics and Laxatives	
Permethrin	Acticin, Nix	Scabicides and Pediculicides	1% Permethrin Per RN Guidelines.
Petrolatum	Vaseline	Emollients, Demulcents and Protectants	
Piperonyl Butoxide/ Pyrethrins	RID	Scabicides and Pediculicides	For external use only.
Polymyxin B/ Neomycin/ Bacitracin	Neosporin Topical Ointment	Antibacterials (Skin and Mucous Membrane)	
Selenium Sulfide	Selsun	Miscellaneous Local Anti-Infectives	OTC versions- Per RN Guidelines. For external use only.
Silver Sulfadiazine	Silvadene	Miscellaneous Local Anti-Infectives	RN use with wound care order
Tar Shampoo	Ionil T	Keratinoplastic Agents	OTC versions- Per RN Guidelines. For external use only.
Tears, Artificial	Artificial Tears, many brands	EENT Drugs, Miscellaneous	
Vitamin A&D Ointment		Basic Ointments and protectants	RN use with wound care order
Zinc Oxide	Desitin	Emollient, Demulcents and Protectants	RN use with wound care order

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IHSC National Formulary – Category Listing

Class No.	Therapeutic Class	Generic
920800	5 Alpha-Reductase Inhibitor	Finasteride
562220	5-HT3 Receptor Antagonists	Ondansetron
524004	A-Adrenergic Agonists (EENT)	Brimonidine Tartrate
283604	Adamantanes (CNS)	Amantadine
680400	Adrenals	Dexamethasone
680400	Adrenals	Fludrocortisone
680400	Adrenals	Methylprednisolone
680400	Adrenals	Prednisone
680400	Adrenals	Triamcinolone Hexacetonide
81404	Allylamines	Terbinafine
81202	Aminoglycoside	Gentamicin Sulfate
81202	Aminoglycoside	Streptomycin
401000	Ammonia Detoxicants	Lactulose
680800	Androgen	Testosterone (Depo Injection)
240844	Angiotensin II Receptor	Valsartan/ Hydrochlorothiazide
243208	Angiotensin II Receptor Antagonists	Losartan
243208	Angiotensin II Receptor Antagonists	Losartan/ Hydrochlorothiazide
243204	Angiotensin-Converting Enzyme Inhibitors	Captopril
243204	Angiotensin-Converting Enzyme Inhibitors	Enalapril
243204	Angiotensin-Converting Enzyme Inhibitors	Lisinopril
243204	Angiotensin-Converting Enzyme Inhibitors	Lisinopril/ Hydrochlorothiazide
560400	Antacids and Adsorbents	Aluminum Hydroxide / Magnesium Trisilicate
560400	Antacids and Adsorbents	Aluminum Hydroxide/ Magnesium Hydroxide/ Simethicone
560400	Antacids and Adsorbents	Calcium Carbonate
560400	Antacids and Adsorbents	Charcoal, Activated
560400	Antacids and Adsorbents	Magnesium Oxide
560400	Antacids and Adsorbents	Sodium Bicarbonate
80800	Anthelmintics	Albendazole
80800	Anthelmintics	Ivermectin
520200	Antiallergic Agents	Ketotifen
240404	Antiarrhythmic Agent Class III	Amiodarone
520404	Antibacterials (EENT)	Erythromycin, Ophthalmic
520404	Antibacterials (EENT)	Gentamicin Sulfate
520404	Antibacterials (EENT)	Neomycin/ Polymyxin B Sulfate/ Dexamethasone Ophthalmic drop
520404	Antibacterials (EENT)	Neomycin/ Polymyxin B/ Hydrocortisone
520404	Antibacterials (EENT)	Ofloxacin Ophthalmic Drop
520404	Antibacterials (EENT)	Ofloxacin Otic
520404	Antibacterials (EENT)	Polymyxin B/ Neomycin/ Gramicidin Ophthalmic
520404	Antibacterials (EENT)	Polymyxin B/ Trimethoprim Ophthalmic
520404	Antibacterials (EENT)	Sulfacetamide
520404	Antibacterials (EENT)	Tobramycin Ophthalmic
840404	Antibacterials (Skin and Mucous Membrane)	Bacitracin
840404	Antibacterials (Skin and Mucous Membrane)	Erythromycin Topical Gel 2%
840404	Antibacterials (Skin and Mucous Membrane)	Metronidazole
840404	Antibacterials (Skin and Mucous Membrane)	Mupirocin
840404	Antibacterials (Skin and Mucous Membrane)	Polymyxin B/ Neomycin/ Bacitracin
283608	Anticholinergic Agents (CNS)	Benztropine Mesylate
283608	Anticholinergic Agents (CNS)	Trihexyphenidyl
201204	Anticoagulants	Apixaban
201204	Anticoagulants	Enoxaparin
201204	Anticoagulants	Heparin Sodium
201204	Anticoagulants	Warfarin

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Class No.	Therapeutic Class	Generic
281292	Anticonvulsants, Miscellaneous	Carbamazepine
281292	Anticonvulsants, Miscellaneous	Divalproex Sodium
281292	Anticonvulsants, Miscellaneous	Gabapentin
281292	Anticonvulsants, Miscellaneous	Lamotrigine
281292	Anticonvulsants, Miscellaneous	Levetiracetam
281292	Anticonvulsants, Miscellaneous	Magnesium Sulfate
281292	Anticonvulsants, Miscellaneous	Oxcarbazepine
281292	Anticonvulsants, Miscellaneous	Topiramate
281292	Anticonvulsants, Miscellaneous	Valproic Acid
281604	Antidepressants	Amitriptyline
281604	Antidepressants	Bupropion
281604	Antidepressants	Citalopram
281604	Antidepressants	Desipramine
281604	Antidepressants	Doxepin
281604	Antidepressants	Duloxetine
281604	Antidepressants	Escitalopram
281604	Antidepressants	Fluoxetine
281604	Antidepressants	Imipramine
281604	Antidepressants	Mirtazapine
281604	Antidepressants	Paroxetine
281604	Antidepressants	Sertraline Hydrochloride
281604	Antidepressants	Trazodone
281604	Antidepressants	Venlafaxine
682020	Antidiabetic Agents	Glyburide
560800	Antidiarrhea Agents	Bismuth Subsalicylate
560800	Antidiarrhea Agents	Lactobacillus
560800	Antidiarrhea Agents	Loperamide Hydrochloride
921200	Antidotes	Leucovorin Calcium
562200	Antiemetics	Trimethobenzamide Hydrochloride
561000	Antiflatulents	Simethicone
81492	Antifungals	Griseofulvin Suspension
840408	Antifungals (Skin and Mucous Membrane)	Gentian Violet
840808	Antifungals (Skin and Mucous Membrane)	Clotrimazole
840808	Antifungals (Skin and Mucous Membrane)	Miconazole
921600	Antigout Agents	Allopurinol
921600	Antigout Agents	Colchicine
562208	Antihistamines (GI Drugs)	Meclizine
562208	Antihistamines (GI Drugs)	Prochlorperazine
563600	Anti-Inflammatory Agents (GI Drugs)	Mesalamine
840600	Anti-Inflammatory Agents (Skin and Mucous Membrane)	Clobetasol
840600	Anti-Inflammatory Agents (Skin and Mucous Membrane)	Fluocinonide
840600	Anti-Inflammatory Agents (Skin and Mucous Membrane)	Hydrocortisone Suppository
840600	Anti-Inflammatory Agents (Skin and Mucous Membrane)	Hydrocortisone, Topical
840600	Anti-Inflammatory Agents (Skin and Mucous Membranes)	Triamcinolone Acetonide
840600	Anti-Inflammatory Agents (Skin and Mucous Membranes)	Triamcinolone Dental Paste
240692	Antilipemic Agents, Miscellaneous	Niacin
83008	Antimalarials	Chloroquine Phosphate
83008	Antimalarials	Hydroxychloroquine
83008	Antimalarials	Primaquine
83008	Antimalarials	Pyrimethamine

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Class No.	Therapeutic Class	Generic
83008	Antimalarials	Quinine
282800	Antimanic Agents	Lithium Carbonate
283292	Antimigraine Agents - Miscellaneous	Acetaminophen / Aspirin/ Caffeine
283228	Antimigraine Agents - Selective Serotonin Agonists	Sumatriptan Succinate
861204	Antimuscarinics	Oxybutynin
120808	Antimuscarinics/ Antispasmodics	Aclidinium
120808	Antimuscarinics/ Antispasmodics	Dicyclomine Hydrochloride
120808	Antimuscarinics/ Antispasmodics	Ipratropium
120808	Antimuscarinics/ Antispasmodics	Ipratropium/ Albuterol oral inhaler
120808	Antimuscarinics/ Antispasmodics	Umeclidinium/ Vilanterol
100000	Antineoplastic Agents	Hydroxyurea
100000	Antineoplastic Agents	Mercaptopurine
100000	Antineoplastic Agents	Methotrexate
682404	Antiparathyroid Agents	Cinacalcet
83092	Antiprotozoals, Miscellaneous	Atovaquone
83092	Antiprotozoals, Miscellaneous	Metronidazole
83092	Antiprotozoals, Miscellaneous	Pentamidine Isethionate
840800	Antipruritics and Anesthetics	Lidocaine Hydrochloride
840800	Antipruritics and Anesthetics	Phenazopyridine
840800	Antipruritics and Local Anesthetics	Benzocaine
840800	Antipruritics and Local Anesthetics	Dibucaine
281608	Antipsychotic Agents	Aripiprazole
281608	Antipsychotic Agents	Chlorpromazine Hydrochloride
281608	Antipsychotic Agents	Fluphenazine
281608	Antipsychotic Agents	Fluphenazine Decanoate
281608	Antipsychotic Agents	Haloperidol
281608	Antipsychotic Agents	Haloperidol Decanoate
281608	Antipsychotic Agents	Lurasidone
281608	Antipsychotic Agents	Olanzapine
281608	Antipsychotic Agents	Perphenazine
281608	Antipsychotic Agents	Risperidone
281608	Antipsychotic Agents	Thiothixene
281608	Antipsychotic Agents	Ziprasidone
81808	Antiretrovirals	Abacavir
81808	Antiretrovirals	Abacavir/ Lamivudine
81808	Antiretrovirals	Abacavir/ Lamivudine/ Zidovudine
81808	Antiretrovirals	Abacavir/ Dolutegravir/ Lamivudine
81808	Antiretrovirals	Adefovir
81808	Antiretrovirals	Amprenavir
81808	Antiretrovirals	Atazanavir
81808	Antiretrovirals	Atazanavir/ Cobicistat
81808	Antiretrovirals	Darunavir
81808	Antiretrovirals	Darunavir/ Cobicistat
81808	Antiretrovirals	Delavirdine
81808	Antiretrovirals	Didanosine
81808	Antiretrovirals	Dolutegravir
81808	Antiretrovirals	Dolutegravir/ Abacavir/ Lamivudine
81808	Antiretrovirals	Efavirenz
81808	Antiretrovirals	Efavirenz/ Emtricitabine/ Tenofovir
81808	Antiretrovirals	Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir
81808	Antiretrovirals	Emtricitabine
81808	Antiretrovirals	Emtricitabine/ Rilpivirine/ Tenofovir
81808	Antiretrovirals	Emtricitabine/Tenofovir
81808	Antiretrovirals	Enfuvirtide
81808	Antiretrovirals	Etravirine
81808	Antiretrovirals	Fosamprenavir

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Class No.	Therapeutic Class	Generic
81808	Antiretrovirals	Indinavir
81808	Antiretrovirals	Lamivudine
81808	Antiretrovirals	Lopinavir/ Ritonavir
81808	Antiretrovirals	Maraviroc
81808	Antiretrovirals	Nelfinavir
81808	Antiretrovirals	Nevirapine
81808	Antiretrovirals	Raltegravir Potassium
81808	Antiretrovirals	Rilpivirine
81808	Antiretrovirals	Ritonavir
81808	Antiretrovirals	Saquinavir
81808	Antiretrovirals	Stavudine
81808	Antiretrovirals	Telbivudine
81808	Antiretrovirals	Tenofovir Disoproxil Fumarate
81808	Antiretrovirals	Tipranavir
81808	Antiretrovirals	Zalcitabine
81808	Antiretrovirals	Zidovudine
81808	Antiretrovirals	Zidovudine/ Lamivudine
683608	Antithyroid Agents	Methimazole
683608	Antithyroid Agents	Propylthiouracil
81604	Antituberculosis	Aminosalicylic Acid
81604	Antituberculosis	Capreomycin
81604	Antituberculosis	Cycloserine
81604	Antituberculosis	Ethambutol
81604	Antituberculosis	Ethionamide
81604	Antituberculosis	Isoniazid
81604	Antituberculosis	Pyrazinamide
81604	Antituberculosis	Rifampin
480800	Antitussives	Benzonatate
81408	Azoles	Fluconazole
81408	Azoles	Ketoconazole
282404	Barbiturates	Phenobarbital
281204	Barbiturates (Anticonvulsants)	Primidone
842404	Basic Lotions and Liniments	Ammonium lactate
842404	Basic Lotions and Liniments	Calamine
842404	Basic Lotions and Liniments	Camphor/menthol
842412	Basic Ointments and Protectants	Vitamin A&D Ointment
282408	Benzodiazepines	Clonazepam
282408	Benzodiazepines	Diazepam
282408	Benzodiazepines	Lorazepam
682004	Biguanides	Metformin
922400	Bone Resorption Inhibitors	Alendronate
242892	Calcium Channel Blocking Agents	Diltiazem
242892	Calcium Channel Blocking Agents	Verapamil
402000	Caloric Agents	Dextrose 5% in normal saline
402000	Caloric Agents	Dextrose in sterile water
402000	Caloric Agents	Dextrose Instant
402000	Caloric Agents	Dietary Supplement, Oral
524012	Carbonic Anhydrase Inhibitors	Acetazolamide
524012	Carbonic Anhydrase Inhibitors	Dorzolamide Hydrochloride
524012	Carbonic Anhydrase Inhibitors	Dorzolamide Hydrochloride/ Timolol
240400	Cardiac Drugs	Lidocaine Hydrochloride
240400	Cardiac Drugs	Quinidine Sulfate
240408	Cardiotonic Agents	Digoxin
561200	Cathartics and Laxatives	Bisacodyl
561200	Cathartics and Laxatives	Calcium Polycarbophil
561200	Cathartics and Laxatives	Docusate Sodium

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Class No.	Therapeutic Class	Generic
561200	Cathartics and Laxatives	Glycerin suppository
561200	Cathartics and Laxatives	Magnesium Citrate
561200	Cathartics and Laxatives	Magnesium Hydroxide
561200	Cathartics and Laxatives	PEG (Polyethylene Glycol 3350 + Electrolytes Solution)
561200	Cathartics and Laxatives	Polyethylene Glycol 3350
561200	Cathartics and Laxatives	Psyllium
561200	Cathartics and Laxatives	Sodium Phosphate, Rectal
841600	Cell Stimulants and Proliferants	Tretinoin Topical
240816	Central α-Agonists	Clonidine Hydrochloride
240816	Central α-Agonists	Methyldopa
81206	Cephalosporins	Cefazolin
81206	Cephalosporins	Cefdinir
81206	Cephalosporins	Ceftriaxone
81206	Cephalosporins	Cephalexin
681200	Contraceptives	Drospirenone/ Ethinyl Estradiol
681200	Contraceptives	Levonorgestrel
681200	Contraceptives	Levonorgestrel IUD
681200	Contraceptives	Levonorgestrel/ Ethinyl estradiol
681200	Contraceptives	Norethindrone
681200	Contraceptives	Norethindrone/ Ethinyl Estradiol
681200	Contraceptives	Norgestimate/ Ethinyl Estradiol
681200	Contraceptives	Ulipristal
520800	Corticosteroids (EENT)	Flunisolide (Nasal)
520808	Corticosteroids (EENT)	Dexamethasone
520808	Corticosteroids (EENT)	Fluticasone (Nasal)
520808	Corticosteroids (EENT)	Prednisolone Ophthalmic
481008	Corticosteroids (Respiratory)	Budesonide/ Formoterol
481008	Corticosteroids (Respiratory)	Fluticasone Propionate Oral Inhaler
340000	Dental Agents	Benzocaine
561600	Digestants	Pancrelipase
242808	Dihydropyridines	Amlodipine
242808	Dihydropyridines	Nifedipine
240820	Direct Vasodilators	Hydralazine
240820	Direct Vasodilators	Minoxidil
923600	Disease-Modifying Antirheumatic Agents	Leflunomide
402816	Diuretics-Potassium Sparing	Spironolactone
402816	Diuretics-Potassium Sparing	Triamterene/ Hydrochlorothiazide
120804	Dopamine Precursors	Carbidopa and Levodopa
283620	Dopamine Receptor Agonists	Bromocriptine
283620	Dopamine Receptor Agonists	Cabergoline
283620	Dopamine Receptor Agonists	Pramipexole
520492	EENT Anti-Infectives, Miscellaneous	Aluminum Acetate/Acetic Acid Otic
520492	EENT Anti-Infectives, Miscellaneous	Acetic Acid Otic
520492	EENT Anti-Infectives, Miscellaneous	Carbamide Peroxide
520492	EENT Anti-Infectives, Miscellaneous	Chlorhexidine Gluconate
520492	EENT Anti-Infectives, Miscellaneous	Sulfacetamide/Prednisolone Ophthalmic
529200	EENT Drugs, Miscellaneous	Borate/Boric Acid/H2O/NaCl
529200	EENT Drugs, Miscellaneous	Sodium chloride (Nasal)
529200	EENT Drugs, Miscellaneous	Tears, Artificial
520820	EENT Nonsteroidal Anti-Inflammatory Agents	Ketorolac Ophthalmic
524008	EENT Preparations - β-Adrenergic Blocking Agents	Dorzolamide Hydrochloride/ Timolol
524008	EENT Preparations - β-Adrenergic Blocking Agents	Timolol Maleate
842400	Emollient, Demulcents and Protectants	Zinc Oxide

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Class No.	Therapeutic Class	Generic
842400	Emollients, Demulcents and Protectants	Petrolatum
681612	Estrogen Agonist-Antagonists	Tamoxifen
681604	Estrogens	Estradiol
681604	Estrogens	Estradiol Cypionate
481600	Expectorants	Guaifenesin
240606	Fibric Acid Derivatives	Fenofibrate
240606	Fibric Acid Derivatives	Gemfibrozil
40400	First Generation Antihistamines	Chlorpheniramine Maleate
40400	First Generation Antihistamines	Diphenhydramine Hydrochloride
40492	First Generation Antihistamines, Derivative	Cyproheptadine
562800	Gastrointestinal Agents - Antiulcer Agents and Acid Suppressants	Ranitidine Hydrochloride
562800	Gastrointestinal Agents - Antiulcer Agents and Acid Suppressants	Sucralfate
682212	Glycogenolytic Agents	Glucagon, Human Recombinant
201600	Hematopoietic Agents	Epoetin Alfa
201600	Hematopoietic Agents	Filgrastim
240608	HMG CoA Reductase Inhibitors	Pravastatin
240608	HMG CoA Reductase Inhibitors	Simvastatin
240608	HMG-CoA Reductase Inhibitors	Atorvastatin
281212	Hydantoins	Phenytoin
922000	Immunomodulatory Agents	Dimethyl Fumarate
922000	Immunomodulatory Agents	Fingolimod
922000	Immunomodulatory Agents	Glatiramer Acetate
924400	Immunosuppressive Agents	Azathioprine
924400	Immunosuppressive agents	Cyclosporine
924400	Immunosuppressive Agents	Mycophenolate
924400	Immunosuppressive Agents	Tacrolimus
682008	Insulins	Insulin
401819	Ion-Removing Agent	Sevelamer
200404	Iron Preparations	Ferrous Sulfate
403600	Irrigating Solutions	Sodium Chloride, Irrigation Solution
843200	Keratinoplastic Agents	Tar Shampoo
842800	Keratolytic Agent	Benzoyl Peroxide
842800	Keratolytic Agents	Salicylic Acid
842800	Keratolytic Agents	Silver Nitrate Applicator
842800	Keratolytic Agents	Sulfur/Salicylic Acid
481024	Leukotriene Modifiers	Montelukast
720000	Local Anesthetics	Lidocaine/Epinephrine
720000	Local Anesthetics	Lidocaine Hydrochloride
720000	Local Anesthetics	Mepivacaine
521600	Local Anesthetics (EENT)	Antipyrine/Benzocaine
521600	Local Anesthetics (EENT)	Benzocaine
521600	Local Anesthetics (EENT)	Proparacaine Hydrochloride
720000	Local Anesthetics (Parenteral)	Bupivacaine Hydrochloride/Epinephrine
402808	Loop Diuretics	Furosemide
81212	Macrolides	Azithromycin
81212	Macrolides	Clarithromycin
81212	Macrolides	Erythromycin/Sulfisoxazole
81212	Macrolides	Erythromycin Ethylsuccinate
81212	Macrolides	Erythromycin Stearate
280892	Miscellaneous Analgesics and Antipyretics	Acetaminophen
280892	Miscellaneous Analgesics and Antipyretics	Acetaminophen / Aspirin/ Caffeine
280892	Miscellaneous Analgesics and Antipyretics	Acetaminophen/Codeine
280892	Miscellaneous Analgesics and Antipyretics	Acetaminophen/Hydrocodone
280892	Miscellaneous Analgesics and Antipyretics	Acetaminophen/Oxycodone

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Class No.	Therapeutic Class	Generic
81228	Miscellaneous Antibiotics	Clindamycin
81228	Miscellaneous Antibiotics	Vancomycin
81692	Miscellaneous Antimycobacterials	Dapsone
282492	Miscellaneous Anxiolytics, Sedatives and Hypnotics	Buspirone
282492	Miscellaneous Anxiolytics, Sedatives, and Hypnotics	Hydroxyzine
282492	Miscellaneous Anxiolytics, Sedatives, and Hypnotics	Promethazine
840492	Miscellaneous Local Anti-Infectives	Selenium Sulfide
840492	Miscellaneous Local Anti-Infectives	Silver Sulfadiazine
840892	Miscellaneous Local Anti-Infectives	Alcohol, Isopropyl
849200	Miscellaneous Skin and Mucous Membrane Agents	Adapalene
849200	Miscellaneous Skin and Mucous Membrane Agents	Aluminum Acetate Topical
849200	Miscellaneous Skin and Mucous Membrane Agents	Calcipotriene
849200	Miscellaneous Skin and Mucous Membrane Agents	Collagenase
849200	Miscellaneous Skin and Mucous Membrane Agents	Phenylephrine
849200	Miscellaneous Skin and Mucous Membrane Agents	Phenylephrine/ Mineral Oil/ Petrolatum
849200	Miscellaneous Skin and Mucous Membrane Agents	Podofilox
849200	Miscellaneous Skin and Mucous Membrane Agents	Podophyllin
929200	Miscellaneous Therapeutic Agents	Sodium Chloride
522800	Mouthwashes and Gargles	Hydrogen Peroxide
882800	Multivitamin Preparation	Multivitamin
882800	Multivitamin Preparation	Multivitamin, Children's
882800	Multivitamin Preparation	Multivitamin/ Mineral/Folic Acid
522400	Mydriatics	Atropine Ophthalmic
522400	Mydriatics	Cyclopentolate
522400	Mydriatics	Tropicamide
81828	Neuraminidase Inhibitor	Oseltamivir
241208	Nitrates and Nitrites	Isosorbide Dinitrate
241208	Nitrates and Nitrites	Isosorbide Mononitrate
241208	Nitrates and Nitrites	Nitroglycerin
280804	Nonsteroidal Anti-Inflammatory Agents	Acetaminophen / Aspirin/ Caffeine
280804	Nonsteroidal Anti-Inflammatory Agents	Aspirin
280804	Nonsteroidal Anti-Inflammatory Agents	Diclofenac (topical)
280804	Nonsteroidal Anti-Inflammatory Agents	Diclofenac ER
280804	Nonsteroidal Anti-Inflammatory Agents	Ibuprofen
280804	Nonsteroidal Anti-Inflammatory Agents	Indomethacin
280804	Nonsteroidal Anti-Inflammatory Agents	Ketorolac injection
280804	Nonsteroidal Anti-Inflammatory Agents	Meloxicam
280804	Nonsteroidal Anti-Inflammatory Agents	Methyl Salicylate/ Menthol
280804	Nonsteroidal Anti-Inflammatory Agents	Naproxen
81832	Nucleosides and Nucleotides	Acyclovir
81832	Nucleosides and Nucleotides	Entecavir
81832	Nucleosides and Nucleotides	Famciclovir
280808	Opiate Agonist	Acetaminophen/Codeine
280808	Opiate Agonist	Acetaminophen/Hydrocodone
280808	Opiate Agonist	Acetaminophen/Oxycodone
280808	Opiate Agonists	Morphine Sulfate
280808	Opiate Agonists	Tramadol
281000	Opiate Antagonists	Naloxone
280812	Opiate Partial Agonists	Butorphanol
120400	Parasympathomimetic (Cholinergic) Agent	Bethanechol
120400	Parasympathomimetic (Cholinergic) Agent	Pyridostigmine
81216	Penicillins	Amoxicillin
81216	Penicillins	Amoxicillin/Potassium Clavulanate

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Class No.	Therapeutic Class	Generic
81216	Penicillins	Ampicillin, Injectable
81216	Penicillins	Dicloxacillin
81216	Penicillins	Oxacillin
81216	Penicillins	Penicillin G Benzathine
81216	Penicillins	Penicillin G Procaine
81216	Penicillins	Penicillin V Potassium
401819	Phosphate Removing Agents	Calcium Acetate
401819	Phosphate Removing Agents	Lanthanum Carbonate
201218	Platelet-Aggregation Inhibitors	Clopidogrel Bisulfate
81428	Polyenes	Nystatin
683200	Progestins	Medroxy-progesterone
683200	Progestins	Megestrol Acetate
563200	Prokinetic Agents	Metoclopramide Hydrochloride
524028	Prostaglandin Analogs	Latanoprost
562836	Proton Pump Inhibitors	Omeprazole
562836	Proton Pump Inhibitors	Pantoprazole
81218	Quinolones	Ciprofloxacin Hydrochloride
81218	Quinolones	Levofloxacin Oral Solution
81218	Quinolones	Moxifloxacin HCl
401200	Replacement Preparations	Calcium Carbonate
401200	Replacement Preparations	Calcium Carbonate/Vitamin D
401200	Replacement Preparations	Electrolyte Solution
401200	Replacement Preparations	Lactated Ringers
401200	Replacement Preparations	Potassium Chloride
401200	Replacement Preparations	Sodium Chloride
282032	Respiratory and CNS Stimulants	Acetaminophen / Aspirin/ Caffeine
861600	Respiratory Smooth Muscle Relaxants	Theophylline
366800	Roentgenography	Barium Sulfate
840412	Scabicides and Pediculicides	Crotamiton
840412	Scabicides and Pediculicides	Permethrin
840412	Scabicides and Pediculicides	Piperonyl Butoxide/Pyrethrins
40800	Second Generation Antihistamines	Cetirizine
40800	Second Generation Antihistamines	Loratadine
800400	Serums	Immune Globulin
122012	Skeletal Muscle Relaxant	Baclofen
122004	Skeletal Muscle Relaxants	Cyclobenzaprine
122004	Skeletal Muscle Relaxants	Methocarbamol
122004	Skeletal Muscle Relaxants	Tizanidine
81220	Sulfonamides	Erythromycin/Sulfisoxazole
81220	Sulfonamides	Sulfamethoxazole/ Trimethoprim
81220	Sulfonamides	Sulfasalazine
682020	Sulfonylureas	Glipizide
848000	Sunscreen Agents	Titanium Dioxide
121200	Sympathomimetic (Adrenergic) Agents	Salmeterol
81224	Tetracyclines	Doxycycline
81224	Tetracyclines	Tetracycline
402820	Thiazide Diuretics	Hydrochlorothiazide
402820	Thiazide Diuretics	Lisinopril/ Hydrochlorothiazide
402820	Thiazide Diuretics	Losartan/ Hydrochlorothiazide
402820	Thiazide Diuretics	Triamterene/Hydrochlorothiazide
402824	Thiazide-like Diuretics	Chlorthalidone
682028	Thiazolidinediones	Pioglitazone
683604	Thyroid Agents	Levothyroxine
800800	Toxoids	Diphtheria/Tetanus Toxoid (DT)
800800	Toxoids	Diphtheria/ Tetanus Toxoid/ Acellular Pertussis Vaccine (TDap, DPT)

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Class No.	Therapeutic Class	Generic
800800	Toxoids	Tetanus/Diphtheria
800800	Toxoids	Tetanus Toxoid
368400	Tuberculosis (Diagnostic)	Tuberculin Purified Protein Derivative
404000	Uricosuric Agents	Probenecid
83600	Urinary Anti-Infectives	Nitrofurantoin
801200	Vaccines	Hepatitis A Vaccine
801200	Vaccines	Hepatitis B Vaccine
801200	Vaccines	Influenza Virus Vaccine
801200	Vaccines	Measles/ Mumps/ Rubella Vaccine
801200	Vaccines	Measles/ Mumps/ Rubella/ Varicella Vaccine
801200	Vaccines	Meningococcal Conjugate Vaccine
801200	Vaccines	Papillomavirus (HPV Vaccines)
801200	Vaccines	Pneumococcal Vaccine
801200	Vaccines	Poliovirus Vaccine
801200	Vaccines	Rotavirus
801200	Vaccines	Varicella Vaccine
523200	Vasoconstrictors (EENT)	Oxymetazoline
523200	Vasoconstrictors (EENT)	Tetrahydrozoline Ophthalmic
880400	Vitamin A	Vitamin A
880800	Vitamin B Complex	B vitamins/ Vitamin C/Folic Acid
880800	Vitamin B Complex	Cyanocobalamin
880800	Vitamin B Complex	Folic Acid
880800	Vitamin B Complex	Pyridoxine
880800	Vitamin B Complex	Thiamine
881200	Vitamin C	Ascorbic Acid
881600	Vitamin D	Calcitriol
881600	Vitamin D	Vitamin D2 & D3
882400	Vitamin K	Phytonadione
121212	α & β Adrenergic Agonists	Epinephrine
121204	α-Adrenergic Agonists	Phenylephrine
121604	α-Adrenergic Blocking Agent (Sympath)	Ergotamine/Caffeine
121604	α-Adrenergic Blocking Agent (Sympath)	Tamsulosin
242000	α-Adrenergic Blocking Agents	Doxazosin
242000	α-Adrenergic Blocking Agents	Prazosin
242000	α-Adrenergic Blocking Agents	Terazosin
121208	β-Adrenergic Agonist	Albuterol
121208	β-Adrenergic Agonist	Ipratropium/ Albuterol oral inhaler
481204	β-Adrenergic Agonist	Budesonide/ Formoterol
242400	β-Adrenergic Blocking Agents	Atenolol
242400	β-Adrenergic Blocking Agents	Carvedilol
242400	β-Adrenergic Blocking Agents	Labetalol
242400	β-Adrenergic Blocking Agents	Metoprolol
242400	β-Adrenergic Blocking Agents	Propranolol Hydrochloride
242400	β-Adrenergic Blocking Agents	Sotalol

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IHSC National Formulary – Pregnancy Information

This table includes pregnancy implications and pregnancy categories, if available, for each medication on the IHSC national formulary.

Generic Name	Category	Pregnancy Implications
Abacavir		* Abacavir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry.
Abacavir/ Dolutegravir/ Lamivudine		* Abacavir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. * Dolutegravir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to preliminary data collected by the antiretroviral pregnancy registry. However, information from an unscheduled analysis of an ongoing study signaled an increased risk of neural tube defects in women who became pregnant during dolutegravir treatment; this risk was not observed in women who started treatment during pregnancy. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. * Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Abacavir/ Lamivudine		* Abacavir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. * Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without

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Generic Name	Category	Pregnancy Implications
		lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Abacavir/ Lamivudine/ Zidovudine		* Abacavir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. * Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk. * Zidovudine has a high level of transfer across the human placenta; the placenta also metabolizes zidovudine to the active metabolite. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Acetaminophen		* Acetaminophen crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. An increased risk of teratogenic effects has not been observed following maternal use of acetaminophen during pregnancy. Prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester. The use of acetaminophen in normal doses during pregnancy is not associated with an increased risk of miscarriage or still birth; however, an increase in fetal death or spontaneous abortion may be seen following maternal overdose if treatment is delayed. Frequent maternal use of acetaminophen during pregnancy may be associated with wheezing and asthma in early childhood.

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Generic Name	Category	Pregnancy Implications
Acetaminophen / Aspirin/ Caffeine		* Acetaminophen crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. An increased risk of teratogenic effects has not been observed following maternal use of acetaminophen during pregnancy. Prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester. The use of acetaminophen in normal doses during pregnancy is not associated with an increased risk of miscarriage or still birth; however, an increase in fetal death or spontaneous abortion may be seen following maternal overdose if treatment is delayed. Frequent maternal use of acetaminophen during pregnancy may be associated with wheezing and asthma in early childhood. * Aspirin has been noted to cross the placenta and enter fetal circulation. Adverse effects reported in the fetus include mortality, intrauterine growth retardation, salicylate intoxication, bleeding abnormalities, and neonatal acidosis. Use of aspirin close to delivery may cause premature closure of the ductus arteriosus. Adverse effects reported in the mother include anemia, hemorrhage, prolonged gestation, and prolonged labor (Østensen 1998). Low-dose aspirin may be used to prevent preeclampsia in women with a history of early-onset preeclampsia and preterm delivery (<34 0/7 weeks), or preeclampsia in ≥1 prior to pregnancy (ACOG 2013). Treatment is started after 12 weeks' gestation in women at risk for preeclampsia (ACCP [Bates 2012]; LeFevre 2014). Low-dose aspirin is used to treat complications resulting from antiphospholipid syndrome in pregnancy (either primary or secondary to SLE) (ACCP [Bates 2012]; Carp 2004; Tincani 2003). Low-dose aspirin to prevent thrombosis may also be used during the second and third trimesters in women with prosthetic valves (mechanical or bioprosthetic). The use of warfarin is recommended, along with low-dose aspirin, in those with mechanical prosthetic valves (AHA/ACC [Nishimura 2014]). Low-dose aspirin may also be used after the first trimester in women with low-risk conditions requiring antiplatelet therapy (AHA/ASA [Kernan 2014]). When needed in doses required for the management of pain, agents other than aspirin are preferred in pregnant women and use in the third trimester is not recommended (Källén 2016; Shah 2015). * Caffeine: Adverse events were observed in animal reproduction studies. Caffeine crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Grosso 2005). Based on current studies, usual dietary exposure to caffeine is unlikely to cause congenital malformations (Brent 2011). However, available data shows conflicting results related to maternal caffeine use and the risk of other adverse events, such as spontaneous abortion or growth retardation (Brent 2011; Jahanfar 2013). The half-life of caffeine is prolonged during the second and third trimesters of pregnancy and maternal and fetal exposure is also influenced by maternal smoking or drinking (Brent 2011; Koren 2000). Current guidelines recommend limiting caffeine intake from all sources to ≤200 mg/day (ACOG 2010).
Acetaminophen/Codeine		* Acetaminophen crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. An increased risk of teratogenic effects has not been observed following maternal use of acetaminophen during pregnancy. Prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester. The use of acetaminophen in normal doses during pregnancy is not associated with an increased risk of miscarriage or still birth; however, an increase in fetal death or spontaneous abortion may be seen following maternal overdose if treatment is delayed. Frequent maternal use of acetaminophen during pregnancy may be associated with wheezing and asthma in early childhood. * Codeine: [US Boxed Warning]: Prolonged maternal use can cause neonatal opioid withdrawal syndrome in the newborn which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Adverse events were observed in some animal reproduction studies. Opioids cross the placenta. Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal

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		abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to Infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored. Agents other than codeine are commonly used to treat maternal pain during labor and immediately postpartum (ACOG 177 2017) as well as chronic noncancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Acetaminophen/ Hydrocodone		* Acetaminophen crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. An increased risk of teratogenic effects has not been observed following maternal use of acetaminophen during pregnancy. Prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester. The use of acetaminophen in normal doses during pregnancy is not associated with an increased risk of miscarriage or still birth; however, an increase in fetal death or spontaneous abortion may be seen following maternal overdose if treatment is delayed. Frequent maternal use of acetaminophen during pregnancy may be associated with wheezing and asthma in early childhood. *Hydrocodone: [U.S. Boxed Warning]: Prolonged maternal use of opioids during pregnancy can cause neonatal withdrawal syndrome in the newborn which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Opioids cross the placenta. Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored. Agents other than hydrocodone are recommended to treat maternal pain during labor and immediately postpartum (ACOG 177 2017) as well as chronic noncancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Acetaminophen/ Oxycodone		* Acetaminophen crosses the placenta and can be detected in cord blood, newborn serum, and urine immediately after delivery. An increased risk of teratogenic effects has not been observed following maternal use of acetaminophen during pregnancy. Prenatal constriction of the ductus arteriosus has been noted in case reports following maternal use during the third trimester. The use of acetaminophen in normal doses during pregnancy is not associated with an increased risk of miscarriage or still birth; however, an increase in fetal death or spontaneous abortion may be seen following maternal overdose if treatment is delayed. Frequent maternal use of acetaminophen during pregnancy may be associated with wheezing and asthma in early childhood. *Oxycodone: [US Boxed Warning]: Prolonged maternal use of opioids during pregnancy can cause neonatal withdrawal syndrome in the newborn which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Oxycodone crosses

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		the placenta (Kokki 2012). Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored. Agents other than oxycodone are commonly used to treat maternal pain during labor and immediately postpartum (ACOG 177 2017) as well as chronic noncancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Acetazolamide	C	Adverse events have been observed in animal reproduction studies. Limited data is available following the use of acetazolamide in pregnant women for the treatment of idiopathic intracranial hypertension. Pregnant women exposed to acetazolamide during pregnancy for the treatment of seizure disorders are encouraged to enroll themselves into the AED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at aedpregnancyregistry.org
Acetic Acid Otic	C	Animal reproduction studies have not been conducted.
Aclidinium	C	Adverse events have been observed in animal reproduction studies.
Acyclovir	B	Teratogenic effects were not observed in animal reproduction studies. Acyclovir has been shown to cross the human placenta (Henderson 1992). Results from a pregnancy registry, established in 1984 and closed in 1999, did not find an increase in the number of birth defects with exposure to acyclovir when compared to those expected in the general population. However, due to the small size of the registry and lack of long-term data, the manufacturer recommends using during pregnancy with caution and only when clearly needed. Acyclovir is recommended for the treatment of genital herpes in pregnant women (CDC [Workowski 2015]).
Adapalene	C	Adverse effects were observed in animal reproduction studies. Retinoids may cause harm when administered during pregnancy. A case report described maternal use of adapalene 1 month prior to pregnancy and through 13 weeks' gestation; cerebral and ocular malformations were reported in the exposed fetus which resulted in termination of pregnancy (Autret 1997). In clinical trials, women of childbearing potential were required to have a negative pregnancy test prior to therapy.
Adefovir	C	Adverse events have been observed in animal reproduction studies. Health care providers are encouraged to enroll women exposed to adefovir during pregnancy in the Hepsera pregnancy registry (800-258-4263).
Albendazole	C	Adverse events were observed in animal reproduction studies. Albendazole should not be used during pregnancy, if at all possible. The manufacturer recommends a pregnancy test prior to therapy in women of reproductive potential. Women should be advised to avoid pregnancy during and for at least 1 month following therapy. Discontinue if pregnancy occurs during treatment.
Albuterol	C	Adverse events have been observed in some animal reproduction studies. Albuterol crosses the placenta (Boulton 1997). Congenital anomalies (cleft palate, limb defects) have rarely been reported following maternal use during pregnancy. Multiple medications were used in most cases, no specific pattern of defects has been reported, and no relationship to albuterol has been established. The amount of albuterol available systemically following inhalation is significantly less in comparison to oral doses. Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, preeclampsia, preterm birth, low birth weight infants). Poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used asthma medications. Albuterol is the preferred short acting beta-agonist when treatment for asthma is needed during

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		pregnancy (ACOG 2008; GINA 2016; NAEPP 2007). If high doses are required during labor and delivery, monitoring of glucose concentrations in the newborn for 24 hours is recommended, especially in preterm infants (GINA 2016). Albuterol may affect uterine contractility. Maternal pulmonary edema and other adverse events have been reported when albuterol was used for tocolysis. Albuterol is not approved for use as a tocolytic; use caution when needed to treat bronchospasm in pregnant women. Use of the injection (Canadian product; not available in the US.) is specifically contraindicated in women during the first or second trimester who may be at risk of threatened abortion.
Alcohol, Isopropyl		
Alendronate	C	Adverse events were observed in animal reproduction studies. It is not known if bisphosphonates cross the placenta, but fetal exposure is expected (Djokanovic 2008; Stathopoulos 2011). Bisphosphonates are incorporated into the bone matrix and gradually released over time. The amount available in the systemic circulation varies by dose and duration of therapy. Theoretically, there may be a risk of fetal harm when pregnancy follows the completion of therapy; however, available data have not shown that exposure to bisphosphonates during pregnancy significantly increases the risk of adverse fetal events (Djokanovic 2008; Levy 2009; Stathopoulos 2011). Until additional data is available, most sources recommend discontinuing bisphosphonate therapy in women of reproductive potential as early as possible prior to a planned pregnancy; use in premenopausal women should be reserved for special circumstances when rapid bone loss is occurring (Bhalla 2010; Pereira 2012; Stathopoulos 2011). Because hypocalcemia has been described following in utero bisphosphonate exposure, exposed infants should be monitored for hypocalcemia after birth (Djokanovic 2008; Stathopoulos 2011).
Allopurinol	C	Adverse events were observed in some animal reproduction studies. Allopurinol crosses the placenta (Torrance 2009). An increased risk of adverse fetal events has not been observed (limited data) (Hoeltzenbein 2013).
Aluminum Acetate/ Acetic Acid Otic		* Aluminum Acetate: Animal reproduction studies have not been conducted. The amount of aluminum acetate available systemically following topical application is unknown. * Acetic Acid: Animal reproduction studies have not been conducted.
Aluminum Acetate Topical		Animal reproduction studies have not been conducted. The amount of aluminum acetate available systemically following topical application is unknown.
Aluminum Hydroxide/ Magnesium Trisilicate		Most aluminum- and magnesium-containing antacids are considered low risk during pregnancy
Aluminum Hydroxide/ Magnesium Hydroxide/ Simethicone		Most aluminum- and magnesium-containing antacids are considered low risk during pregnancy
Amantadine	C	Adverse events have been observed in animal reproduction studies and teratogenic events have been observed in humans (case reports) (Seier 2017). When treatment for Parkinson disease is needed, agents other than amantadine are recommended in pregnant women (Seier 2017). Untreated influenza infection is associated with an increased risk of adverse events to the fetus and an increased risk of complications or death to the mother. Other agents are currently recommended for the treatment or prophylaxis influenza in pregnant women and women up to 2 weeks postpartum. Appropriate antiviral agents are currently recommended as an adjunct to vaccination and should not be used as a substitute for vaccination in pregnant women (CDC 2011; CDC 2014).
Aminosalicylic Acid	C	Teratogenic effects have been reported in animal reproduction studies. Salicylates have been noted to cross the placenta and enter fetal circulation. Aminosalicylic acid has been used safely during pregnancy; however, it should only be used if there are no alternatives for the treatment of multidrug-resistant tuberculosis (MMWR, 2003).

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Amiodarone		Adverse events have been observed in some animal reproduction studies. Amiodarone crosses the placenta (~10% to 50%) and may cause fetal harm when administered to a pregnant woman. Reported risks include neonatal bradycardia, QT prolongation, and periodic ventricular extrasystoles; neonatal hypothyroidism (with or without goiter); neonatal hyperthyroxinemia; neurodevelopmental abnormalities independent of thyroid function; jerk nystagmus with synchronous head titubation; fetal growth retardation; and/or premature birth. Oral or IV amiodarone should be used in pregnant women only to treat arrhythmias refractory to other treatments or when other treatments are contraindicated (Page [ACC/AHA/HRS 2015]; ESG/AEPC/DGesGM/ESC 2011).
Amitriptyline	C	Adverse events have been observed in some animal reproduction studies. Amitriptyline crosses the human placenta; CNS effects, limb deformities, and developmental delay have been noted in case reports (causal relationship not established). Tricyclic antidepressants may be associated with irritability, jitteriness, and convulsions (rare) in the neonate (Yonkers 2009). Crying, constipation, problems with urinating, and nausea may also occur in neonates exposed during pregnancy (Larsen 2015) The ACOG recommends that therapy for depression during pregnancy be individualized; treatment should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician (ACOG 2008). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Tricyclic antidepressants are not the preferred therapy for depression in pregnant women but may be helpful when agitation is also present. If a TCA is needed, amitriptyline one of the preferred agents. Maternal serum concentrations should be monitored during pregnancy (Larsen 2015; Yonkers 2009). Although not a first-line agent, amitriptyline may be used for the treatment of post-traumatic stress disorder in pregnant women (Bandelow 2008). Migraine prophylaxis should be avoided during pregnancy; if needed, amitriptyline may be used if other agents are ineffective or contraindicated (Pringsheim 2012). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Amlodipine		Amlodipine crosses the placenta. Cord blood concentrations were approximately one-third of maternal serum at delivery, and concentrations in the newborn were below the limit of quantification (<0.1 ng/mL) when measured in eight infants within 48 hours of delivery (Morgan 2017). Information related to the use of amlodipine in pregnancy is limited (Ahn 2007; Nahapetian 2008; Vigil-De Gracia 2014; Yu 2015). Due to pregnancy induced pharmacologic changes, amlodipine pharmacokinetics may be altered immediately postpartum; large individual patient variability was observed (Naito 2015b). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, agents other than amlodipine are preferred (ACOG 2013).
Ammonium Lactate	B	Lactic acid is a normal component in blood and tissues. Topical application in animals has not shown fetal harm.
Amoxicillin	B	Adverse events have not been observed in animal reproduction studies. Amoxicillin crosses the placenta (Muller 2009). Maternal use of amoxicillin has generally not resulted in an increased risk of adverse fetal effects; however, a possible association with cleft lip with cleft palate has been observed in some studies (more data is needed) (Lin 2012; Puhó 2007). Amoxicillin may be used for the management of Bacillus anthracis in pregnant women when penicillin susceptibility is documented (Meaney-Delman 2014). Amoxicillin is an alternative antibiotic for the treatment of chlamydial infections in pregnancy (CDC [Workowski 2015]). Amoxicillin can also be used in the

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		management of preterm premature rupture of membranes and in certain situations prior to vaginal delivery in women at high risk for endocarditis (ACOG 120 2011; ACOG 139 2013). Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of amoxicillin may be altered (Andrew 2007). Oral ampicillin-class antibiotics are poorly absorbed during labor.
Amoxicillin/Potassium Clavulanate	B	Adverse events have not been observed in animal reproduction studies. Both amoxicillin and clavulanic acid cross the placenta. Maternal use of amoxicillin/clavulanate has generally not resulted in an increased risk of birth defects. A possible increased risk of necrotizing enterocolitis in neonates or bowel disorders in children exposed to amoxicillin/clavulanate in utero has been observed. In women with acute infections during pregnancy, amoxicillin/clavulanate may be given if an antibiotic is required and appropriate based on bacterial sensitivity; however, use is not recommended in the management of preterm premature rupture of membranes. Oral ampicillin-class antibiotics are poorly absorbed during labor.
Amprenavir		Fosamprenavir has a low level of transfer across the human placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines note there are insufficient data to recommend use as initial therapy in antiretroviral-naive pregnant females. However, if used in pregnant females, fosamprenavir may be given with standard ritonavir-boosted twice-daily dosing. Unboosted fosamprenavir and once-daily dosing with ritonavir are not recommended. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Antipyrine/Benzocaine		
Apixaban	B	Adverse events were not observed in animal reproduction studies. Based on placenta perfusion studies, apixaban is expected to cross the placenta (Bapat 2016). Information specific to the use of apixaban in pregnancy is limited (Königsbrügge 2014). Because data are insufficient to evaluate the safety of oral factor Xa inhibitors in pregnant females, use during pregnancy should be avoided (Bates 2012).
Aripiprazole	C	Adverse events have been observed in animal reproduction studies. Aripiprazole crosses the placenta; aripiprazole and dehydro-aripiprazole can be detected in the cord blood at delivery (Nguyen 2011; Watanabe 2011). Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the

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		newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited, as such, routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to an agent that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). If treatment is needed in a woman planning a pregnancy or if treatment is initiated during pregnancy, use of an agent other than aripiprazole is preferred (Larsen 2015). Health care providers are encouraged to enroll women exposed to aripiprazole during pregnancy in the National Pregnancy Registry for Atypical Antipsychotics (866-961-2388 or http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/).
Ascorbic Acid	C	Animal reproduction studies have not been conducted. Maternal plasma concentrations of ascorbic acid decrease as pregnancy progresses due to hemodilution and increased transfer to the fetus. Some pregnant women (eg, smokers) may require supplementation greater than the RDA (IOM 2000).
Aspirin		Aspirin has been noted to cross the placenta and enter fetal circulation. Adverse effects reported in the fetus include mortality, intrauterine growth retardation, salicylate intoxication, bleeding abnormalities, and neonatal acidosis. Use of aspirin close to delivery may cause premature closure of the ductus arteriosus. Adverse effects reported in the mother include anemia, hemorrhage, prolonged gestation, and prolonged labor (Østensen 1998). Low-dose aspirin may be used to prevent preeclampsia in women with a history of early-onset preeclampsia and preterm delivery (<34 0/7 weeks), or preeclampsia in ≥1 prior to pregnancy (ACOG 2013). Treatment is started after 12 weeks' gestation in women at risk for preeclampsia (ACCP [Bates 2012]; LeFevre 2014). Low-dose aspirin is used to treat complications resulting from antiphospholipid syndrome in pregnancy (either primary or secondary to SLE) (ACCP [Bates 2012]; Carp 2004; Tincani 2003). Low-dose aspirin to prevent thrombosis may also be used during the second and third trimesters in women with prosthetic valves (mechanical or bioprosthetic). The use of warfarin is recommended, along with low-dose aspirin, in those with mechanical prosthetic valves (AHA/ACC [Nishimura 2014]). Low-dose aspirin may also be used after the first trimester in women with low-risk conditions requiring antiplatelet therapy (AHA/ASA [Kernan 2014]). When needed in doses required for the management of pain, agents other than aspirin are preferred in pregnant women and use in the third trimester is not recommended (Källén 2016; Shah 2015).
Atazanavir		Atazanavir has a low level of transfer across the human placenta with cord blood concentrations reported as 13% to 21% of maternal serum concentrations at delivery. An increased risk of teratogenic effects has not been observed based on information collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. Hyperbilirubinemia or hypoglycemia may occur in neonates following in utero exposure to atazanavir,

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Generic Name	Category	Pregnancy Implications
		although data are conflicting (monitor). The Health and Human Services (HHS) Perinatal HIV Guidelines recommend atazanavir as a preferred PI as initial therapy in antiretroviral-naive pregnant females when combined with low-dose ritonavir boosting. Atazanavir is not recommended in treatment-experienced pregnant females taking both H2-receptor blockers and tenofovir disoproxil fumarate. Pharmacokinetic studies suggest that standard dosing during pregnancy may provide decreased plasma concentrations and some experts recommend increased doses during the second and third trimesters. However, the manufacturer notes that dose adjustment is not required unless using concomitant H2-receptor blockers or tenofovir disoproxil fumarate in antiretroviral-experienced pregnant females. Therapeutic drug monitoring may be useful. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Atazanavir/ Cobicistat		*Atazanavir has a low level of transfer across the human placenta with cord blood concentrations reported as 13% to 21% of maternal serum concentrations at delivery. An increased risk of teratogenic effects has not been observed based on information collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. Hyperbilirubinemia or hypoglycemia may occur in neonates following in utero exposure to atazanavir, although data are conflicting (monitor). The Health and Human Services (HHS) Perinatal HIV Guidelines recommend atazanavir as a preferred PI as initial therapy in antiretroviral-naive pregnant females when combined with low-dose ritonavir boosting. Atazanavir is not recommended in treatment-experienced pregnant females taking both H2-receptor blockers and tenofovir disoproxil fumarate. Pharmacokinetic studies suggest that standard dosing during pregnancy may provide decreased plasma concentrations and some experts recommend increased doses during the second and third trimesters. However, the manufacturer notes that dose adjustment is not required unless using concomitant H2-receptor blockers or tenofovir disoproxil fumarate in antiretroviral-experienced pregnant females. Therapeutic drug monitoring may be useful. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring

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Generic Name	Category	Pregnancy Implications
		during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Cobicistat has low placental transfer. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should
Atenolol	D	Atenolol crosses the placenta and is found in cord blood. Maternal use of atenolol may cause harm to the fetus. Adverse events, such as bradycardia, hypoglycemia and reduced birth weight, have been observed following in utero exposure to atenolol. Adequate facilities for monitoring infants at birth is generally recommended. The maternal pharmacokinetic parameters of atenolol during the second and third trimesters are within the ranges reported in nonpregnant patients (Hebert 2005). Untreated chronic maternal hypertension and preeclampsia are associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). Although beta-blockers may be used when treatment of hypertension in pregnancy is indicated, agents other than atenolol are preferred (ACOG 2013; Magee 2014; Regitz-Zagrosek 2011).
Atorvastatin	X	Studies in animals and pregnant women have shown evidence of fetal abnormalities and use is contraindicated in women who are or may become pregnant. There are reports of congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long term outcomes of primary hypercholesterolemia treatment. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Atovaquone	C	Adverse events were observed in animal reproduction studies. Diagnosis and treatment of Pneumocystis jirovecii pneumonia (PCP) in pregnant women is the same as in nonpregnant women; however, information specific to the use of atovaquone in pregnancy is limited (HHS [OI adult 2015]).
Atropine Ophthalmic		Atropine crosses the placenta following systemic maternal use (Shutt 1979). Atropine is systemically available following ophthalmic administration. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples 1988).
Azathioprine	D	Azathioprine crosses the placenta. Product labeling notes congenital anomalies, immunosuppression, hematologic toxicities (lymphopenia, pancytopenia), and intrauterine growth retardation from case reports following use in maternal renal allograft recipients. However, intrauterine growth retardation and preterm delivery are

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		also reported in pregnancies following a kidney transplant. Stable immunosuppression is required in pregnant women who have had a kidney transplant and an increased risk of fetal malformations has not been observed with azathioprine; lower doses are recommended (Durst 2015; Hou 2013). Available guidelines suggest that use of azathioprine is acceptable for the treatment of rheumatoid arthritis in pregnant women (Flint 2016), although use for this indication is contraindicated by the manufacturer. Azathioprine may also be used for the adjunctive treatment of lupus nephritis in pregnant women (Hahn 2012). Women with Crohn disease or ulcerative colitis who are on maintenance therapy with azathioprine may continue treatment during pregnancy (Nguyen 2016). Agents other than azathioprine are recommended for the treatment of immune thrombocytopenia in pregnant women (Neunert 2011). The manufacturer recommends that women of childbearing potential should avoid becoming pregnant during treatment. Azathioprine is compatible for use in males with female partners of reproductive potential (Flint 2016). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Azithromycin	B	Adverse events were not observed in animal reproduction studies. Azithromycin crosses the placenta (Ramsey 2003). The maternal serum half-life of azithromycin is unchanged in early pregnancy and decreased at term; however, high concentrations of azithromycin are sustained in the myometrium and adipose tissue (Fischer 2012; Ramsey 2003). Azithromycin is recommended for the treatment of several infections, including chlamydia, gonococcal infections, and Mycobacterium avium complex (MAC) in pregnant patients (consult current guidelines) (CDC [Workowski 2015]; HHS [opportunistic; adult] 2015).
B Vitamins/ Vitamin C/Folic Acid		Water soluble vitamins cross the placenta (IOM, 1998). Refer to individual vitamins for additional information and specific requirements during pregnancy.
Bacitracin		Although large studies have not been conducted, absorption is limited following topical application; use during pregnancy has not been associated with an increased risk of adverse fetal events (Leachman, 2006; Murase, 2014).
Baclofen	C	Adverse events have been observed in animal reproduction studies. Withdrawal symptoms in the neonate were noted in a case report following the maternal use of oral baclofen 20 mg 4 times/day throughout pregnancy (Ratnayaka 2001). Plasma concentrations following administration of intrathecal baclofen are significantly less than those with oral doses; exposure to the fetus is expected to be limited (Morton 2009).
Barium Sulfate		Barium is not systemically absorbed; use is not expected to result in exposure to the fetus. In general, elective radiography of the abdomen is avoided during pregnancy but should not be withheld when essential for diagnosis (ACOG 2016).
Benzocaine		
Benzonatate	C	Animal reproduction studies have not been conducted. Information related to use in pregnancy is limited (Heinonen 1977).
Benzoyl Peroxide	C	Animal reproduction studies have not been conducted. Topical products are recommended as initial therapy for the treatment of acne in pregnant females; benzoyl peroxide is one of the preferred agents (Chien 2016; Kong 2013; Leechman 2006).
Benztropine Mesylate		Animal reproduction studies have not been conducted. Paralytic ileus (which resolved rapidly) was reported in two newborns exposed to a combination of benztropine and chlorpromazine during the second and third trimesters and the last 6 weeks of pregnancy, respectively (Falterman 1980).
Bethanechol	C	Animal reproduction studies have not been conducted.
Bisacodyl		Systemic exposure following maternal use of bisacodyl is limited. Plasma concentrations of BHPM (the active metabolite of bisacodyl) are low (median: 61 ng/mL; range: 20 to 118 ng/mL) and the pharmacokinetics are highly variable following oral doses of 10 mg/day for 7 days to women immediately postpartum (Friedrich 2011). Treatment of constipation in pregnant women is similar to that of nonpregnant patients

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		and medications may be used when diet and lifestyle modifications are not effective. Agents other than bisacodyl are preferred as initial treatment. Stimulant laxatives, including bisacodyl, are not recommended for chronic use, but may be used intermittently when needed (ACG [Christie 2007]).
Bismuth Subsalicylate		Following oral administration, bismuth and salicylates cross the placenta. The use of salicylates in pregnancy may adversely affect the newborn (Lione, 1988). Use during pregnancy is not recommended (Mahadevan 2007).
Borate/Boric Acid/H2O/NaCl		
Brimonidine Tartrate	B	Teratogenic effects were not observed in animal reproduction studies.
Bromocriptine	B	Bromocriptine crosses the placenta (Molitch 2015). Data collected from women taking bromocriptine during pregnancy suggest the incidence of birth defects is not increased with use. However, the majority of women discontinued use within 8 weeks of pregnancy. Women with hyperprolactinemia may be infertile, have amenorrhea and galactorrhea. A mechanical contraceptive should be used during therapy until normal ovulatory menses is established. Contraception can then be discontinued if pregnancy is desired. Bromocriptine should be discontinued if pregnancy is confirmed unless needed for treatment of a rapidly expanding macroadenoma. When used for the treatment of acromegaly or Parkinson disease, consider discontinuing therapy during pregnancy. If treatment is withdrawn, monitor for signs and symptoms of an enlarging prolactin secreting tumor. Regardless of indication, if bromocriptine is needed in a pregnant woman, monitor closely for hypertensive disorders during pregnancy and immediately postpartum. During treatment with bromocriptine, fertility may occur prior to restoration of menses in infertile women, therefore a pregnancy test is recommended every 4 weeks during the amenorrheic period. Once menses resume, pregnancy tests should be done any time a menstrual period is missed. Women not seeking pregnancy should be advised to use appropriate contraception.
Budesonide/ Formoterol	B	* Budesonide: Studies of pregnant women using inhaled budesonide have not demonstrated an increased risk of congenital abnormalities. Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, pre-eclampsia, preterm birth, low birth weight infants). Poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used asthma medications. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; budesonide is preferred (ACOG 2008; GINA 2017; Namazy 2016). * Formoterol: Adverse events were observed in some animal reproduction studies. Beta-agonists may interfere with uterine contractility if administered during labor.
Bupivacaine Hydrochloride/Epinephrine	C	* Bupivicaine: Adverse events were observed in animal reproduction studies. Bupivacaine crosses the placenta. Bupivacaine is approved for use at term in obstetrical anesthesia or analgesia. [U.S. Boxed Warning]: The 0.75% is not recommended for obstetrical anesthesia. Bupivacaine 0.75% solutions have been associated with cardiac arrest following epidural anesthesia in obstetrical patients and use of this concentration is not recommended for this purpose. Use in obstetrical paracervical block anesthesia is contraindicated. * Epinephrine: Adverse events have been observed in animal reproduction studies. Epinephrine crosses the placenta (Sandler 1964). Uterine vasoconstriction, decreased uterine blood flow, and fetal anoxia may occur. Epinephrine is recommended for the treatment of anaphylaxis in pregnant women. Specific dosing is not available; use with caution and monitor hemodynamic response (Hepner 2013). Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015). Although epinephrine injection may be used for asthma exacerbations in pregnancy, systemic therapy has not been proven to be better than use of preferred inhaled agents (NAEPP 2005).

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Generic Name	Category	Pregnancy Implications
Buprenorphine/ Naloxone		Neonatal opioid withdrawal syndrome may occur after chronic maternal exposure to opioids. In the treatment of addiction involving opioid use in pregnant women, the buprenorphine/naloxone combination product is not recommended for use (insufficient evidence); however, the buprenorphine monoproduct is a reasonable and recommended option for use (Kampman [ASAM 2015]). Women who become pregnant while on this combination should generally be transitioned to the single agent (buprenorphine) product (ACOG 2012). See individual agents.
Bupropion	C	Adverse events have been observed in some animal reproduction studies. Bupropion and its metabolites were found to cross the placenta in in vitro studies (Earhart 2010). An increased risk of congenital malformations has not been observed following maternal use of bupropion during pregnancy; however, data specific to cardiovascular malformations is inconsistent. The long-term effects on development and behavior have not been studied. The ACOG recommends that antidepressant therapy during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). There is insufficient information related to the use of bupropion to recommend use in pregnancy (ACOG 2010). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Buspirone	B	Adverse events have not been observed in animal reproduction studies.
Cabergoline	B	Adverse events have not been observed in most animal reproduction studies. Treatment of hyperprolactinemia may restore fertility in previously infertile women. Although available evidence suggests cabergoline use early in pregnancy does not cause harm to the fetus, it is recommended that therapy be discontinued once pregnancy is discovered. If treatment during pregnancy is required, other agents are preferred. Monitoring of prolactin levels should be suspended during pregnancy (Melmed 2011). Not recommended for use in women with pregnancy-induced hypertension (eg, preeclampsia, eclampsia, postpartum hypertension) unless benefit outweighs potential risk.
Calamine		
Calcipotriene	C	Adverse events have been observed in some animal reproduction studies. If treatment during pregnancy is needed, other agents may be preferred (Hsu 2012; Zeichner 2010).
Calcitriol	C	Adverse effects have been observed in some animal reproduction studies. Maternal calcitriol may be detected in the fetal circulation. Mild hypercalcemia has been reported in a newborn following maternal use of calcitriol during pregnancy. Adverse effects on fetal development were not observed with use of calcitriol during pregnancy in women (N=9) with pseudovitamin D-dependent rickets. Doses were adjusted every 4 weeks to keep calcium concentrations within normal limits (Edouard 2011). If calcitriol is used for the management of hypoparathyroidism in pregnancy, dose adjustments may be needed as pregnancy progresses and again following delivery. Vitamin D and calcium levels should be monitored closely and kept in the lower normal range (Callies 1998).
Calcium Acetate	C	Animal reproduction studies have not been conducted. Calcium crosses the placenta. The amount of calcium reaching the fetus is determined by maternal physiological changes. Intestinal absorption of calcium increases during pregnancy. If use is required in pregnant patients with end stage renal disease, fetal harm is not expected if maternal calcium concentrations are monitored and maintained within normal limits as recommended (IOM, 2011).

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Calcium Carbonate		Calcium crosses the placenta. Intestinal absorption of calcium increases during pregnancy. The amount of calcium reaching the fetus is determined by maternal physiological changes. Calcium requirements are the same in pregnant and nonpregnant females (IOM, 2011). Calcium-based antacids are considered low risk during pregnancy; excessive use should be avoided (Mahadevan, 2006).
Calcium Carbonate/ Vitamin D		Available evidence suggests safe use during pregnancy.
Calcium Polycarbophil		When administered with adequate fluids, use is considered safe for the treatment of occasional constipation during pregnancy (Wald, 2003).
Camphor/menthol		
Capreomycin	C	Adverse events have been reported in animal reproduction studies. [US Boxed Warning]: Safety has not been established in pregnant women; avoid use during pregnancy because of the risk of fetal nephrotoxicity and congenital hearing loss (MMWR 2003).
Captopril	D	[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. Captopril crosses the placenta (Hurault de Ligny 1987). Drugs that act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. Their use in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. Teratogenic effects may occur following maternal use of an ACE inhibitor during the first trimester, although this finding may be confounded by maternal disease. Because adverse fetal events are well documented with exposure later in pregnancy, ACE inhibitor use in pregnant women is not recommended (Seely 2014; Weber 2014). Infants exposed to an ACE inhibitor in utero should be monitored for hyperkalemia, hypotension, and oliguria. Oligohydramnios may not appear until after irreversible fetal injury has occurred. Exchange transfusions or dialysis may be required to reverse hypotension or improve renal function, although data related to the effectiveness in neonates is limited. Chronic maternal hypertension itself is also associated with adverse events in the fetus/infant and mother. ACE inhibitors are not recommended for the treatment of uncomplicated hypertension in pregnancy (ACOG 2013) and they are specifically contraindicated for the treatment of hypertension and chronic heart failure during pregnancy by some guidelines (Regitz-Zagrosek 2011). In addition, ACE inhibitors should generally be avoided in women of reproductive age (ACOG 2013). If treatment for hypertension or chronic heart failure in pregnancy is needed, other agents should be used (ACOG 2013; Regitz-Zagrosek 2011).
Carbamazepine	D	Studies in pregnant women have demonstrated a risk to the fetus. Carbamazepine and its metabolites can be found in the fetus and may be associated with teratogenic effects, including spina bifida, craniofacial defects, cardiovascular malformations, and hypospadias. The risk of teratogenic effects is higher with anticonvulsant polytherapy than monotherapy. Developmental delays have also been observed following in utero exposure to carbamazepine (per manufacturer); however, socioeconomic factors, maternal and paternal IQ, and polytherapy may contribute to these findings. Pregnancy may cause small decreases of carbamazepine plasma concentrations in the second and third trimesters; monitoring should be considered. When used for the treatment of bipolar disorder, use of carbamazepine should be avoided during the first trimester of pregnancy if possible. The use of a single medication for the treatment of bipolar disorder or epilepsy in pregnancy is preferred. Carbamazepine may decrease plasma concentrations of hormonal contraceptives; breakthrough bleeding or unintended pregnancy may occur and alternate or back-up methods of contraception should be considered. Patients exposed to carbamazepine during pregnancy are encouraged to enroll themselves into the AED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Carbamide Peroxide		

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Carbidopa/Levodopa	C	Adverse events have been observed in some animal reproduction studies using this combination. Carbidopa can be detected in the umbilical cord, but absorption in fetal tissue is minimal. Levodopa crosses the placenta and can be metabolized by the fetus and detected in fetal tissue (Merchant 1995). The incidence of Parkinson disease in pregnancy is relatively rare, and information related to the use of carbidopa/levodopa in pregnant women is limited (Ball 1995; Cook 1985; Golbe 1987; Serikawa 2011; Shulman 2000). Current guidelines note that the available information is insufficient to make a recommendation for the treatment of restless legs syndrome in pregnant women (Aurora 2012).
Carvedilol		Adverse events have been observed in animal reproduction studies. Adverse events, such as fetal/neonatal bradycardia, hypoglycemia, and reduced birth weight, have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth is generally recommended. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother. Although beta-blockers may be used when treatment of hypertension or heart failure in pregnancy is indicated, agents other than carvedilol are preferred
Cefazolin	B	Adverse effects have not been observed in animal reproduction studies. Cefazolin crosses the placenta. Adverse events have not been reported in the fetus following administration of cefazolin prior to cesarean section. Cefazolin is recommended for group B streptococcus prophylaxis in pregnant patients with a nonanaphylactic penicillin allergy. It is also one of the antibiotics recommended for prophylactic use prior to cesarean delivery and may be used in certain situations prior to vaginal delivery in women at high risk for endocarditis. Due to pregnancy-induced physiologic changes, the pharmacokinetics of cefazolin are altered. The half-life is shorter, the AUC is smaller, and the clearance and volume of distribution are increased.
Cefdinir	B	Teratogenic events have not been observed in animal reproduction studies. An increase in most types of birth defects was not found following first trimester exposure to cephalosporins.
Ceftriaxone	B	Adverse events have not been observed in animal reproduction studies. Ceftriaxone crosses the placenta. Pregnancy was found to influence the single dose pharmacokinetics of ceftriaxone when administered prior to delivery (Popović 2007). The pharmacokinetics of ceftriaxone following multiple doses in the third trimester are similar to those of nonpregnant patients (Bourget Fernandez 1993). Ceftriaxone is recommended for use in pregnant women for the treatment of gonococcal infections, Lyme disease, and may be used in certain situations prior to vaginal delivery in women at high risk for endocarditis (consult current guidelines) (ACOG 120, 2011; CDC [Workowski 2015]; Wormser 2006).
Cephalexin	B	Adverse events were not observed in animal reproduction studies. Cephalexin crosses the placenta and produces therapeutic concentrations in the fetal circulation and amniotic fluid (Creatsas 1980). Peak concentrations in pregnant patients are similar to those in nonpregnant patients. Prolonged labor may decrease oral absorption (Griffith 1983; Paterson 1972).
Cetirizine		Maternal use of cetirizine has not been associated with an increased risk of major malformations. Cetirizine may be used for the treatment of rhinitis and urticaria during pregnancy (NAEPP 2005; Wallace 2008; Zuberbier 2014).
Charcoal, Activated		Activated charcoal is not absorbed systemically following oral administration. Use during pregnancy is not expected to result in significant exposure to the fetus. In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003).
Chlorhexidine Gluconate	B/C	Adverse events have not been observed in animal reproduction studies following use of the oral rinse; use of periodontal chip has not been studied. Chlorhexidine oral rinse is poorly absorbed from the GI tract.

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Generic Name	Category	Pregnancy Implications
Chloroquine Phosphate		In animal reproduction studies, drug accumulated in fetal ocular tissues and remained for several months following drug elimination from the rest of the body. Chloroquine and its metabolites cross the placenta and can be detected in the cord blood and urine of the newborn infant (Akintonwa 1988; Essien 1982; Law 2008). In one study, chloroquine and its metabolites were measurable in the cord blood 89 days (mean) after the last maternal dose (Law 2008). Malaria infection in pregnant women may be more severe than in nonpregnant women and has a high risk of maternal and perinatal morbidity and mortality. Therefore, pregnant women and women who are likely to become pregnant are advised to avoid travel to malaria-risk areas. Chloroquine is recommended for the treatment of pregnant women for uncomplicated malaria in chloroquine-sensitive regions; when caused by chloroquine-sensitive P. vivax or P. ovale, pregnant women should be maintained on chloroquine prophylaxis for the duration of their pregnancy (refer to current guidelines) (CDC 2013).
Chlorpheniramine Maleate		Maternal chlorpheniramine use has generally not resulted in an increased risk of birth defects (Aselton 1985; Gilboa 2009; Heinonen 1977; Jick 1981). Antihistamines may be used for the treatment of rhinitis, urticaria, and pruritus with rash in pregnant women (although second generation antihistamines may be preferred) (Angier 2010; Murase 2014; Wallace 2008; Zuberbier 2014). Antihistamines are not recommended for treatment of pruritus associated with intrahepatic cholestasis in pregnancy (Ambros-Rudolph 2011; Kremer 2011).
Chlorpromazine Hydrochloride		Embryotoxicity was observed in animal reproduction studies. Jaundice or hyper- or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization.
Chlorthalidone	B	Adverse events have not been observed in animal reproduction studies. Chlorthalidone crosses the placenta and can be detected in cord blood. Maternal use may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Use of thiazide diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. Women who require thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use (ACOG 2013).
Cinacalcet		Information related to the use of cinacalcet in pregnant women is limited (Edling 2014; Horius 2009; Nadarasa 2014; Rey 2016; Vera 2016).
Ciprofloxacin/Dexamethasone		
Ciprofloxacin Hydrochloride	C	Adverse events have been observed in some animal reproduction studies. Ciprofloxacin crosses the placenta and produces measurable concentrations in the amniotic fluid and cord serum (Ludlam 1997). Based on available data, an increased risk of teratogenic effects has not been observed following ciprofloxacin use during pregnancy (Bar-Oz 2009; Padberg 2014). Ciprofloxacin is recommended for prophylaxis and treatment of pregnant women exposed to anthrax (Meaney-Delman 2014). Serum concentrations of ciprofloxacin may be lower during pregnancy than in nonpregnant patients (Giamarellou 1989).
Citalopram	C	Adverse events have been observed in animal reproduction studies. Citalopram and its metabolites cross the human placenta. An increased risk of teratogenic effects, including cardiovascular defects, may be associated with maternal use of citalopram or other SSRIs; however, available information is conflicting. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated

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		with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, women who are pregnant may require adjusted doses of citalopram to achieve euthymia. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Clarithromycin	C	Adverse events have been documented in some animal reproduction studies. Clarithromycin crosses the placenta (Witt 2003). The manufacturer recommends that clarithromycin not be used in a pregnant woman unless there are no alternative therapies. Clarithromycin is not recommended as a first-line agent for the treatment or prophylaxis of Mycobacterium avium complex or for treatment of bacterial respiratory disease in HIV-infected pregnant patients (HHS [OI adult 2017]).
Clindamycin		Clindamycin crosses the placenta and can be detected in the cord blood and fetal tissue (Philipson 1973; Weinstein 1976). Clindamycin injection contains benzyl alcohol which may also cross the placenta. Clindamycin pharmacokinetics are not affected by pregnancy (Philipson 1976; Weinstein 1976). Clindamycin is recommended for use in pregnant women for the prophylaxis of group B streptococcal disease in newborns (alternative therapy) (ACOG 485, 2011); prophylaxis and treatment of Toxoplasma gondii encephalitis (alternative therapy), or Pneumocystis pneumonia (PCP) (alternative therapy) (HHS [OI adult 2015]); bacterial vaginosis (CDC [Workowski 2015]); anthrax (Meaney-Delman 2014); or malaria (CDC 2013). Clindamycin is also one of the antibiotics recommended for prophylactic use prior to cesarean delivery and may be used in certain situations prior to vaginal delivery in women at high risk for endocarditis (ACOG 120, 2011).
Clobetasol	C	Information related to the use of clobetasol in pregnancy is limited (Westermann 2012). Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014). The treatment of psoriasis in pregnancy is initiated with conservative treatment as in nonpregnant females. When a topical steroid is needed, low to moderate potency corticosteroids are preferred initially. High potency topical steroids should be used only when clearly needed and after the first trimester (Bae 2012).
Clonazepam		Clonazepam crosses the placenta. Teratogenic effects have been observed with some benzodiazepines; however, additional studies are needed. The incidence of premature birth and low birth weights may be increased following maternal use of benzodiazepines; hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. Neonatal withdrawal symptoms may occur within

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		days to weeks after birth and "floppy infant syndrome" (which also includes withdrawal symptoms) has been reported with some benzodiazepines, including clonazepam (Bergman 1992; Iqbal 2002; Wikner 2007). A combination of factors influences the potential teratogenicity of anticonvulsant therapy. When treating pregnant females with epilepsy, monotherapy with the lowest effective dose and avoidance medications known to have a high incidence of teratogenic effects is recommended (Harden 2009; Wlodarczyk 2012). When treating pregnant females with panic disorder, psychosocial interventions should be considered prior to pharmacotherapy (APA 2009). Patients exposed to clonazepam during pregnancy are encouraged to enroll themselves into the AED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Clonidine Hydrochloride	C	Adverse events have been observed in some animal reproduction studies. Clonidine crosses the placenta; concentrations in the umbilical cord plasma are similar to those in the maternal serum and concentrations in the amniotic fluid may be 4 times those in the maternal serum. The pharmacokinetics of clonidine may be altered during pregnancy (Buchanan 2009). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are preferred (ACOG 2012). [US Boxed Warning]: Epidural clonidine is not recommended for obstetrical or postpartum pain due to risk of hemodynamic instability.
Clopidogrel Bisulfate	B	Adverse events have not been observed in animal reproduction studies. Information related to use during pregnancy is limited (Bauer 2012; DeSantis 2011; Myers 2011).
Clotrimazole	B	Following topical and vaginal administration, small amounts of imidazoles are absorbed systemically (Duhm 1974). Vaginal topical azole products (7-day therapies only) are the preferred treatment of vulvovaginal candidiasis in pregnant women. This product may weaken latex condoms and diaphragms (CDC [Workowski 2015]).
Colchicine	C	Adverse events were observed in animal reproduction studies. Colchicine crosses the human placenta. Use during pregnancy in the treatment of familial Mediterranean fever has not shown an increase in miscarriage, stillbirth, or teratogenic effects (limited data).
Collagenase		It is not known if collagenase is absorbed systemically following topical application.
Crotamiton	C	Animal reproduction studies have not been conducted; use during pregnancy only if clearly needed.
Cyanocobalamin		Animal reproduction studies have not been conducted. Water soluble vitamins cross the placenta. Absorption of vitamin B12 may increase during pregnancy. Vitamin B12 requirements may be increased in pregnant women compared to nonpregnant women. Serum concentrations of vitamin B12 are higher in the neonate at birth than the mother (IOM, 1998).
Cyclobenzaprine	B	Adverse events have not been observed in animal reproduction studies. The manufacturer recommends avoiding use during pregnancy unless clearly needed.
Cyclopentolate	C	Animal reproduction studies have not been conducted.
Cycloserine	C	Adverse events have not been observed in animal reproduction studies. Cycloserine crosses the placenta and can be detected in the fetal blood and amniotic fluid. The American Thoracic Society recommends use in pregnant women only if there are no alternatives (CDC 2003).
Cyclosporine	C	Adverse events were not observed following the use of oral cyclosporine in animal reproduction studies (using doses that were not maternally toxic). In humans, cyclosporine crosses the placenta; maternal concentrations do not correlate with those found in the umbilical cord. Cyclosporine may be detected in the serum of newborns for several days after birth (Claris 1993). Based on clinical use, premature births and low birth weight were consistently observed in pregnant transplant patients (additional pregnancy complications also present). Formulations may contain alcohol; the alcohol content should be taken into consideration in pregnant women. The pharmacokinetics of cyclosporine may be influenced by pregnancy (Grimer 2007). Cyclosporine may be used in pregnant renal, liver, or heart transplant patients (Cowan 2012; EBPG Expert Group on Renal Transplantation 2002; McGuire 2009; Parhar 2012). If therapy is needed for psoriasis, other agents are preferred; however, cyclosporine may be used as

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		an alternative agent along with close clinical monitoring; use should be avoided during the first trimester if possible (Bae 2012). If treatment is needed for lupus nephritis, other agents are recommended to be used in pregnant women (Hahn 2012). Following transplant, normal menstruation and fertility may be restored within months; however, appropriate contraception is recommended to prevent pregnancy until 1-2 years following the transplant to improve pregnancy outcomes (Cowan 2012; EBPG Expert Group on Renal Transplantation 2002; McGuire 2009; Parhar 2012). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Cyproheptadine	B	Adverse events were observed in some animal reproduction studies. Per the product labeling, an increased risk of congenital abnormalities was not observed following maternal use of cyproheptadine during the first, second, or third trimesters in two studies of pregnant women; however the possibility of harm cannot be ruled out. Although cyproheptadine is approved for the treatment of allergic conditions such as rhinitis and urticaria, other agents are preferred for use in pregnant women (Scadding 2008; Wallace 2008; Zuberbier 2014). Antihistamines are not recommended for treatment of pruritus associated with intrahepatic cholestasis in pregnancy (Ambros-Rudolph 2011; Kremer 2014).
Dapsone	C	Dapsone crosses the placenta (Brabin 2004). Per the manufacturer, dapsone has not shown an increased risk of congenital anomalies when given during all trimesters of pregnancy. Several reports have described adverse effects in the newborn after in utero exposure to dapsone, including neonatal hemolytic disease, methemoglobinemia, and hyperbilirubinemia (Hocking 1968; Kabra 1998; Thornton 1989). Dapsone may be used in pregnant women requiring maintenance therapy of either leprosy or dermatitis herpetiformis. Dapsone may be used as an alternative agent for management of Pneumocystis jirovecii pneumonia (PCP) or Toxoplasma gondii encephalitis in pregnant, HIV-infected patients (HHS [OI Adult] 2016). Because of the theoretical increased risk for hyperbilirubinemia and kernicterus, neonatal care providers should be informed if maternal dapsone is used near term (HHS [OI Adult] 2016).
Darunavir		Darunavir has a low level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines recommend darunavir as a preferred protease inhibitor (PI) for initial use in antiretroviral-naive pregnant patients when combined with low-dose ritonavir boosting. Serum concentrations are decreased during pregnancy; therefore, ritonavir-boosted twice-daily dosing should be used. According to product labeling, once-daily dosing of darunavir should only be considered in women who are already pregnant, and virologically stable on a once daily dose, and in whom changing to a twice daily regimen would compromise tolerability or compliance. However, the current HHS perinatal guidelines do not recommend once daily dosing during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis.

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		Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Darunavir/ Cobicistat		*Darunavir has a low level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines recommend darunavir as a preferred protease inhibitor (PI) for initial use in antiretroviral-naive pregnant patients when combined with low-dose ritonavir boosting. Serum concentrations are decreased during pregnancy; therefore, ritonavir-boosted twice-daily dosing should be used. According to product labeling, once-daily dosing of darunavir should only be considered in women who are already pregnant, and virologically stable on a once daily dose, and in whom changing to a twice daily regimen would compromise tolerability or compliance. However, the current HHS perinatal guidelines do not recommend once daily dosing during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Cobicistat has low placental transfer. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend

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		cobicistat as initial therapy in antiretroviral-naive pregnant females. Cobicistat exposure is decreased in pregnancy; however, pharmacokinetic data are insuff
Delavirdine		Adverse events were observed in some animal reproduction studies. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Desipramine		Animal reproduction studies are inconclusive. Tricyclic antidepressants may be associated with irritability, jitteriness, and convulsions (rare) in the neonate (Yonkers 2009). The ACOG recommends that therapy for depression during pregnancy be individualized; treatment should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician (ACOG 2008). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Dexamethasone	C	Adverse events have been observed with corticosteroids in animal reproduction studies. Dexamethasone crosses the placenta (Brownfoot 2013); and is partially metabolized by placental enzymes to an inactive metabolite (Murphy 2007). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids during pregnancy; monitor. Because antenatal corticosteroid administration may reduce the incidence of intraventricular hemorrhage, necrotizing enterocolitis, neonatal mortality, and respiratory distress syndrome, the injection is often used for antenatal fetal lung maturation in patients with preterm premature rupture of membranes or preterm labor who are at risk of preterm delivery (most data is available for betamethasone). A single course of corticosteroids is recommended for women between

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		24 and 34 weeks' gestation who are at risk of delivering within 7 days, including those with ruptured membranes or multiple gestations. A single course of corticosteroids may be considered for women beginning at 23 weeks' gestation, who are at risk of delivering within 7 days, in consultation with the family. In addition, a single course of corticosteroids may be given to women between 34 0/7 weeks and 36 6/7 weeks who are at risk of preterm delivery within 7 days and who have not previously received corticosteroids; use of concomitant tocolytics is not currently recommended and administration of late preterm corticosteroids has not been evaluated in women with intrauterine infection, multiple gestations, pregestational diabetes, or women who delivered previously by cesarean section at term. Multiple repeat courses are not recommended. However, in women with pregnancies less than 34 weeks' gestation at risk for delivery within 7 days and who had a course of antenatal corticosteroids >14 days prior, a single repeat course may be considered; use of a repeat course in women with premature rupture of membranes is controversial (ACOG 171 2016; ACOG 713 2017; ACOG 188 2018). When systemic corticosteroids are needed in pregnancy, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Leachman 2006; Lunghi 2010; Makol 2011; Østensen 2009). Dexamethasone should not be used to treat primary adrenal insufficiency in pregnant women (Bornstein 2016).
Dextrose/Sodium Chloride		Appropriate use of dextrose injection would not be expected to cause adverse developmental outcomes to the fetus when used during pregnancy. Maternal hyperglycemia or malnutrition may be associated with adverse pregnancy outcomes. In females with nausea and vomiting of pregnancy who cannot tolerate oral liquids for prolonged periods or who are clinically dehydrated, intravenous hydration that includes dextrose is recommended. Due to potential maternal complications, enteral therapy is preferred over parenteral if nutrition support is required. Total parenteral nutrition (which may include dextrose) should be reserved for use in women with severe nausea and vomiting not responsive to enteral therapy (ACOG 189 2018). Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015).
Dextrose in Sterile Water		Appropriate use of dextrose injection would not be expected to cause adverse developmental outcomes to the fetus when used during pregnancy. Maternal hyperglycemia or malnutrition may be associated with adverse pregnancy outcomes. In females with nausea and vomiting of pregnancy who cannot tolerate oral liquids for prolonged periods or who are clinically dehydrated, intravenous hydration that includes dextrose is recommended. Due to potential maternal complications, enteral therapy is preferred over parenteral if nutrition support is required. Total parenteral nutrition (which may include dextrose) should be reserved for use in women with severe nausea and vomiting not responsive to enteral therapy (ACOG 189 2018). Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015).
Dextrose Instant		Appropriate use of dextrose injection would not be expected to cause adverse developmental outcomes to the fetus when used during pregnancy. Maternal hyperglycemia or malnutrition may be associated with adverse pregnancy outcomes. In females with nausea and vomiting of pregnancy who cannot tolerate oral liquids for prolonged periods or who are clinically dehydrated, intravenous hydration that includes dextrose is recommended. Due to potential maternal complications, enteral therapy is preferred over parenteral if nutrition support is required. Total parenteral nutrition (which may include dextrose) should be reserved for use in women with severe nausea and vomiting not responsive to enteral therapy (ACOG 189 2018). Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support

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		guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015).
Diazepam	D	Adverse events have been observed in animal reproduction studies. In humans, diazepam and its metabolites (N-desmethyldiazepam, temazepam, and oxazepam) cross the placenta. Teratogenic effects have been observed with diazepam; however, additional studies are needed. The incidence of premature birth and low birth weights may be increased following maternal use of benzodiazepines; hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. Neonatal withdrawal symptoms may occur within days to weeks after birth and "floppy infant syndrome" (which also includes withdrawal symptoms) has been reported with some benzodiazepines (including diazepam) (Bergman 1992; Iqbal 2002; Wikner 2007). A combination of factors influences the potential teratogenicity of anticonvulsant therapy. When treating women with epilepsy, monotherapy with the lowest effective dose and avoidance of medications known to have a high incidence of teratogenic effects is recommended (Harden 2009; Wlodarczyk 2012).
Dibucaine		
Diclofenac (Topical)	B (3% gel) C (1% gel, solution, patch) D (> 30 weeks gestation, 1% gel, solution, patch)	Diclofenac crosses the placenta following systemic administration. The amount of diclofenac available systemically following topical application is less in comparison to oral doses. Reversible constriction of the ductus arteriosus in utero has been observed following topical application of diclofenac (Torloni 2006). Because they may cause premature closure of the ductus arteriosus, the manufacturer's labeling notes that the use of NSAIDs late in pregnancy should be avoided; the product labeling for the diclofenac topical patch specifically states use should be avoided starting at 30-weeks gestation.
Diclofenac ER	C/D (>30 weeks gestation)	Diclofenac crosses the placenta. Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, nonclosure of the ductus arteriosus postnatally may occur and be resistant to medical management (Bermas 2014; Bloor 2013). Because they may cause premature closure of the ductus arteriosus, product labeling for diclofenac specifically states use should be avoided starting at 30-weeks gestation. Use of NSAIDs can be considered for the treatment of mild rheumatoid arthritis flares in pregnant women; however, use should be minimized or avoided early and late in pregnancy (Bermas 2014; Saavedra Salinas 2015). If treatment of migraine is needed in pregnant women, agents other than diclofenac are preferred (Amundsen 2015). The chronic use of NSAIDs, including diclofenac, in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bermas 2014; Bloor 2013).
Dicloxacillin	B	Adverse events have not been observed in animal reproduction studies. Dicloxacillin crosses the placenta (Depp 1970). Maternal use of penicillins has generally not resulted in an increased risk of birth defects.
Dicyclomine Hydrochloride		Adverse events have not been observed in animal reproduction studies. In epidemiologic studies, birth defects were not observed following maternal doses up to 40 mg daily throughout the first trimester; information has not been located when used in pregnant women at recommended doses (80 to 160 mg daily). Agents other than dicyclomine may be preferred for the treatment of irritable bowel syndrome in pregnant women (Enck 2016).

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Didanosine	B	Didanosine has a low to moderate level of transfer across the human placenta. Based on data from the Antiretroviral Pregnancy Registry, an increased rate of birth defects has been observed following maternal use of didanosine during the first trimester and later during pregnancy; no pattern of defects has been observed and clinical relevance is uncertain. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. [US Boxed Warning]: Fatal lactic acidosis has been reported in pregnant women using didanosine and stavudine in combination with other antiretroviral agents. According to the manufacturer, this combination should be used with caution during pregnancy and only if the potential benefit clearly outweighs the potential risk; however, current guidelines note that this combination should not be used in pregnant females with HIV. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In addition to lactic acidosis, the combination of didanosine and stavudine has been shown to increase the risk of birth defects and neurodevelopmental disability. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend didanosine for initial therapy in antiretroviral-naive pregnant females due to toxicity. In addition, because of the high risk of toxicity, didanosine should be stopped in females who become pregnant during therapy and women should be switched to a preferred or alternative regimen. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Dietary Supplement, Oral		
Digoxin	C	Animal reproduction studies have not been conducted. Digoxin crosses the placenta and serum concentrations are similar in the mother and fetus at delivery. Digoxin is recommended in the treatment of fetal tachycardia determined to be SVT. In pregnant women, use of digoxin is recommended as a first-line agent for chronic treatment of highly symptomatic SVT; the lowest effective dose is recommended (Page [ACC/AHA/HRS 2015]).
Diltiazem	C	Adverse events have been observed in animal reproduction studies. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are preferred (ACOG 2013). Women with hypertrophic cardiomyopathy who are controlled with diltiazem prior to pregnancy may continue therapy, but increased fetal monitoring is recommended (Gersh 2011).

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Dimethyl Fumarate		Adverse events were observed in animal reproduction studies. Women exposed to dimethyl fumarate during pregnancy are encouraged to enroll in the Pregnancy Registry by calling 866-810-1462 or visiting www.tecfiderapregnancyregistry.com.
Diphenhydramine Hydrochloride	B	Adverse events have not been observed in animal reproduction studies. Diphenhydramine crosses the placenta (Miller 2000; Parkin 1974). In general, the use of first generation antihistamines immediately before parturition may cause respiratory depression in the newborn (Zuberbier 2014). Diphenhydramine may be used for the treatment of allergic conditions in pregnant women when a first generation antihistamine is indicated (Babalola 2013; Murase 2014; Zuberbier 2014). Antihistamines are not recommended for treatment of pruritus associated with intrahepatic cholestasis in pregnancy (Ambros-Rudolph 2011; Kremer 2014).
Diphtheria/Tetanus Toxoid (DT)	C	Reproduction studies have not been conducted. DT is not recommended for use in persons ≥7 years of age. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]). The Advisory Committee on Immunization Practices (ACIP) recommends a single Tdap vaccination during each pregnancy; ideally between 27 and 36 weeks gestation. Pregnant women who are not immunized or are only partially immunized should complete the primary series with Td. Tetanus immune globulin and a tetanus toxoid containing vaccine are recommended by the ACIP as part of the standard wound management to prevent tetanus in pregnant women; the use of a tetanus-toxoid containing vaccine during pregnancy is recommended for wound management if ≥5 years have passed since the last Td vaccination (CDC/ACIP 2013).
Diphtheria/ Tetanus Toxoid/ Acellular Pertussis Vaccine (TDap, DPT)	B/C	Animal reproduction studies have not been conducted with all products; when conducted, adverse effects to the fetus were not observed in developmental toxicity studies. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]). Using data collected from 2005 to 2010 VAERS, there were not any patterns of adverse maternal, fetal, or neonatal outcomes identified following maternal use of the Tdap vaccine (Zheteyeva 2012). Additional VAERS data collected between 2011 and 2015 (after the current recommendations for use in pregnancy were in effect), also did not observe any new or unexpected maternal or newborn adverse events following maternal vaccination (Moro 2016). All pregnant females should receive a single dose of Tdap during each pregnancy, regardless of previous vaccination status, preferably during the early part of 27 of 36 weeks gestation. Alternately, administration of Tdap can be given immediately postpartum to all females who have not previously been vaccinated with Tdap in order to protect the mother and infant from pertussis (ACIP [Kroger 2017]; CDC/ACIP 62[7] 2013). In case of an ongoing local pertussis epidemic, pregnant females should be vaccinated with Tdap for their own protection as is recommended for nonpregnant females, regardless of fetal gestational age. In addition, if a tetanus toxoid-containing vaccine is needed as standard care for wound management, Tdap may be given regardless of fetal gestational age if otherwise indicated. However, if Tdap is used prior to 27 to 36 weeks gestation in these instances, females should not receive more than 1 dose during the same pregnancy (ACOG 2017).
Divalproex Sodium	X - Migraine Prophylaxis D - all other indications	Adverse events have been observed in animal reproduction studies and in human pregnancies. [US Boxed Warning]: May cause major congenital malformations, such as neural tube defects (eg, spina bifida) and decreased IQ scores following in utero exposure. Use is contraindicated in pregnant women for the prevention of migraine. Use is not recommended in women of childbearing potential for any other condition unless valproate is essential to manage her condition and alternative therapies are not appropriate. Effective contraception should be used during therapy. Valproic acid crosses the placenta (Harden 2009b). Neural tube defects, craniofacial defects, cardiovascular malformations, hypospadias, and limb malformations have been reported. Information from the North American Antiepileptic Drug Pregnancy Registry notes the rate of major malformations to be 9% to 11% following an average exposure to valproate monotherapy 1,000 mg/day; this is an increase in congenital malformations when compared with monotherapy with other antiepileptic drugs (AED). Based on data

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		from the CDC National Birth Defects Prevention Network, the risk of spinal bifida is approximately 1% to 2% following valproate exposure (general population risk estimated to be 0.06% to 0.07%). Nonteratogenic adverse effects have also been reported. Decreased IQ scores have been noted in children exposed to valproate in utero when compared to children exposed to other antiepileptic medications or no antiepileptic medications; the risk of autism spectrum disorders may also be increased. Fatal hepatic failure and hypoglycemia in infants have been noted in case reports following in utero exposure to valproic acid. Clotting factor abnormalities (hypofibrinogenemia, thrombocytopenia, or decrease in other coagulation factors) may develop in the mother following valproate use during pregnancy; close monitoring of coagulation factors is recommended. Current guidelines recommend complete avoidance of valproic acid and derivatives for the treatment of epilepsy in pregnant women whenever possible (Harden 2009a), especially when used for conditions not associated with permanent injury or risk of death. Effective contraception should be used during treatment. When pregnancy is being planned, consider tapering off of therapy prior to conception if appropriate; abrupt discontinuation of therapy may cause status epilepticus and lead to maternal and fetal hypoxia. Folic acid decreases the risk of neural tube defects in the general population; supplementation with folic acid should be used prior to conception and during pregnancy in all women, including those taking valproate. A pregnancy registry is available for women who have been exposed to valproic acid. Patients may enroll themselves in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling (888) 233-2334. Additional information is available at www.aedpregnancyregistry.org.
Docusate Sodium		Hypomagnesemia was reported in a newborn following chronic maternal overuse of docusate sodium throughout pregnancy (Schindler 1984). Treatment of constipation in pregnant women is similar to that of nonpregnant patients and medications may be used when diet and lifestyle modifications are not effective. Agents other than docusate are preferred for initial treatment. Docusate sodium may be used if needed, but may not be as effective as other agents (ACG [Christie 2007]).
Dolutegravir		* Dolutegravir has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to preliminary data collected by the antiretroviral pregnancy registry. However, information from an unscheduled analysis of an ongoing study signaled an increased risk of neural tube defects in women who became pregnant during dolutegravir treatment; this risk was not observed in women who started treatment during pregnancy. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction.
Dorzolamide Hydrochloride	C	Adverse events have been observed in animal reproduction studies following systemic administration. IOP is usually lower during pregnancy. If topical medications for the treatment of glaucoma in pregnant women cannot be discontinued because small increases in IOP cannot be tolerated, the minimum effective dose should be used in combination with punctual occlusion to decrease exposure to the fetus (Johnson, 2001).
Dorzolamide Hydrochloride/ Timolol	C	* Dorzolamide: Adverse events have been observed in animal reproduction studies following systemic administration. IOP is usually lower during pregnancy. If topical medications for the treatment of glaucoma in pregnant women cannot be discontinued because small increases in IOP cannot be tolerated, the minimum effective dose should be used in combination with punctual occlusion to decrease exposure to the fetus (Johnson, 2001). * Timolol: Adverse events were not observed in the initial animal reproduction studies.

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		Timolol crosses the placenta (Schneider 1988) and decreased fetal heart rate has been observed following maternal use of timolol during pregnancy (Devoe 1986). Adverse events, such as fetal/neonatal hypoglycemia and reduced birth weight, have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth is generally recommended. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). Although beta-blockers may be used when treatment of hypertension in pregnancy is indicated, agents other than timolol are preferred (ACOG 2013; Magee 2014). In addition, other agents are preferred when migraine prophylaxis is needed in pregnant women (Pringsheim 2012).
Doxazosin		Adverse events were observed in some animal reproduction studies. Doxazosin crosses the placenta (Versmissen 2016). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are generally preferred (ACOG, 2013).
Doxepin	C	Adverse events were observed in animal reproduction studies. Tricyclic antidepressants may be associated with irritability, jitteriness, and convulsions (rare) in the neonate (Yonkers 2009). The ACOG recommends that therapy for depression during pregnancy be individualized; treatment should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician (ACOG 2008). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Doxycycline	D	Tetracyclines cross the placenta (Mylonas 2011). Therapeutic doses of doxycycline during pregnancy are unlikely to produce substantial teratogenic risk, but data are insufficient to say that there is no risk. In general, reports of exposure have been limited to short durations of therapy in the first trimester. Tetracyclines accumulate in developing teeth and long tubular bones (Mylonas 2011). Permanent discoloration of teeth (yellow, gray, brown) can occur following in utero exposure and is more likely to occur following long-term or repeated exposure. Doxycycline is the recommended agent for the treatment of Rocky Mountain spotted fever (RMSF) in pregnant women (CDC [Biggs 2016]). For other indications, many guidelines consider use of doxycycline to be contraindicated during pregnancy, or to be a relative contraindication in pregnant women if other agents are available and appropriate for use (Anderson 2013; CDC 2011; HHS [OI adult 2015]; Stevens 2014; Workowski [CDC 2015]; IDSA [Wormser 2006]). Doxycycline should not be used for the treatment of rosacea in pregnant women. When systemic antibiotics are needed for dermatologic conditions, other agents are preferred (Kong 2013; Murase 2014). As a class, tetracyclines are generally considered second-line antibiotics in pregnant women and their use should be avoided (Mylonas 2011).
Drospirenone/ Ethinyl Estradiol		Use is contraindicated in pregnant women. Combination hormonal contraceptives are used to prevent pregnancy; treatment should be discontinued if pregnancy occurs. In general, the use of combination hormonal contraceptives, when inadvertently used early in pregnancy, have not been associated adverse fetal or maternal effects (Curtis 2016b). The manufacturer states that combination hormonal contraceptives should not be started until ≥4 weeks after delivery in women who choose not to breastfeed, or ≥4 weeks after a second trimester abortion or miscarriage. Due to the increased risk of venous thromboembolism (VTE) postpartum, combination hormonal contraceptives should not be started in any woman <21 days following delivery. The risk decreases to baseline by

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		postpartum day 42. Use of combination hormonal contraceptives in women between 21 and 42 days after delivery should take into consideration the individual woman's risk factors for VTE (eg, age ≥35 years, previous VTE, thrombophilia, immobility, preeclampsia, transfusion at delivery, cesarean delivery, peripartum cardiomyopathy, BMI ≥30 kg/m2, postpartum hemorrhage, or smoking) (Curtis 2016b).
Duloxetine	C	Adverse events have been observed in animal reproduction studies. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hyper- or hypotonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SNRIs/SSRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. The long-term effects of in utero SNRI/SSRI exposure on infant development and behavior are not known. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Health care providers are encouraged to enroll women exposed to duloxetine during pregnancy in the Cymbalta Pregnancy Registry (866-814-6975 or http://cymbaltapregnancyregistry.com). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Efavirenz		Efavirenz has a moderate level of transfer across the human placenta. Based on data from the Antiretroviral Pregnancy Registry, an increased risk of overall birth defects has not been observed following first trimester exposure to efavirenz. Neural tube and other CNS defects have been reported; however, a meta-analysis has shown that the risk for neural tube defects after efavirenz exposure in the first trimester are not greater than those in the general population. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider efavirenz to be a component of an alternative regimen for initial use in antiretroviral-naive pregnant females. Use may be considered for females having drug interactions with other medications or who require the convenience of once daily dosing (and are not eligible for rilpivirine); screening for antenatal and postpartum depression is recommended. Pharmacokinetic data from available studies do not suggest dose alterations are needed during pregnancy. Although not recommended by the manufacturer, HHS guidelines do not restrict the use of efavirenz in the first trimester. For females who present in the first trimester already on an efavirenz-containing regimen and who have adequate viral suppression, efavirenz may be continued. If an efavirenz-containing regimen must be discontinued for more than a few days due to toxicity, consider evaluating for rebound viremia and drug

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		resistance; consult current guidelines. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. The manufacturer recommends women of reproductive potential undergo pregnancy testing prior to initiation of efavirenz. Barrier contraception should be used in combination with other (hormonal) methods of contraception during therapy and for 12 weeks after efavirenz is discontinued. However, current HHS Perinatal HIV Guidelines do not restrict use in females planning a pregnancy. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Efavirenz/ Emtricitabine/ Tenofovir		* Efavirenz has a moderate level of transfer across the human placenta. Based on data from the Antiretroviral Pregnancy Registry, an increased risk of overall birth defects has not been observed following first trimester exposure to efavirenz. Neural tube and other CNS defects have been reported; however, a meta-analysis has shown that the risk for neural tube defects after efavirenz exposure in the first trimester are not greater than those in the general population. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider efavirenz to be a component of an alternative regimen for initial use in antiretroviral-naive pregnant females. Use may be considered for females having drug interactions with other medications or who require the convenience of once daily dosing (and are not eligible for rilpivirine); screening for antenatal and postpartum depression is recommended. Pharmacokinetic data from available studies do not suggest dose alterations are needed during pregnancy. Although not recommended by the manufacturer, HHS guidelines do not restrict the use of efavirenz in the first trimester. For females who present in the first trimester already on an efavirenz-containing regimen and who have adequate viral suppression, efavirenz may be continued. If an efavirenz-containing regimen must be discontinued for more than a few days due to toxicity, consider evaluating for rebound viremia and drug resistance; consult current guidelines. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. The manufacturer recommends women of reproductive potential undergo pregnancy testing prior to

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		initiation of efavirenz. Barrier contraception should be used in combination with other (hormonal) methods of contraception during therapy and for 12 weeks after efavirenz is discontinued. However, current HHS Perinatal HIV Guidelines do not restrict use in females planning a pregnancy. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Emtricitabine has a high level of transfer across the human placenta; no increased risk of overall birth defects has been observed according to data collected by the anti
Electrolyte Solution		
Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir		* Elvitegravir has a high level of transfer across the placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend an elvitegravir-containing regimen as initial therapy in antiretroviral-naive pregnant females due to inadequate serum concentrations observed during pregnancy. Pharmacokinetic data are insufficient to make dosing recommendations during pregnancy. If pregnancy occurs during therapy, consideration should be given to changing to a more effective regimen. If continued, close monitoring, including therapeutic drug monitoring if available, is recommended. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV.m Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Cobicistat has low placental transfer. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend cobicistat as initial therapy in antiretroviral-naive pregnant females. Cobicistat exposure is decreased in pregnancy; however, pharmacokinetic data are insufficient to make

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		dosing recommendations. Use of a preferred agent is recommended until more data on cobicistat are available. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy,
Emtricitabine	B	Emtricitabine has a high level of transfer across the human placenta; no increased risk of overall birth defects has been observed according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general nucleoside reverse transcriptase inhibitors are well tolerated and the benefits of use generally outweigh potential risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider emtricitabine with tenofovir disoproxil fumarate to be a preferred NRTI backbone for initial therapy in antiretroviral-naive pregnant females. The guidelines also consider emtricitabine plus tenofovir disoproxil fumarate a recommended dual NRTI backbone in regimens for HIV/HBV-coinfected pregnant females. Use caution with hepatitis B coinfection; hepatitis B flare may occur if emtricitabine is discontinued. Emtricitabine is also a recommended component of an initial regimen when acute HIV infection is detected during pregnancy. The pharmacokinetics of emtricitabine are not significantly altered during pregnancy and dosing adjustments are not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Emtricitabine is one of the agents recommended for pre-exposure prophylaxis in couples with differing HIV status who are planning a pregnancy. The partner without HIV should begin therapy 1 month prior to attempting conception and continue therapy for 1 month after attempting conception. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Emtricitabine/ Rilpivirine/ Tenofovir		* Emtricitabine has a high level of transfer across the human placenta; no increased risk of overall birth defects has been observed according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be

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		evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general nucleoside reverse transcriptase inhibitors are well tolerated and the benefits of use generally outweigh potential risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider emtricitabine with tenofovir disoproxil fumarate to be a preferred NRTI backbone for initial therapy in antiretroviral-naive pregnant females. The guidelines also consider emtricitabine plus tenofovir disoproxil fumarate a recommended dual NRTI backbone in regimens for HIV/HBV-coinfected pregnant females. Use caution with hepatitis B coinfection; hepatitis B flare may occur if emtricitabine is discontinued. Emtricitabine is also a recommended component of an initial regimen when acute HIV infection is detected during pregnancy. The pharmacokinetics of emtricitabine are not significantly altered during pregnancy and dosing adjustments are not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Emtricitabine is one of the agents recommended for pre-exposure prophylaxis in couples with differing HIV status who are planning a pregnancy. The partner without HIV should begin therapy 1 month prior to attempting conception and continue therapy for 1 month after attempting conception. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Tenofovir has a high level of transfer across the human placenta following maternal use of tenofovir disoproxil fumarate. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however,
Emtricitabine/ Tenofovir		* Emtricitabine has a high level of transfer across the human placenta; no increased risk of overall birth defects has been observed according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general nucleoside reverse transcriptase inhibitors are well tolerated and the benefits of use generally outweigh potential risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider emtricitabine with tenofovir disoproxil fumarate to be a preferred NRTI backbone for initial therapy in antiretroviral-naive pregnant females.

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		The guidelines also consider emtricitabine plus tenofovir disoproxil fumarate a recommended dual NRTI backbone in regimens for HIV/HBV-coinfected pregnant females. Use caution with hepatitis B coinfection; hepatitis B flare may occur if emtricitabine is discontinued. Emtricitabine is also a recommended component of an initial regimen when acute HIV infection is detected during pregnancy. The pharmacokinetics of emtricitabine are not significantly altered during pregnancy and dosing adjustments are not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Emtricitabine is one of the agents recommended for pre-exposure prophylaxis in couples with differing HIV status who are planning a pregnancy. The partner without HIV should begin therapy 1 month prior to attempting conception and continue therapy for 1 month after attempting conception. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017). * Rilpivirine has moderate to high placental transfer. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to con
Enalapril		[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. Enalapril crosses the placenta; the active metabolite enalaprilat can be detected in the newborn (Schubiger 1988). Drugs that act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. The use of these drugs in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. Teratogenic effects may occur following maternal use of an ACE inhibitor during the first trimester, although this finding may be confounded by maternal disease. Because adverse fetal events are well documented with exposure later in pregnancy, ACE inhibitor use in pregnant women is not recommended (Seely 2014; Weber 2014). Infants exposed to an ACE inhibitor in utero should be monitored for hyperkalemia, hypotension, and oliguria. Oligohydramnios may not appear until after irreversible fetal injury has occurred. Exchange transfusions or dialysis may be required to reverse hypotension or improve renal function, although data related to the effectiveness in neonates is limited. Chronic maternal hypertension itself is also associated with adverse events in the fetus/infant and mother. ACE inhibitors are not recommended for the treatment of uncomplicated hypertension in pregnancy (ACOG 2013) and they are specifically contraindicated for the treatment of hypertension and chronic heart failure during pregnancy by some guidelines (Regitz-Zagrosek 2011). In addition, ACE inhibitors should generally be avoided in women of reproductive age (ACOG 2013). If treatment for hypertension or chronic heart failure in pregnancy is needed, other agents should be used (ACOG 2013; Regitz-Zagrosek 2011).
Enfuvirtide	B	Enfuvirtide has minimal to low transfer across the human placenta. Data collected by the antiretroviral pregnancy registry is insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery,

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		although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines note that there are insufficient data to recommend use of enfuvirtide as initial therapy in antiretroviral-naive pregnant females. Pharmacokinetic data are insufficient to make dosing recommendations during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Enoxaparin	B	Adverse events were not observed in animal reproduction studies. Low molecular weight heparin (LMWH) does not cross the placenta; increased risks of fetal bleeding or teratogenic effects have not been reported (Bates 2012). LMWH is recommended over unfractionated heparin for the treatment of acute venous thromboembolism (VTE) in pregnant women. LMWH is also recommended over unfractionated heparin for VTE prophylaxis in pregnant women with certain risk factors (eg, homozygous factor V Leiden, antiphospholipid antibody syndrome with ≥3 previous pregnancy losses). Prophylaxis is not routinely recommended for women undergoing assisted reproduction therapy; however, LMWH therapy is recommended for women who develop severe ovarian hyperstimulation syndrome. LMWH should be discontinued at least 24 hours prior to induction of labor or a planned cesarean delivery. For women undergoing cesarean section and who have additional risk factors for developing VTE, the prophylactic use of LMWH may be considered (Bates 2012). LMWH may also be used in women with mechanical heart valves (consult current guidelines for details) (Bates 2012; Nishimura 2014). Women who require long-term anticoagulation with warfarin and who are considering pregnancy, LMWH substitution should be done prior to conception when possible. When choosing therapy, fetal outcomes (ie, pregnancy loss, malformations), maternal outcomes (ie, VTE, hemorrhage), burden of therapy, and maternal preference should be considered (Bates 2012). Monitoring antifactor Xa levels is recommended (Bates 2012; Nishimura 2014). Multiple-dose vials contain benzyl alcohol (avoid in pregnant women due to association with gasping syndrome in premature infants); use of preservative-free formulations is recommended.
Entecavir	C	Teratogenic effects have been observed in animal studies. Information related to use in pregnancy is limited; use only if other options are inappropriate (DHHS [OI], 2013). Pregnant women taking entecavir should enroll in the pregnancy registry by calling 1-800-258-4263.
Epinephrine	C	Adverse events have been observed in animal reproduction studies. Epinephrine crosses the placenta (Sandler 1964). Uterine vasoconstriction, decreased uterine blood flow, and fetal anoxia may occur. Epinephrine is recommended for the treatment of anaphylaxis in pregnant women. Specific dosing is not available; use with caution and monitor hemodynamic response (Hepner 2013). Medications used for the treatment of cardiac

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		arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015). Although epinephrine injection may be used for asthma exacerbations in pregnancy, systemic therapy has not been proven to be better than use of preferred inhaled agents (NAEPP 2005).
Epoetin Alfa	C	Adverse events were observed in animal reproduction studies. In vitro studies suggest that recombinant erythropoietin does not cross the human placenta (Reisenberger 1997). Polyhydramnios and intrauterine growth retardation have been reported with use in women with chronic kidney disease (adverse effects also associated with maternal disease). Hypospadias and pectus excavatum have been reported with first trimester exposure (case report). Recombinant erythropoietin alfa has been evaluated as adjunctive treatment for severe pregnancy associated iron deficiency anemia (Breymann 2001; Krafft 2009) and has been used in pregnant women with iron-deficiency anemia associated with chronic kidney disease (CKD) (Furaz-Czerpak 2012; Josephson 2007). Amenorrheic premenopausal women should be cautioned that menstruation may resume following treatment with recombinant erythropoietin (Furaz-Czerpak 2012). Multidose formulations containing benzyl alcohol are contraindicated for use in pregnant women; if treatment during pregnancy is needed, single dose preparations should be used. Women who become pregnant during treatment with epoetin alfa are encouraged to enroll in Amgen's Pregnancy Surveillance Program (1-800-772-6436).
Ergotamine/ Caffeine	X	* Ergotamine may cause prolonged constriction of the uterine vessels and/or increased myometrial tone leading to reduced placental blood flow. This has contributed to fetal growth retardation in animals. * Caffeine: Adverse events were observed in animal reproduction studies. Caffeine crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Grosso 2005). Based on current studies, usual dietary exposure to caffeine is unlikely to cause congenital malformations (Brent 2011). However, available data shows conflicting results related to maternal caffeine use and the risk of other adverse events, such as spontaneous abortion or growth retardation (Brent 2011; Jahanfar 2013). The half-life of caffeine is prolonged during the second and third trimesters of pregnancy and maternal and fetal exposure is also influenced by maternal smoking or drinking (Brent 2011; Koren 2000). Current guidelines recommend limiting caffeine intake from all sources to ≤200 mg/day (ACOG 2010).
Erythromycin Topical Gel 2%	B	Adverse events were not observed in animal reproduction studies. Erythromycin has been shown to cross the placenta following oral dosing. Refer to the Erythromycin (Systemic) monograph for details. The amount of erythromycin available systemically following topical application is considered to be very low (Akhavan, 2003). Systemic absorption would be required in order for erythromycin to cross the placenta and reach the fetus. Topical erythromycin may be used for the treatment of acne in pregnancy (Dréno, 2013; Eichenfield, 2013; Gollnick, 2003).
Erythromycin, Ophthalmic	B	Adverse events were not observed in animal reproduction studies. Erythromycin has been shown to cross the placenta following oral dosing. Refer to the Erythromycin (Systemic) monograph for details. The amount of erythromycin available systemically following ophthalmic application is not known. Systemic absorption would be required in order for erythromycin to cross the placenta and reach the fetus.
Escitalopram	C	Adverse events have been observed in animal reproduction studies. Escitalopram crosses the placenta and is distributed into the amniotic fluid. An increased risk of teratogenic effects, including cardiovascular defects, may be associated with maternal use of escitalopram or other SSRIs; however, available information is conflicting. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension

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		of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Escitalopram is the S-enantiomer of the racemic derivative citalopram; also refer to the Citalopram monograph. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of escitalopram may be altered. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Estradiol	X	Use is contraindicated during pregnancy. In general, the use of estrogen and progestin as in combination hormonal contraceptives has not been associated with teratogenic effects when inadvertently taken early in pregnancy.
Estradiol Cypionate	X	Use is contraindicated during pregnancy. In general, the use of estrogen and progestin as in combination hormonal contraceptives has not been associated with teratogenic effects when inadvertently taken early in pregnancy.
Ethambutol	C	Adverse events were observed in animal reproduction studies. Ophthalmic abnormalities have been reported in infants born to women receiving ethambutol as a component of antituberculous therapy. Due to the risk of untreated tuberculosis to the mother and fetus, treatment is recommended when the probability of maternal disease is moderate to high. Ethambutol is one of the recommended agents to treat tuberculosis in pregnant women (Nahid 2016).
Ethionamide		Ethionamide crosses the placenta. Use during pregnancy is not recommended (Blumberg 2003).
Etravirine	B	Etravirine has a variable (moderate to high) level of transfer across the human placenta. Only limited data has been reported to the antiretroviral pregnancy registry and information is insufficient to evaluate teratogenic effects in humans. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend use in antiretroviral-naive pregnant females. The pharmacokinetics of etravirine are not significantly altered in pregnancy and dosing adjustment is not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be

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		continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Famciclovir	B	Adverse events have not been observed in animal reproduction studies. Based on available data, use during pregnancy appears to be well tolerated (CDC [Workowski 2015]; HHS [opportunistic; adult] 2015). Health care providers are encouraged to enroll women exposed to famciclovir during pregnancy in the Famvir Pregnancy reporting system (888-669-6682).
Fenofibrate	C	Adverse events were observed in animal reproduction studies. Triglyceride and lipid concentrations increase during pregnancy as required for normal fetal development. When increases are greater than expected, supervised dietary intervention should be initiated. In women who develop very severe hypertriglyceridemia and are at risk for pancreatitis, use of fenofibrate beginning in the second trimester is one intervention that may be considered. Agents other than fenofibrate should be used for hypercholesterolemia (Avis 2009; Berglund 2012; Jacobson 2015; Wong 2015).
Ferrous Sulfate		Iron crosses the placenta and fetal stores are obtained from the mother (McArdle 2011). Iron requirements are increased in pregnant women compared to nonpregnant females (IOM 2001). All pregnant women should be tested for iron deficiency anemia and treated with supplemental iron if needed (ACOG 2008; CDC 1998). Untreated iron deficiency anemia during pregnancy may be associated with an increased risk of low birth weight, preterm delivery, and perinatal mortality, as well as postpartum depression in the mother and decreased mental functioning in the offspring (ACOG 2008; CDC 1998; IOM 2001). Treatment improves maternal hematologic status and neonatal birth weight (Haider 2013).
Filgrastim	C	Adverse events were observed in animal reproduction studies. Filgrastim has been shown to cross the placenta in humans. Information related to the use of granulocyte-colony stimulating factor (G-CSF) in pregnant patients with congenital, cyclic, or idiopathic neutropenia (Boxer 2015; Zeidler 2014) and G-CSF-induced allogeneic peripheral blood stem cells donation is limited (Leitner 2001; Shibata 2003). One review suggests avoiding use during the first trimester until additional outcome information is available (Pessach 2013). Data collected from the Severe Chronic Neutropenia International Registry (SCNIR) note dosing for chronic conditions may need adjusted in pregnant women; the lowest effective dose to maintain the absolute neutrophil count is recommended (Zeidler 2014).
Finasteride	X	Use is contraindicated in females of childbearing potential. Abnormalities of external male genitalia were reported in animal reproduction studies. Pregnant females are advised to avoid contact with crushed or broken tablets. Adequate contraception is recommended if used off-label in the management hirsutism in females associated with PCOS (ACOG 2009).
Fingolimod		Adverse events have been observed in animal reproduction studies. Elimination of fingolimod takes approximately 2 months; to avoid potential fetal harm, women of childbearing potential should use effective contraception to avoid pregnancy during and for 2 months after discontinuing treatment. Data collection to monitor pregnancy and infant outcomes following exposure to fingolimod is ongoing. Health care providers are encouraged to enroll pregnant women, or pregnant women may enroll themselves, in the Gilenya Pregnancy Registry (1-877-598-7237 or https://www.gilenyapregnancyregistry.com).
Fluconazole		Following exposure during the first trimester, malformations have been noted in humans when fluconazole was used in higher doses (≥400 mg/day) over extended periods of time (eg, for the duration of pregnancy or intermittently throughout pregnancy). Abnormalities reported include brachycephaly, abnormal facies, abnormal calvarial development, cleft palate, femoral bowing, thin ribs and long bones, arthrogryposis, and congenital heart disease. Use of lower doses (150 mg as a single

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		dose) suggest increased risks to the fetus, however, additional study is needed. Use of oral fluconazole for vaginal candidiasis is not recommended in pregnant women (HHS [OI adult 2017]; Workowski [CDC 2015]). Most azole antifungals, including fluconazole, are recommended to be avoided during the first trimester of pregnancy (IDSA [Pappas 2016]). The manufacturer recommends females of childbearing potential taking higher doses (≥400 mg/day) use effective contraception during therapy and for ~1 week after the final fluconazole dose.
Fludrocortisone	C	Animal reproduction studies have not been conducted with fludrocortisone; adverse events have been observed with corticosteroids in animal reproduction studies. Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts (Park-Wyllie 2000; Pradat 2003). Systemic corticosteroids may also influence fetal growth (decreased birth weight); however, information is conflicting (Lunghi 2010). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Leachman 2006; Lunghi 2010). Fludrocortisone may be used to treat women during pregnancy who require therapy for congenital adrenal hyperplasia or primary adrenal insufficiency (Bornstein 2016; Speiser 2010).
Flunisolide (Nasal)	C	Adverse effects were observed in some animal reproduction studies. Intranasal corticosteroids are recommended for the treatment of rhinitis during pregnancy; the lowest effective dose should be used (NAEPP, 2005; Wallace, 2008).
Fluocinonide	C	Adverse events have been observed with corticosteroids in animal reproduction studies. Topical corticosteroids are preferred over systemic for treating conditions, such as psoriasis or atopic dermatitis in pregnant women; high-potency corticosteroids are not recommended during the first trimester. Topical products are not recommended for extensive use, in large quantities, or for long periods of time in pregnant women (Bae 2011; Koutroulis 2011; Leachman 2006). Information specific to the use of fluocinonide during pregnancy is limited (Valkova 2006).
Fluoxetine	C	Adverse events have been observed in animal reproduction studies. Fluoxetine and its metabolite cross the human placenta. Available studies evaluating teratogenic effects following maternal use of fluoxetine in the first trimester have shown inconsistent results. An increased risk of cardiovascular events was observed in one study; however, no specific pattern was observed and a causal relationship has not been established. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments of fluoxetine to achieve euthymia. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45

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		years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Fluphenazine		Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician (ACOG 2008).
Fluphenazine Decanoate		Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician (ACOG 2008).
Fluticasone (Nasal)	C	Adverse events have been observed in some animal reproduction studies. Fluticasone can be detected in cord blood following maternal use via oral inhalation during pregnancy; one woman in the study was also using intranasal fluticasone (Battista 2016). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. Intranasal corticosteroids, including fluticasone, may be acceptable for the treatment of rhinitis during pregnancy when used at recommended doses (Lal 2016; Wallace 2008). Pregnant females adequately controlled on fluticasone may continue therapy; if initiating treatment during pregnancy, use of an agent with more data during pregnancy may be preferred (Namazy 2016; Wallace 2008).
Fluticasone Propionate Oral Inhaler		Fluticasone can be detected in cord blood following maternal use via oral inhalation during pregnancy (Battista 2016). Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, preeclampsia, preterm birth, low birth weight infants). Poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used asthma medications (ACOG 2008, GINA 2017). Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy (ACOG 2008, GINA 2017; Namazy 2016). Pregnant females adequately controlled on fluticasone for asthma may continue therapy; if initiating treatment during pregnancy, use of an agent with more data in pregnant females may be preferred (Namazy 2016).
Folic Acid		Water soluble vitamins cross the placenta (IOM 1998). Folate requirements increase during pregnancy (IOM 1998). Folate supplementation during the periconceptual period decreases the risk of neural tube defects. All females planning a pregnancy or who may potentially become pregnant should begin folic acid supplementation prior to conception. Higher doses are required in females at high risk of neural tube defects (ACOG 2017; USPSTF 2017). Folic acid is also indicated for the treatment of anemias due to folate deficiency in pregnant women.
Fosamprenavir		Fosamprenavir has a low level of transfer across the human placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic

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		ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines note there are insufficient data to recommend use as initial therapy in antiretroviral-naive pregnant females. However, if used in pregnant females, fosamprenavir may be given with standard ritonavir-boosted twice-daily dosing. Unboosted fosamprenavir and once-daily dosing with ritonavir are not recommended. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Furosemide	C	Adverse events have been observed in animal reproduction studies. Furosemide crosses the placenta (Riva 1978). Furosemide has been used to treat heart failure in pregnant women (ESC 2011; Johnson-Coyle 2012). Monitor fetal growth if used during pregnancy; may increase birth weight.
Gabapentin	C	Adverse events have been observed in animal reproduction studies. Gabapentin crosses the placenta. In a small study (n=6), the umbilical/maternal plasma concentration ratio was ~1.74. Neonatal concentrations declined quickly after delivery and at 24 hours of life were ~27% of the cord blood concentrations at birth (gabapentin neonatal half-life ~14 hours) (Ohman 2005). Pregnancy registry outcome data following maternal use of gabapentin during pregnancy is limited (Holmes 2012). Folic acid supplementation is recommended prior to and during pregnancy in women using gabapentin (Borgelt 2016; Picchietti 2015). Gabapentin is used off-label for the treatment of restless leg syndrome; however, current guidelines note there is insufficient evidence to recommend its use in pregnant women for this indication (Picchietti 2015). Pharmacological agents should not be used for the treatment of alcohol use disorder in pregnant women unless needed for the treatment of acute alcohol withdrawal or a coexisting disorder. Patients exposed to gabapentin during pregnancy are encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Gemfibrozil		Adverse events have been observed in animal reproduction studies. Gemfibrozil crosses the placenta (Tsai 2004). Triglyceride concentrations increase during pregnancy as required for normal fetal development. When increases are greater than expected, supervised dietary intervention should be initiated. In women who develop very severe hypertriglyceridemia and are at risk for pancreatitis, use of gemfibrozil beginning in the second trimester is one intervention that may be considered (Avis 2009; Berglund 2012; Jacobson 2015; Wong 2015).
Gentamicin Sulfate	D	[US Boxed Warning]: Aminoglycosides may cause fetal harm if administered to a pregnant woman. Gentamicin crosses the placenta. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of gentamicin may be altered (Popović 2007). Gentamicin use has been evaluated for various infections in pregnant women including the treatment of acute pyelonephritis (Jolley 2010) and as an alternative antibiotic for prophylactic use prior to cesarean delivery (Bratzler 2013).
Gentian Violet		

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Glatiramer Acetate	B	Adverse events were not observed in animal reproduction studies. Limited information is available related to the use of glatiramer acetate in pregnancy (Amato 2015; Fragoso 2014; Ghezzi 2013; Giannini 2012). Until additional information is available, consideration should be given to discontinuing treatment if a woman becomes pregnant, or 1 month prior to becoming pregnant in women with mild disease (Coyle, 2012; Ghezzi 2013; Houtchens, 2013; Lu, 2013).
Glipizide		Glipizide was found to cross the placenta in vitro (Elliott 1994). Severe hypoglycemia lasting 4 to 10 days has been noted in infants born to mothers taking a sulfonylurea at the time of delivery. In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy, maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013). Agents other than glipizide are currently recommended to treat diabetes in pregnant women (ADA 2018c). The manufacturer recommends if glipizide is used during pregnancy, it should be discontinued at least 1 month before the expected delivery date.
Glucagon, Human Recombinant		Adverse events have not been observed in animal reproduction studies.
Glyburide		Glyburide crosses the placenta. Some pharmacokinetic properties of glyburide may change during pregnancy (Hebert 2009). Severe hypoglycemia lasting 4 to 10 days has been noted in infants born to mothers taking a sulfonylurea at the time of delivery. Additional adverse maternal and fetal events have been noted in some studies and may be influenced by maternal glycemic control and/or differences in study design (Bertini 2005; Ekpebegh 2007; Joy 2012; Langer 2000; Langer 2005). In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy, maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013). Agents other than glyburide are currently recommended to treat diabetes in pregnant women (ADA 2018c). According to the manufacturer, if glyburide is used during pregnancy, it should be discontinued at least 2 weeks before the expected delivery date.
Glycerin suppository		Glycerin suppositories are generally considered safe to use during pregnancy (Cullen, 2007; Wald, 2003).
Griseofulvin Suspension	X	Teratogenic effects have been observed in animal reproduction studies. Griseofulvin crosses the placenta (Pacifici, 2006). Because adverse events have also been observed in humans (two cases of conjoined twins), use during pregnancy is contraindicated. Effective contraception should be used during therapy and for 1 month after therapy is discontinued in women of reproductive potential. Men should avoid fathering a child for at least 6 months after therapy.
Guaifenesin		When treatment for cough is needed during pregnancy, guaifenesin at standard OTC doses is generally considered acceptable. Some sources recommend use be reserved for significant maternal need; products containing alcohol should be avoided (Conover 2003; Ward 2005).
Haloperidol	C	Adverse events were observed in animal reproduction studies. Haloperidol crosses the placenta in humans (Newport 2007). Although haloperidol has not been found to be a major human teratogen, an association with limb malformations following first trimester exposure in humans cannot be ruled out (ACOG 2008; Diav-Citrin 2005). Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. If needed, the minimum effective maternal dose should be used in order to decrease the risk of EPS (ACOG 2008).

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Haloperidol Decanoate	C	Adverse events were observed in animal reproduction studies. Haloperidol crosses the placenta in humans (Newport 2007). Although haloperidol has not been found to be a major human teratogen, an association with limb malformations following first trimester exposure in humans cannot be ruled out (ACOG 2008; Diav-Citrin 2005). Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. If needed, the minimum effective maternal dose should be used in order to decrease the risk of EPS (ACOG 2008).
Heparin Sodium	C	Increased resorptions were observed in some animal reproduction studies. Heparin does not cross the placenta. Heparin may be used for the prevention and treatment of thromboembolism in pregnant women; however the use of low molecular weight heparin (LMWH) is preferred. Twice-daily heparin should be discontinued prior to induction of labor or a planned cesarean delivery. In pregnant women with mechanical heart valves, adjusted-dose LMWH or adjusted-dose heparin may be used throughout pregnancy or until week 13 of gestation when therapy can be changed to warfarin. LMWH or heparin should be resumed close to delivery. In women who are at a very high risk for thromboembolism (older generation prosthesis in mitral position or history of thromboembolism), warfarin can be used throughout pregnancy and replaced with LMWH or heparin near term; the use of low-dose aspirin is also recommended. When choosing therapy, fetal outcomes (ie, pregnancy loss, malformations), maternal outcomes (ie, VTE, hemorrhage), burden of therapy, and maternal preference should be considered (Guyatt 2012).Some products contain benzyl alcohol as a preservative; their use in pregnant women is contraindicated by some manufacturers; use of a preservative free formulation is recommended.
Hepatitis A Vaccine	C	Animal reproduction studies have not been conducted. The safety of vaccination during pregnancy has not been determined, however, the theoretical risk to the infant is expected to be low. Inactivated vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]).
Hepatitis B Vaccine	C	Animal reproduction studies have not been conducted. The ACIP recommends HBsAg testing for all pregnant females. Pregnancy itself is not a contraindication to vaccination; vaccination is recommended for those identified as being at risk for HBV infection (CDC/ACIP [Schillie 2018]).
Hepatitis B Vaccine, adjuvanted recombinant		The ACIP recommends HBsAg testing for all pregnant women (CDC/ACIP [Schillie 2018a]). When vaccination is clinically indicated, the ACIP recommends use of a different hepatitis B vaccine until additional information related to this formulation in pregnancy is available (CDC/ACIP [Schillie 2018b]). Females exposed to this vaccine during pregnancy are encouraged to enroll in the HEPLISAV-B Pregnancy Registry 1-844-443-7734.
Hydralazine	C	Adverse events have been observed in some animal reproduction studies. Hydralazine crosses the placenta (Lamont 1986; Liedholm 1982). Intravenous hydralazine is recommended for use in the management of acute onset, severe hypertension (systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg) with preeclampsia or eclampsia in pregnant and postpartum women (ACOG 2017). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for chronic hypertension in pregnancy is needed, other oral agents are preferred as initial therapy (ACOG 2013; Magee 2014).
Hydrochlorothiazide	B	Adverse events have not been observed in animal reproduction studies. Hydrochlorothiazide crosses the placenta. Maternal use may cause may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Use of thiazide diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother (ACOG 2013). Women who required thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use (ACOG 2013).

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Hydrocortisone Suppository	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014). The treatment of psoriasis in pregnancy is initiated with conservative treatment as in nonpregnant females. When a topical steroid is needed, low to moderate potency corticosteroids are preferred initially. High potency topical steroids should be used only when clearly needed and after the first trimester (Bae 2012).
Hydrocortisone, Topical	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014). The treatment of psoriasis in pregnancy is initiated with conservative treatment as in nonpregnant females. When a topical steroid is needed, low to moderate potency corticosteroids are preferred initially. High potency topical steroids should be used only when clearly needed and after the first trimester (Bae 2012).
Hydrogen Peroxide		
Hydroxychloroquine		Hydroxychloroquine can be detected in the cord blood at delivery in concentrations similar to those in the maternal serum (Costedoat-Chalumeau 2002). In animal reproduction studies with chloroquine, accumulation in fetal ocular tissues was observed and remained for several months following drug elimination from the rest of the body. Based on available human data, an increased risk of fetal ocular toxicity has not been observed following maternal use of hydroxychloroquine, but additional studies are needed to confirm (Osadchy 2011). Maternal lupus is associated with adverse maternal and fetal events; however, pregnancy outcomes may be improved if conception does not occur until the disease has been inactive for ≥6 months. Hydroxychloroquine is one of the medications recommended for the management of lupus and lupus nephritis in pregnant women. If pregnancy is detected during therapy, it should not be stopped (could precipitate a flare in maternal disease and exposure to the fetus will still continue for 6 to 8 weeks due to tissue binding) (Baer 2011; Bertsias 2012; Hahn 2012; Levy 2001). Maternal use of hydroxychloroquine may also decrease the incidence of cardiac malformations associated with neonatal lupus (Izmirly 2012). Malaria infection in pregnant women may be more severe than in nonpregnant women and has a high risk of maternal and perinatal morbidity and mortality. Therefore, pregnant women and women who are likely to become pregnant are advised to avoid travel to malaria-risk areas. Hydroxychloroquine is recommended as an alternative treatment of pregnant women for uncomplicated malaria in chloroquine-sensitive regions (refer to current guidelines) (CDC 2011). Women exposed to hydroxychloroquine for the treatment of rheumatoid arthritis or systemic lupus erythematosus during pregnancy may be enrolled in the Organization of Teratology Information Specialists (OTIS) Autoimmune Diseases Study pregnancy registry (877-311-8972).

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Hydroxyurea		Adverse effects have been observed in animal reproduction studies. Based on its mechanism of action, hydroxyurea may cause fetal harm if administered during pregnancy. Women of reproductive potential should be advised to avoid becoming pregnant during treatment (verify pregnancy status prior to starting hydroxyurea therapy) and should use effective contraception during and for at least 6 months after completion of therapy. Hydroxyurea use may damage spermatozoa and testicular tissue; males with female partners of reproductive potential should use effective contraception during and for at least 6 months (Siklos) or 1 year (Droxia, Hydrea) after therapy. Azoospermia or oligospermia (sometimes reversible) has been observed in male patients; counsel males of reproductive potential about sperm banking prior to therapy initiation.
Hydroxyzine		Use of hydroxyzine early in pregnancy is contraindicated. Hydroxyzine crosses the placenta. Possible withdrawal symptoms have been observed in neonates following chronic maternal use of hydroxyzine during pregnancy (Prenner 1977; Serreau 2005). Hydroxyzine is approved for pre- and postpartum adjunctive therapy to reduce opioid dosage, treat anxiety, and control emesis. Hydroxyzine may be used as an antipruritic if systemic therapy is needed in pregnant women (use caution late in pregnancy) (Murase 2014); although other agents may be preferred (Powell 2015; Zuberbier 2014). Antihistamines are not recommended for treatment of pruritus associated with intrahepatic cholestasis in pregnancy (Ambros-Rudolph 2011; Kremer 2014).
Ibuprofen		Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, nonclosure of the ductus arteriosus postnatally may occur and be resistant to medical management (Bermas 2014; Bloor 2013). Because NSAIDs cause premature closure of the ductus arteriosus, prescribing information for ibuprofen specifically states use should be avoided starting at 30-weeks gestation. Use of NSAIDs can be considered for the treatment of mild rheumatoid arthritis flares in pregnant women; however, use should be minimized or avoided early and late in pregnancy (Bermas 2014; Saavedra Salinas 2015). If treatment of migraine is needed in pregnant women, ibuprofen is preferred when an NSAID is required; however, other agents are recommended as initial therapy (Amundsen 2015). The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bloor 2013; Bermas 2014).
Imipramine		Animal reproduction studies are inconclusive. Congenital abnormalities have been reported in humans; however, a causal relationship has not been established. Tricyclic antidepressants may be associated with irritability, jitteriness, and convulsions (rare) in the neonate (Yonkers 2009). Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments late in pregnancy to achieve euthymia (Altshuler 1996). The ACOG recommends that therapy for depression during pregnancy be individualized; treatment should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician (ACOG 2008). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers

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		may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Immune Globulin	C	Animal reproduction studies have not been conducted. Immune globulins cross the placenta in increased amounts after 30 weeks gestation. Intravenous immune globulin has been recommended for use in fetal-neonatal alloimmune thrombocytopenia and pregnancy-associated ITP (ACOG 2016; Anderson, 2007; Neunert 2011); use is appropriate for ITP in cases refractory to corticosteroids, when side effects to corticosteroids are significant, or when a rapid increase in platelets is needed (ACOG 2016). Intravenous immune globulin is recommended to prevent measles in nonimmune women exposed during pregnancy (CDC 2013). May also be used in postexposure prophylaxis for rubella to reduce the risk of infection and fetal damage in exposed pregnant women who will not consider therapeutic abortion (per GamaSTAN S/D product labeling; use for postexposure rubella prophylaxis is not currently recommended [CDC 2013]). HyQvia: Women who become pregnant during treatment are encouraged to enroll in the HyQvia Pregnancy Registry (1-866-424-6724).
Indinavir	C	Placental passage in humans with unboosted dosing is minimal. No increased risk of overall birth defects has been observed according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperbilirubinemia may occur in neonates following in utero exposure to indinavir. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Humans Services (HHS) Perinatal HIV Guidelines do not recommend indinavir for initial therapy in antiretroviral-naive pregnant females due to concerns regarding maternal kidney stones or maternal hyperbilirubinemia; if used, must be given in combination with low-dose ritonavir boosting during pregnancy although the optimal dose has not yet been established. Plasma concentrations of unboosted indinavir are decreased during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Indomethacin	C (<30 weeks gestation); C/D (≥30 weeks gestation [manufact	Indomethacin crosses the placenta. Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, nonclosure of the ductus arteriosus postnatally may occur and be resistant to medical management (Bermas 2014; Bloor 2013). Because NSAIDs may cause premature

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	urer specific])	closure of the ductus arteriosus, product labeling for indomethacin specifically states use should be avoided starting at 30-weeks gestation. The clearance of indomethacin may be increased during pregnancy (Rytting 2014). NSAIDs have been used in the management of preterm labor. When choosing a specific agent, the benefits of the available tocolytic agents should be weighed against the potential risks for the individual woman (ACOG 171 2016). Use of NSAIDs can be considered for the treatment of mild rheumatoid arthritis flares in pregnant women; however, use should be minimized or avoided early and late in pregnancy (Bermas 2014; Saavedra Salinas 2015). The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bloor 2013; Bermas 2014).
Influenza Virus Vaccine	B/C (manufacturer specific	Inactivated influenza vaccine has not been shown to cause fetal harm when given to pregnant women, although information related to use in the first trimester is limited. Maternal influenza infection hypothetically may be associated with adverse fetal events. Even so, CDC recommends its use. Following maternal immunization with the inactivated influenza virus vaccine, vaccine-specific antibodies are observed in the newborn (CDC/ACIP [Grohskopf 2017]). Pregnant women are at an increased risk of complications from influenza infection. The inactivated influenza vaccine provides protective concentrations of antibodies in pregnant women and does not increase the risk for adverse maternal outcomes (CDC/ACIP [Grohskopf 2017]). Influenza vaccination with any licensed, recommended, age-appropriate vaccine is recommended for all women who are or will become pregnant during the influenza season and who do not otherwise have contraindications to the vaccine (CDC/ACIP [Grohskopf 2017]). Pregnant women should observe the same precautions as nonpregnant women to reduce the risk of exposure to influenza and other respiratory infections (CDC/HHS 2017). When vaccine supply is limited, focus on delivering the vaccine should be given to women who are pregnant or will be pregnant during the flu season, as well as mothers of newborns and contacts or caregivers of children <5 years of age (CDC/ACIP [Grohskopf 2017]). Vaccination may be done at any time during pregnancy (ACOG 2014). Women exposed to FluLaval Quadrivalent, or Fluarix Quadrivalent vaccine during pregnancy or their health care provider may contact the GlaxoSmithKline registry at 888-452-9622. Women exposed to Afluria Quadrivalent or Flucelvax Quadrivalent vaccine during pregnancy may contact the Seqirus registry at 855-358-8966 or via email at us.medicalinformation@seqirus.com. Health care providers may enroll women exposed to Fluzone Intradermal Quadrivalent or Fluzone Quadrivalent during pregnancy in the Sanofi Pasteur vaccination registry at 800-822-2463.
Insulin		* GLARGINE: In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013; Lambert 2013). Insulin requirements tend to fall during the first trimester of pregnancy and increase in the later trimesters, peaking at 28 to 32 weeks' gestation. Following delivery, insulin requirements decrease rapidly (ACOG 2005). Insulin therapy is the preferred treatment of type 1 and type 2 diabetes in pregnant women, as well as GDM when pharmacologic therapy is needed (ACOG 190 2018; ADA 2018c). Because insulin glargine has an increased affinity to the insulin-like growth factor (IGF-I) receptor, there are theoretical concerns that it may contribute to adverse events when used during pregnancy (Jovanovic 2007; Lambert 2013), although this has not been observed in available studies (Lambert 2013; Lepercq 2012; Pollex 2011). Women who are stable on insulin glargine prior to conception may continue it during pregnancy. Theoretical concerns of insulin glargine should be discussed prior to conception (Blumer 2013). * REGULAR: Animal reproduction studies have not been conducted. Exogenous

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		insulin bound to anti-insulin antibodies can be detected in cord blood (Menon 1990). In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy, maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013; Lambert 2013). Insulin requirements tend to fall during the first trimester of pregnancy and increase in the later trimesters, peaking at 28 to 32 weeks' gestation. Following delivery, insulin requirements decrease rapidly (ACOG 2005). Insulin therapy is the preferred treatment of type 1 and type 2 diabetes in pregnant women, as well as GDM when pharmacologic therapy is needed (ACOG 190 2018; ADA 2018c). Rapid acting insulins may be preferred over regular human insulin in women trying to conceive (Blumer 2013); however, there is no need to switch a pregnant woman who is well-controlled on injectable human insulin to a short acting analogue (Lambert 2013). Regular insulin is used intravenously for glycemic control during labor. * NPH: Animal reproduction studies have not been conducted; however, use provides maternal and fetal benefits. In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2017c; Kitzmiller 2008; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ACOG 2013; ADA 2017c; Blumer 2013; Kitzmiller 2008; Lambert 2013). Insulin therapy is the preferred treatment of type 1 and type 2 diabetes in pregnant women, as well as GDM when pharmacologic therapy is needed (ADA 2017c). Insulin requirements tend to fall during the first trimester of pregnancy and increase in the later trimesters, peaking at 28 to 32 weeks' gestation. Following delivery, insulin requirements decrease rapidly (ACOG 2005). NPH insulin may be used to treat diabetes in pregnant women (Blumer 2013; Kitzmiller 2008; Lambert 2013). * ASPART: Insulin aspart can be detected in cord blood (Pettitt 2007). In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and
Ipratropium		Adverse events have not been observed in animal reproduction studies.
Ipratropium/ Albuterol Oral Inhaler		* Ipratropium: Adverse events have not been observed in animal reproduction studies. * Albuterol: Adverse events have been observed in some animal reproduction studies. Albuterol crosses the placenta (Boulton 1997). Congenital anomalies (cleft palate, limb defects) have rarely been reported following maternal use during pregnancy. Multiple medications were used in most cases, no specific pattern of defects has been reported, and no relationship to albuterol has been established. The amount of albuterol available systemically following inhalation is significantly less in comparison to oral doses. Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, preeclampsia, preterm birth, low birth weight infants). Poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used asthma medications. Albuterol is the preferred short acting beta-agonist when treatment for asthma is needed during pregnancy (ACOG 2008; GINA 2016; NAEPP 2007). If high doses are required during labor and delivery, monitoring of glucose concentrations in the newborn for 24 hours is recommended, especially in preterm infants (GINA 2016). Albuterol may affect uterine contractility. Maternal pulmonary edema and other adverse events have been reported when albuterol was used for tocolysis. Albuterol is not approved for use as a tocolytic; use caution when needed to treat bronchospasm in pregnant women. Use of the injection (Canadian product; not available in the US.) is specifically contraindicated in women during the first or second trimester who may be at risk of threatened abortion.
Isoniazid	C	Adverse events were observed in some animal reproduction studies. Isoniazid crosses the human placenta. Due to the risk of tuberculosis to the fetus, treatment is recommended when the probability of maternal disease is moderate to high. Drug-

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		susceptible TB guidelines recommend isoniazid as part of the initial treatment regimen. Isoniazid is also recommended for the treatment of TB in pregnant women with HIV-coinfection. Pyridoxine supplementation is recommended (Nahid 2016). Due to biologic changes during pregnancy and early postpartum, pregnant women may have increased susceptibility to tuberculosis infection or reactivation of latent disease (Mathad 2012).
Isosorbide Dinitrate	C	Adverse events have been observed in some animal reproduction studies. Nitric oxide donors, such as isosorbide, have been evaluated for pre-eclampsia and cervical ripening; isosorbide dinitrate use in these conditions is not currently recommended (Kalidindi 2012; Ramirez 2011).
Isosorbide Mononitrate	B	Adverse events have been observed in some animal reproduction studies. Nitric oxide donors, such as isosorbide, have been evaluated for pre-eclampsia and cervical ripening; isosorbide mononitrate use in these conditions is not currently recommended (Kalidindi 2012; Ramirez 2011).
Ivermectin		Adverse events have been observed in animal reproduction studies. Although use in pregnancy is likely low risk, other agents are currently recommended for the treatment of pediculosis pubis or scabies in pregnant women (CDC [Workowski 2015]).
Ketoconazole		Adverse events have been observed in animal reproduction studies with oral ketoconazole. Ketoconazole is not detectable in the plasma following chronic use of the shampoo.
Ketorolac Injection	C	[US Boxed Warning]: Ketorolac is contraindicated during labor and delivery (may inhibit uterine contractions and adversely affect fetal circulation). Ketorolac crosses the placenta (Walker 1988). Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, nonclosure of the ductus arteriosus postnatally may occur and be resistant to medical management (Bermas 2014; Bloor 2013). Because they may cause premature closure of the ductus arteriosus, the use of NSAIDs late in pregnancy should be avoided. The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bermas 2014; Bloor 2013).
Ketorolac Ophthalmic	C	Adverse events have been observed in animal reproduction studies. Systemic exposure is decreased with ophthalmic administration (concentrations are ~4% to 8% of the minimum plasma concentration following an oral dose). If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples 1988). However, because it may cause prenatal constriction of the ductus arteriosus, the manufacturer recommends that the use of ketorolac ophthalmic drops late in pregnancy be avoided.
Ketotifen		Topical ocular administration has not been studied.
Labetalol	C	Adverse events have been observed in some animal reproduction studies. Labetalol crosses the placenta and can be detected in cord blood and infant serum after delivery (Haraldsson 1989; Rogers 1990). Fetal/neonatal bradycardia, hypoglycemia, hypotension, and/or respiratory depression have been observed following in utero exposure to labetalol. Reduced birth weight has also been observed following in utero exposure to beta-blockers as a class; adequate facilities for monitoring infants at birth is generally recommended. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother. Oral labetalol is considered an appropriate agent for the treatment of chronic hypertension in pregnancy (ACOG 2013; Magee 2014). Intravenous labetalol is recommended for use in the management of acute onset, severe hypertension (systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg) with preeclampsia or eclampsia in pregnant and postpartum women.

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		In general, avoid use of labetalol in women with asthma or heart failure (ACOG 2015; Magee 2014).
Lactated Ringers		
Lactobacillus		
Lactulose	B	Adverse events have not been observed in animal reproduction studies. Lactulose is poorly absorbed following oral administration. Use of dietary fiber or bulk-forming laxatives along with increased fluid intake is generally considered first line therapy for treating constipation in pregnant women. Short-term use of lactulose is also considered to be safe/low risk when therapy is needed; however, side effects may limit its use (Cullen, 2007; Mahadevan, 2006; Prather, 2004; Wald, 2003).
Lamivudine		Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Lamotrigine	C	Adverse events have been observed in animal reproduction studies. Lamotrigine crosses the human placenta and can be measured in the plasma of exposed newborns (Harden and Pennell 2009; Ohman 2000). An overall increase in the risk for major congenital malformations has not been observed in available studies; however, an increased risk for cleft lip or cleft palate has not been ruled out (Cunnington 2011; Hernández-Díaz 2012; Holmes 2012). An increased risk of malformations following maternal lamotrigine use may be associated with larger doses (Cunnington 2007; Tomson 2011). Polytherapy may increase the risk of congenital malformations; monotherapy with the lowest effective dose is recommended (Harden and Meader 2009). Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments of lamotrigine in order to maintain clinical response; monitoring during pregnancy should be considered (Harden and Pennell 2009). For women with epilepsy who are planning a pregnancy in advance, baseline serum concentrations should be measured once or twice prior to pregnancy during a period when seizure control is optimal. Monitoring can then be continued up to once a month during pregnancy and every second day during the first week postpartum (Patsalos 2008). In women taking lamotrigine who are trying to avoid pregnancy, potentially significant interactions may exist with hormone-containing contraceptives; consult drug interactions database for more detailed information. Pregnancy registries are available for women who have been exposed to lamotrigine. Patients may enroll themselves in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling (888) 233-2334. Additional information is available at www.aedpregnancyregistry.org.
Lanthanum Carbonate	C	Adverse effects have been observed in some animal reproduction studies. The effect on absorption of vitamins and nutrients has not been studied. Lanthanum is not recommended for use during pregnancy.
Latanoprost	C	Adverse events were observed in animal reproduction studies at maternally toxic doses
Leflunomide		[US Boxed Warning]: Leflunomide is contraindicated in pregnant women because of the potential for fetal harm. Adverse events were observed in animal reproduction

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		studies with doses lower than the expected human exposure. Exclude pregnancy before the start of treatment in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment and during an accelerated elimination procedure after treatment is discontinued. Discontinue therapy and use an accelerated elimination procedure if pregnancy occurs during treatment. Women of reproductive potential should not receive therapy until pregnancy has been excluded, they have been counseled concerning fetal risk, and reliable contraceptive measures have been confirmed. Following treatment, pregnancy should be avoided until undetectable serum concentrations (<0.02 mg/L) are verified. This may be accomplished by the use of an enhanced drug elimination procedure using cholestyramine. Serum concentrations <0.02 mg/L should be verified by 2 separate tests performed at least 14 days apart. If serum concentrations are >0.02 mg/L, additional cholestyramine treatment should be considered. As an alternative to cholestyramine, the Canadian labeling recommends that activated charcoal may be used to enhance drug elimination. It is not known if males taking leflunomide may contribute to fetal toxicity. Males taking leflunomide who wish to father a child should consider discontinuing therapy and using the cholestyramine procedure to eliminate the medication. The Canadian labeling recommends avoiding use in males capable of fathering a child and who are not using reliable contraception during and for a total of 2 years after treatment unless an elimination procedure is used; for men receiving treatment and desiring to father a child, serum concentrations of the active metabolite should be verified by 2 separate tests performed at least 14 days apart. If levels <0.02 mg/L are confirmed with the second test, an additional waiting period of 3 months is recommended. Health care providers are encouraged to enroll women exposed to leflunomide during pregnancy in the Pregnancy Registry (877-311-8972 or http://www.pregnancystudies.org/participate-ina-study/).
Leucovorin Calcium	C	Animal reproduction studies have not been conducted. Leucovorin is a biologically active form of folic acid. Adequate amounts of folic acid are recommended during pregnancy. Refer to Folic Acid monograph.
Levetiracetam	C	Adverse effects were observed in animal reproduction studies. Levetiracetam crosses the placenta and can be detected in the newborn following delivery (Johannessen 2005; Lopez-Fraile 2009; Tomson 2007). An increase in the overall rate of major congenital malformations has not been observed following maternal use of levetiracetam. Available studies have not been large enough to determine if there is an increased risk of specific birth defects (Hernandez-Diaz 2012; Mawhinney 2013; Mølgaard-Nielsen 2011; Vajda 2012). In general, maternal polytherapy with antiepileptic drugs may increase the risk of congenital malformations; monotherapy with the lowest effective dose is recommended. Newborns of women taking antiepileptic medications may be at an increased risk of SGA and a 1 minute APGAR score <7 (Harden a2009). Plasma concentrations of levetiracetam gradually decrease during pregnancy, especially during the third trimester, due to physiologic changes which occur; patients should be monitored during pregnancy and postpartum. A registry is available for women exposed to levetiracetam during pregnancy: Pregnant women may enroll themselves into the North American Antiepileptic Drug (AED) Pregnancy Registry (888-233-2334 or http://www.aedpregnancyregistry.org/).
Levofloxacin Oral Solution	C	Adverse events have been observed in some animal reproduction studies. Levofloxacin crosses the placenta and can be detected in the amniotic fluid and cord blood (Ozyüncü 2010a; Ozyüncü 2010b). Information specific to levofloxacin use during pregnancy is limited (Padberg 2014).
Levonorgestrel		Not for use in women confirmed to be pregnant. Adverse effects to the mother or fetus have not been observed following inadvertent exposure during pregnancy (Curtis 2016b). Levonorgestrel may be used as an emergency contraceptive in women with contraindications to conventional oral contraceptive agents (eg, cardiovascular disease, migraines, liver disease) (ACOG 2015; Curtis 2016b). A rapid return of fertility is expected following use for emergency contraception; routine contraceptive measures should be initiated or continued following use to ensure ongoing prevention of

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		pregnancy. Any regular contraceptive method can be started immediately after levonorgestrel; however, a barrier method (or abstinence from sexual intercourse) is also needed for 7 days (ACOG 2015; Curtis 2016a).
Levonorgestrel IUD		Not for use in women confirmed to be pregnant. Adverse effects to the mother or fetus have not been observed following inadvertent exposure during pregnancy (Curtis 2016b). Levonorgestrel may be used as an emergency contraceptive in women with contraindications to conventional oral contraceptive agents (eg, cardiovascular disease, migraines, liver disease) (ACOG 2015; Curtis 2016b). A rapid return of fertility is expected following use for emergency contraception; routine contraceptive measures should be initiated or continued following use to ensure ongoing prevention of pregnancy. Any regular contraceptive method can be started immediately after levonorgestrel; however, a barrier method (or abstinence from sexual intercourse) is also needed for 7 days (ACOG 2015; Curtis 2016a).
Levonorgestrel/ Ethinyl estradiol	X	Use is contraindicated in pregnant women. Combination hormonal contraceptives are used to prevent pregnancy; treatment should be discontinued if pregnancy occurs. In general, the use of combination hormonal contraceptives, when inadvertently used early in pregnancy, have not been associated adverse fetal or maternal effects (Curtis 2016b). Some manufacturers recommend waiting at least 4 to 6 weeks postpartum before starting this combination. Due to the increased risk of venous thromboembolism (VTE) postpartum, combination hormonal contraceptives should not be started in any woman <21 days following delivery. The risk decreases to baseline by postpartum day 42. Use of combination hormonal contraceptives in women between 21 and 42 days after delivery should take into consideration the individual woman's risk factors for VTE (eg, age ≥35 years, previous VTE, thrombophilia, immobility, preeclampsia, transfusion at delivery, cesarean delivery, peripartum cardiomyopathy, BMI ≥30 kg/m2, postpartum hemorrhage, smoking) (Curtis 2016b). When used for emergency contraception, a barrier contraceptive is recommended immediately following use. Any regular (nonemergency) contraceptive method can be started immediately after combined estrogen/progestin emergency contraception; however, a barrier method (or abstinence from sexual intercourse) is also needed for 7 days (ACOG 2015; Curtis 2016a).
Levothyroxine	A	Endogenous thyroid hormones minimally cross the placenta; the fetal thyroid becomes active around the end of the first trimester. Levothyroxine has not been shown to increase the risk of congenital abnormalities. Uncontrolled maternal hypothyroidism may result in adverse neonatal outcomes (eg, premature birth, low birth weight, and respiratory distress) and adverse maternal outcomes (eg, spontaneous abortion, pre-eclampsia, stillbirth, and premature delivery). To prevent adverse events, normal maternal thyroid function should be maintained prior to conception and throughout pregnancy. Thyroid function should be monitored every 4 weeks during the first half of pregnancy, at least once between weeks 26 and 32, and ~6 weeks postpartum. Levothyroxine is considered the treatment of choice for the control of hypothyroidism during pregnancy. Due to alterations of endogenous maternal thyroid hormones, the levothyroxine dose may need to be increased during pregnancy and the dose usually needs to be decreased after delivery (Stagnaro-Green 2011).
Lidocaine/Epinephrine	B	Adverse events have not been observed in animal reproduction studies. See individual agents.
Lidocaine Hydrochloride	B	Adverse events were not observed in animal reproduction studies. Lidocaine and its metabolites cross the placenta and can be detected in the fetal circulation following injection (Cavalli 2004; Mitani 1987). Adverse reactions in the fetus/neonate may affect the CNS, heart, or peripheral vascular tone. Fetal heart monitoring is recommended. Lidocaine injection is approved for obstetric analgesia. Lidocaine administered by local infiltration is used to provide analgesia prior to episiotomy and during repair of obstetric lacerations (ACOG 2002). Administration by the perineal route may result in greater absorption than administration by the epidural route (Cavalli 2004). Cumulative exposure from all routes of administration should be considered. Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support

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		guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015).
Lisinopril		[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. Lisinopril crosses the placenta (Bhatt-Mehta 1993; Filler 2003). Drugs that act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. The use of these drugs in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. Teratogenic effects may occur following maternal use of an ACE inhibitor during the first trimester, although this finding may be confounded by maternal disease. Because adverse fetal events are well documented with exposure later in pregnancy, ACE inhibitor use in pregnant women is not recommended (Seely 2014; Weber 2014). Infants exposed to an ACE inhibitor in utero should be monitored for hyperkalemia, hypotension, and oliguria. Oligohydramnios may not appear until after irreversible fetal injury has occurred. Exchange transfusions or dialysis may be required to reverse hypotension or improve renal function, although data related to the effectiveness in neonates is limited. Chronic maternal hypertension itself is also associated with adverse events in the fetus/infant and mother. ACE inhibitors are not recommended for the treatment of uncomplicated hypertension in pregnancy (ACOG 2013) and they are specifically contraindicated for the treatment of hypertension and chronic heart failure during pregnancy by some guidelines (Regitz-Zagrosek 2011). In addition, ACE inhibitors should generally be avoided in women of reproductive age (ACOG 2013). If treatment for hypertension or chronic heart failure in pregnancy is needed, other agents should be used (ACOG 2013; Regitz-Zagrosek 2011).
Lisinopril/ Hydrochlorothiazide	D	[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. Lisinopril crosses the placenta (Bhatt-Mehta 1993; Filler 2003).
Lithium Carbonate		Adverse events have been observed in animal reproduction studies. Lithium crosses the placenta in concentrations similar to those in the maternal plasma (Newport 2005). Cardiac malformations in the infant, including Ebstein anomaly, are associated with use of lithium during the first trimester of pregnancy. Other adverse events including polyhydramnios, fetal/neonatal cardiac arrhythmias, hypoglycemia, diabetes insipidus, changes in thyroid function, premature delivery, floppy infant syndrome, or neonatal lithium toxicity are associated with lithium exposure when used later in pregnancy (ACOG 2008). The incidence of adverse events may be associated with higher maternal doses (Newport 2005). Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments of lithium to achieve euthymia and avoid toxicity (ACOG 2008; Grandjean 2009; Yonkers 2011). For planned pregnancies, use of lithium during the first trimester should be avoided if possible (Grandjean 2009). If lithium is needed during pregnancy, the minimum effective dose should be used, maternal serum concentrations should be monitored, and consideration should be given to start therapy after the period of organogenesis; lithium should be suspended 24 to 48 hours prior to delivery or at the onset of labor when delivery is spontaneous, then restarted when the patient is medically stable after delivery (ACOG 2008; Grandjean 2009; Newport 2005). Fetal echocardiography should be considered if first trimester exposure occurs (ACOG 2008).
Loperamide Hydrochloride	C	Adverse effects have not been observed in animal reproduction studies. Information related to loperamide use in pregnancy is limited and data is conflicting (Einarson 2000; Källén 2008). For acute diarrhea in pregnant women, some clinicians recommend oral rehydration and dietary changes; loperamide in small amounts may be used only if symptoms are disabling (Wald 2003).
Lopinavir/ Ritonavir		Lopinavir has a low level of transfer across the human placenta; fetal exposure is increased with ritonavir. Based on information collected by the Antiretroviral Pregnancy Registry, an increased risk of teratogenic effects has not been observed in humans. Maternal antiretroviral therapy (ART) may increase the risk of preterm

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		delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. Although there are an abundance of data related to the use of lopinavir/ritonavir during pregnancy, the Health and Human Services (HHS) Perinatal HIV Guidelines consider lopinavir/ritonavir to be an alternative protease inhibitor for initial therapy in antiretroviral-naive pregnant women due to the need for twice daily dosing and increased incidence of nausea. Lopinavir/ritonavir is not recommended for use in pregnant women with lopinavir-associated resistance substitutions. In addition, once-daily dosing is not recommended during pregnancy and use of the oral solution should be avoided (due to alcohol and propylene glycol content). Pharmacokinetic studies suggest that standard dosing during pregnancy may provide decreased plasma concentrations; dose adjustments are required in women during the second and third trimesters of pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Loratadine		Maternal use of loratadine has not been associated with an increased risk of major malformations. Loratadine may be used for the treatment of allergic rhinitis and urticaria during pregnancy (NAEPP 2005; Wallace 2008; Zuberbier 2014).
Lorazepam		Lorazepam and its metabolite cross the human placenta. Teratogenic effects in humans have been observed with some benzodiazepines (including lorazepam); however, additional studies are needed. The incidence of premature birth and low birth weights may be increased following maternal use of benzodiazepines; hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. Neonatal withdrawal symptoms may occur within days to weeks after birth and “floppy infant syndrome” (which also includes withdrawal symptoms) have been reported with some benzodiazepines (including lorazepam). Elimination of lorazepam in the newborn infant is slow; following in utero exposure, term infants may excrete lorazepam for up to 8 days (Bergman 1992; Iqbal 2002; Wikner 2007).
Losartan	D	[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. The use of drugs which act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. Use is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. The exposed fetus should be monitored for fetal growth, amniotic fluid volume, and organ formation. Infants exposed in utero should be monitored for hyperkalemia, hypotension, and oliguria (exchange transfusions or dialysis may be needed). These adverse events are generally associated with maternal use in the second and third trimesters. Untreated

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		chronic maternal hypertension is also associated with adverse events in the fetus, infant, and mother. The use of angiotensin II receptor blockers is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential (ACOG, 2013).
Losartan/ Hydrochlorothiazide		Losartan: [US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. The use of drugs which act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. Use is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. The exposed fetus should be monitored for fetal growth, amniotic fluid volume, and organ formation. Infants exposed in utero should be monitored for hyperkalemia, hypotension, and oliguria (exchange transfusions or dialysis may be needed). These adverse events are generally associated with maternal use in the second and third trimesters. Untreated chronic maternal hypertension is also associated with adverse events in the fetus, infant, and mother. The use of angiotensin II receptor blockers is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential (ACOG, 2013). Hydrochlorothiazide: Adverse events have not been observed in animal reproduction studies. Hydrochlorothiazide crosses the placenta. Maternal use may cause may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Use of thiazide diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother (ACOG 2013). Women who required thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use (ACOG 2013).
Lurasidone		Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. Lurasidone may cause hyperprolactinemia, which may decrease reproductive function in both males and females. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited and routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to a typical antipsychotic that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). Health care providers are encouraged to enroll women 18 to 45 years of age exposed to lurasidone during pregnancy in the Atypical Antipsychotics Pregnancy Registry (866-961-2388 or http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry).
Magnesium Citrate		Magnesium crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Idama 1998; Osada 2002). The American Gastroenterological Association considers the use of magnesium citrate as a laxative to be low risk in pregnancy, but long term use should be avoided (not the preferred treatment of chronic constipation) (Mahadevan 2006).
Magnesium Hydroxide		Magnesium crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Idama 1998; Osada 2002). Magnesium hydroxide is considered to be acceptable for treating heartburn of pregnancy, as well as aspiration prophylaxis during labor (Richter [ACG 2007])
Magnesium Oxide		Magnesium crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Idama 1998; Osada 2002)

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Magnesium Sulfate	D	Magnesium crosses the placenta; serum concentrations in the fetus are similar to those in the mother (Idama 1998; Osada 2002). Continuous maternal use for >5 to 7 days (in doses such as those used for preterm labor, an off-label use) may cause fetal hypocalcemia and bone abnormalities, as well as fractures in the neonate. Magnesium sulfate injection is used for the prevention and treatment of seizures in pregnant or postpartum women with severe pre-eclampsia or eclampsia (ACOG 2013; ACOG 652 2016). Magnesium sulfate may also be used prior to early preterm delivery for neuroprotection to reduce the risk of cerebral palsy (ACOG 455 2010; ACOG 652 2016; Reeves 2011); specific regimens are not available, but treatment may be of benefit when birth is anticipated before 32 weeks gestation (ACOG 171 2016; ACOG 172 2016; ACOG 652 2016). Tocolytics may be used for the short-term (48 hour) prolongation of pregnancy to allow for the administration of antenatal steroids and should not be used prior to fetal viability or when the risks of use to the fetus or mother are greater than the risk of preterm birth; maintenance therapy with tocolytics is ineffective and not recommended. Magnesium sulfate can be used up to 48 hours in women at risk of delivery within 7 days; however, it is not the preferred tocolytic (ACOG 171 2016; ACOG 652 2016). Magnesium sulfate injection may be used in conjunction with other tocolytics for neuroprotection; however, an increased risk of maternal complications may be observed when used in combination with some tocolytic agents (ACOG 171 2016). Magnesium toxicity should be suspected in pregnant women receiving magnesium in respiratory and/or cardiac arrest. Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Jeejeebhoy [AHA] 2015).
Maraviroc		Maraviroc has moderate transfer across the human placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines note there are insufficient data to recommend use of maraviroc as initial therapy in antiretroviral-naive pregnant females. Dose adjustments are not needed in pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Measles/ Mumps/ Rubella Vaccine	C	Animal reproduction studies have not been conducted. It is not known whether this vaccine can cause fetal harm or affect reproduction capacity. Based on information collected following inadvertent administration during pregnancy, adverse events have not been observed following use of rubella vaccine. However, theoretical risks cannot

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		be ruled out; use of this vaccine is contraindicated in pregnant females and should not be administered to women trying to conceive. The manufacturer recommends that pregnancy be avoided for 3 months after vaccine administration. The Advisory Committee on Immunization Practices (ACIP) recommends that pregnancy should be avoided for 28 days following vaccination. The risk of congenital rubella syndrome following vaccination is significantly less than the risk associated following infection; therefore, inadvertent administration of MMR during pregnancy is not considered an indication to terminate pregnancy. Adverse consequences of natural infection in unvaccinated pregnant women have been reported. Measles infection during pregnancy may increase the risk of premature labor, preterm delivery, spontaneous abortion and low birth weights. Rubella infection during the first trimester may lead to miscarriages, stillbirths, and congenital rubella syndrome (includes auditory, ophthalmic, cardiac and neurologic defects; intrauterine and postnatal growth retardation); fetal rubella infection can occur during any trimester of pregnancy. Maternal mumps infection during the first trimester may increase the risk of spontaneous abortion or intrauterine fetal death. Sterility in males and infertility in prepubescent females may also occur with natural mumps infection. Prenatal screening is recommended for all pregnant women who lack evidence of rubella immunity. Women of childbearing age without documentation of rubella vaccination or serologic evidence of immunity should be vaccinated (for women of childbearing potential, birth prior to 1957 is not acceptable evidence of immunity to rubella). Women who are pregnant should be vaccinated upon completion or termination of pregnancy, prior to discharge. Household contacts of pregnant women may be vaccinated (CDC/ACIP [McLean, 2013]).
Measles/ Mumps/ Rubella/ Varicella Vaccine		Animal reproduction studies have not been conducted. Use is contraindicated in pregnant females and pregnancy should be avoided for 3 months (per manufacturer labeling) following vaccination. The ACIP and manufacturer of Priorix-Tetra (Canadian product) recommends that pregnancy should be avoided for 1 month following vaccination with any of the individual components of this vaccine. Any exposures to the vaccine during pregnancy or within 3 months prior to pregnancy should be reported to the manufacturer (Merck & Co, 877-888-4231) or to VAERS (800-822-7967) as suspected adverse reactions. Refer to the Varicella Virus Vaccine monograph and the Measles, Mumps, and Rubella Virus Vaccine monograph for additional information.
Meclizine	B	Adverse events have been observed in animal reproduction studies. Based on epidemiologic studies, maternal meclizine use has generally not resulted in an increased risk of fetal abnormalities.
Medroxy-progesterone		Most products are contraindicated in women who are pregnant, suspected to be pregnant or as a diagnostic test for pregnancy. In general, there is not an increased risk of birth defects following inadvertent use of the injectable medroxyprogesterone acetate (MPA) contraceptives early in pregnancy. Hypospadias has been reported in male babies and clitoral enlargement and labial fusion have been reported in female babies exposed to MPA during the first trimester of pregnancy. High doses impair fertility. Ectopic pregnancies have been reported with use of the MPA contraceptive injection. Median time to conception/return to ovulation following discontinuation of MPA contraceptive injection is 10 months following the last injection and is unrelated to the duration of use.
Megestrol Acetate	D (tablet) X (suspension)	Adverse events were demonstrated in animal reproduction studies. May cause fetal harm if administered to a pregnant woman. Use during pregnancy is contraindicated (suspension) and appropriate contraception is recommended in women who may become pregnant. In clinical studies, megestrol was shown to cause breakthrough vaginal bleeding in women.
Meloxicam		Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, non-closure of the ductus arteriosus postnatally may occur and be

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		resistant to medical management (Bermas 2014; Bloor 2013). Because NSAIDs may cause premature closure of the ductus arteriosus, product labeling for meloxicam specifically states use should be avoided starting at 30-weeks gestation. Use of NSAIDs can be considered for the treatment of mild rheumatoid arthritis flares in pregnant women; however, use should be minimized or avoided early and late in pregnancy (Bermas 2014; Saavedra Salinas 2015). The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bermas 2014; Bloor 2013).
Meningococcal Conjugate Vaccine	B	Adverse events were not observed in animal reproduction studies conducted with Menactra. Limited information is available following inadvertent use of Menactra during pregnancy (Zheteyeva 2013). Patients should contact the Sanofi Pasteur Inc. vaccine registry at 1-800-822-2463 if they are pregnant or become aware they were pregnant at the time of Menactra vaccination. Adverse events were not observed in animal reproduction studies conducted with Menveo. Limited information is available following inadvertent use of Menveo during pregnancy. Patients should contact GlaxoSmithKline at 1-877-413-4759 if they are pregnant or become aware they were pregnant at the time of Menveo vaccination. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]). Pregnancy should not preclude vaccination if indicated (CDC/ACIP [Cohn 2013]).
Mepivacaine	C	Animal reproduction studies have not been conducted. Mepivacaine has been used in obstetrical analgesia.
Mercaptopurine		May cause fetal harm if administered during pregnancy. Case reports of fetal loss have been noted with mercaptopurine administration during the first trimester; adverse effects have also been noted with second and third trimester use. Women of reproductive potential should avoid becoming pregnant during treatment.
Mesalamine	B	Adverse events have not been observed in animal reproduction studies. Mesalamine is known to cross the placenta. An increased rate of congenital malformations has not been observed in human studies. Preterm birth, still birth and decreased birth weight have been observed; however, these events may also be due to maternal disease. Dibutyl phthalate (DBP) may be an inactive ingredient in the enteric coating of some products (eg Asacol, Asacol HD); adverse effects in male rats were noted at doses greater than the recommended human dose. Refer to product labeling for current formulation. When treatment for inflammatory bowel disease is needed during pregnancy, mesalamine may be used, although products with DBP should be avoided (Habal 2012; Mottet 2009).
Metformin	B	Metformin has been found to cross the placenta in concentrations which may be comparable to those found in the maternal plasma. Pharmacokinetic studies suggest that clearance of metformin may increase during pregnancy and dosing may need adjusted in some women when used during the third trimester (Charles 2006; de Oliveira Baraldi 2011; Eyal 2010; Gardiner 2003; Hughes 2006; Vanky 2005). An increased risk of birth defects or adverse fetal/neonatal outcomes has not been observed following maternal use of metformin for GDM or type 2 diabetes when glycemic control is maintained (Balani 2009; Coetzee 1979; Coetzee 1984; Ekpebegh 2007; Niromanesh 2012; Rowan 2008; Rowan 2010; Tertti 2008). However, available guidelines note that long-term safety data is not available (ACOG 190 2018; ADA 2018c) In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013). Agents other than metformin are currently recommended to treat diabetes in pregnant women (ADA 2018c). However metformin may be used as an alternative agent in some patients requiring therapy for gestational diabetes mellitus (ACOG 190 2018).

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Methimazole	D	Methimazole crosses the placenta. Birth defects have been observed in neonates exposed to maternal methimazole in the first trimester of pregnancy and include anomalies of the upper gastrointestinal tract (esophageal atresia or tracheoesophageal fistula), respiratory tract (choanal atresia), skin (aplasia cutis), and facial dysmorphism. Additional abdominal wall defects (umbilicocele), ventricular septal defects, and defects of the eye and urinary system have also been reported (Alexander 2017). Hypothyroidism may occur in the newborn. Uncontrolled maternal hyperthyroidism may result in adverse neonatal and maternal outcomes. Antithyroid drugs are the treatment of choice for the control of hyperthyroidism during pregnancy, although recommendations for specific agents vary by guideline (ACOG 2015; Alexander 2017; De Groot 2012). Dose requirements of methimazole may be decreased as pregnancy progresses. To prevent adverse pregnancy outcomes, maternal TT4/FT4 should be at or just above the pregnancy specific upper limit of normal (Alexander 2017).
Methocarbamol	C	Animal reproduction studies have not been conducted. The manufacturer notes that fetal and congenital abnormalities have been reported following in utero exposure (Hall 1982).
Methotrexate	X	[US Boxed Warning]: Some products are contraindicated in pregnant women. Methotrexate has been reported to cause fetal death and/or congenital abnormalities. Methotrexate is not recommended for women of childbearing potential unless there is clear medical evidence that the benefits can be expected to outweigh the considered risks. Pregnant women with psoriasis or rheumatoid arthritis should not receive methotrexate. Studies in animals and pregnant women have shown evidence of fetal abnormalities; therefore, the manufacturer classifies methotrexate as pregnancy category X (for psoriasis or RA). A pattern of congenital malformations associated with maternal methotrexate use is referred to as the aminopterin/methotrexate syndrome. Features of the syndrome include CNS, skeletal, and cardiac abnormalities. Low birth weight and developmental delay have also been reported. The use of methotrexate may impair fertility and cause menstrual irregularities or oligospermia during treatment and following therapy. It is not known if fertility impairment is reversible. Methotrexate is approved for the treatment of trophoblastic neoplasms (gestational choriocarcinoma, chorioadenoma destruens, and hydatidiform mole) and has been used for the medical management of ectopic pregnancy and the medical management of abortion. Pregnancy should be excluded prior to therapy in women of childbearing potential. Use for the treatment of neoplastic diseases only when the potential benefit to the mother outweighs the possible risk to the fetus. Pregnancy should be avoided for ≥3 months following treatment in male patients and at least 6 months and ≥1 ovulatory cycle in female patients. A registry is available for pregnant women exposed to autoimmune medications including methotrexate. For additional information contact the Organization of Teratology Information Specialists, OTIS Autoimmune Diseases Study, at 877-311-8972.
Methyl Salicylate/ Menthol		There are no adequate or well controlled studies in pregnant women. Use of the topical patch during the last 3 months of pregnancy is contraindicated by the manufacturer due to increased risk to the fetus and increased risk of complications during delivery.
Methyldopa	B/C (injectable)	Methyldopa crosses the placenta and appears in cord blood. Available data show use during pregnancy does not cause fetal harm and improves fetal outcomes. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for chronic hypertension during pregnancy is needed, methyldopa is one of the preferred agents. If an injectable agent is needed for the urgent control of acute hypertension in pregnancy, other agents are preferred (ACOG 2013).
Methylprednisolone		Methylprednisolone crosses the placenta (Anderson 1981). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest effective dose for

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		the shortest duration of time, avoiding high doses during the first trimester (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant women, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006). Pregnant women with poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used medications. Uncontrolled asthma is associated with an increased risk of perinatal mortality, preeclampsia, preterm birth, and low birth weight infants. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; however, systemic corticosteroids should be used to control acute exacerbations or treat severe persistent asthma (ACOG 2008; GINA 2016; Namazy 2016). Methylprednisolone may be considered for adjunctive treatment of severe nausea and vomiting in pregnant women. Due to risks of adverse fetal events associated with first trimester exposure, use is reserved for refractory cases in women with dehydration (ACOG 189 2018). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Metoclopramide Hydrochloride		Metoclopramide crosses the placenta and can be detected in cord blood and amniotic fluid (Arvela 1983; Bylsma-Howell 1983). Available studies do not report an increased risk of adverse pregnancy-related outcomes following maternal use. Extrapyramidal symptoms or methemoglobinemia may potentially occur in the neonate. Metoclopramide is one of the agents that may be considered for adjunctive treatment of nausea and vomiting in pregnant women when symptoms persist following initial pharmacologic therapy. Oral or IM therapy may be given in patients who are not dehydrated; IV therapy should be used when dehydration is present (ACOG 189 2018). Metoclopramide may be used for prophylaxis of nausea and vomiting associated with cesarean delivery (ASA 2016; Smith 2011).
Metoprolol	C	Adverse events have been observed in animal reproduction studies. Metoprolol and the metabolite alpha-hydroxymetoprolol cross the placenta and can be detected in cord blood (Lindeberg 1987; Ryu 2016). Adverse events, such as fetal/neonatal bradycardia, hypoglycemia, and reduced birth weight, have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth is generally recommended. The pharmacokinetics of metoprolol may be changed during pregnancy; the degree of changes may be dependent upon maternal CYP2D6 genotype (Ryu 2016). Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). Recommendations for the treatment of hypertension in pregnancy vary by guideline, but use of metoprolol may be considered (ESC [Regitz-Zagrosek 2011]; Magee 2014). Heart failure, peripartum cardiomyopathy, and valvular heart disease may cause severe complications in pregnant women; metoprolol is recommended when use of a beta-blocker is indicated (AHA/ACC [Nishimura 2014]; ESC [Regitz-Zagrosek 2011]; Sliwa 2010). Use of metoprolol may be considered for some arrhythmias, including SVT, when a beta-blocker is needed (ACC/AHA/HRS [Page 2015]; ESC [Regitz-Zagrosek 2011]). Use of metoprolol may be considered if migraine prophylaxis is needed in a pregnant woman (Pringsheim 2012).
Metronidazole		Metronidazole crosses the placenta. Cleft lip with or without cleft palate has been reported following first trimester exposure to metronidazole; however, most studies have not shown an increased risk of congenital anomalies or other adverse events to the fetus following maternal use during pregnancy. Because metronidazole was carcinogenic in some animal species, concern has been raised whether metronidazole should be used during pregnancy. Available studies have not shown an increased risk of infant cancer following metronidazole exposure during pregnancy; however, the ability to detect a signal for this may have been limited. Metronidazole pharmacokinetics are similar between pregnant and nonpregnant patients (Amon 1981; Visser 1984; Wang

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		2011). Bacterial vaginosis and vaginal trichomoniasis are associated with adverse pregnancy outcomes and metronidazole is recommended for the treatment of symptomatic pregnant patients. The dose of oral metronidazole for the treatment of bacterial vaginosis during pregnancy is the same as the CDC recommended twice daily dose in nonpregnant females. When treating vaginal trichomoniasis, the CDC recommends the single oral dose regimen in pregnancy. Although use of metronidazole for vaginal trichomoniasis during the first trimester is contraindicated by the manufacturer; available guidelines note treatment can be given at any stage of pregnancy (Workowski [CDC 2015]). Metronidazole may also be used for the treatment of giardiasis in pregnant women (some sources recommend second and third trimester administration only) (Gardner 2001; HHS [OI adult 2017]) and symptomatic amebiasis during pregnancy (HHS [OI adult 2017]; Li 1996). Short courses may be used for the treatment of pouchitis or perianal disease in pregnant women with inflammatory bowel disease (avoid use in the first trimester) (van der Woude 2015).The use of other agents is preferred when treatment is needed during pregnancy for Clostridium difficile (Surawicz 2013). Consult current recommendations for appropriate use in pregnant women.
Miconazole		Following vaginal administration, small amounts are absorbed systemically (Stevens 2002). Vaginal topical azole products (7-day therapies only) are the preferred treatment of vulvovaginal candidiasis in pregnant women. This product may weaken latex condoms and diaphragms (CDC [Workowski 2015]).
Minoxidil	C	Adverse events were observed in some animal studies. Neonatal hypertrichosis has been reported following exposure to minoxidil during pregnancy.
Mirtazapine	C	Adverse events were observed in some animal reproduction studies. A significant increase in major teratogenic effects has not been observed in humans following exposure to mirtazapine during pregnancy; however, some nonteratogenic adverse events (similar to those observed with SSRI agents) have been reported (Djulus 2006; Einarson 2009; Lennestal 2007). Mirtazapine was found to cross the placenta following a maternal overdose (Hatzidaki 2008). The ACOG recommends that therapy with antidepressants during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. Consideration should be given to using agents with safety data in pregnancy. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Montelukast	B	Adverse events have not been observed in animal reproduction studies. Birth defects have been reported (rarely) following maternal use; however, a causal relationship with montelukast has not been established. Based on available data, an increased risk of teratogenic effects has not been observed with montelukast use in pregnancy (BTS 2016; GINA 2016). Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, preeclampsia, preterm birth, low birth weight infants). Poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used asthma medications. When clinically indicated, treatment with montelukast should not be withheld during pregnancy (BTS 2016; GINA 2016).
Morphine Sulfate		[US Boxed Warning]: Prolonged maternal use of opioids during pregnancy can cause neonatal withdrawal syndrome in the newborn, which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If

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		prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Morphine crosses the placenta. Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to Infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored. Morphine is commonly used for the treatment of pain during labor and immediately postpartum (ACOG 177 2017). Not all preparations are recommended for use and morphine should not be used when other analgesic techniques are more appropriate. Agents other than morphine are used to treat chronic non-cancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Moxifloxacin HCl		Adverse events have been observed in some animal reproduction studies. Moxifloxacin crosses the placenta and can be detected in the amniotic fluid and cord blood (Ozyüncü and Beksac 2010; Ozyüncü and Nemutlu, 2010). Information specific to moxifloxacin use in pregnant women is limited (Padberg, 2014).
Multivitamin		Refer to individual vitamin monographs for requirements during pregnancy.
Multivitamin, Children's		Refer to individual vitamin monographs for requirements during pregnancy.
Multivitamin/ Mineral/Folic Acid		Refer to individual vitamin monographs for requirements during pregnancy.
Mupirocin		Systemic absorption following topical application is minimal.
Mycophenolate	D	[US Boxed Warning]: Mycophenolate is associated with an increased risk of congenital malformations and first trimester pregnancy loss when used by pregnant women. Females of reproductive potential must be counseled about pregnancy prevention and planning. Alternative agents with less potential for embryofetal toxicity should be considered for women planning a pregnancy. The following congenital malformations have been reported following exposure during pregnancy: External ear abnormalities, cleft lip and palate, anomalies of the distal limbs, heart, esophagus, kidney, and nervous system. The combination of ear, eye, and lip/palate abnormalities has been identified as mycophenolate embryopathy (Perez-Aytes 2017). Spontaneous abortions have also been noted. Females of reproductive potential (girls who have entered puberty and women with a uterus who have not passed through clinically confirmed menopause) should have a negative pregnancy test with a sensitivity of ≥25 milliunits/mL immediately before mycophenolate therapy and the test should be repeated 8 to 10 days later. Pregnancy tests should then be repeated during routine follow-up visits. Acceptable forms of contraception should be used during treatment and for 6 weeks after therapy is discontinued. The effectiveness of hormonal contraceptive agents may be affected by mycophenolate. Current guidelines recommend that pregnancy be delayed following a kidney transplant until 1 year has passed without an acute rejection; this time period may be adjusted as clinically appropriate. Women planning a pregnancy and who are already taking mycophenolate following a kidney transplant should be switched to a different medication and mycophenolate should be discontinued for at least 6 weeks before pregnancy is attempted (KDIGO 2009). Mycophenolate is not recommended for the treatment of psoriasis in pregnant women (Menter 2009). Mycophenolate should not be used during pregnancy in women with lupus nephritis; women who become pregnant during mycophenolate therapy should be switched to a different medication (KDIGO 2012). For women with lupus nephritis taking mycophenolate and who are planning a pregnancy, mycophenolate should be discontinued at least 6 weeks prior to trying to

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		conceive (Hahn 2012). Health care providers should report female exposures to mycophenolate during pregnancy or within 6 weeks of discontinuing therapy to the Mycophenolate Pregnancy Registry (800-617-8191). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Naloxone	C	Adverse events were not observed in animal reproduction studies. Naloxone crosses the placenta and may precipitate opioid withdrawal in the fetus. Naloxone is not recommended for use in pregnant women with opioid use disorder except in situations of life threatening overdose (Kampman [ASAM 2015]). Use to diagnose opioid dependence during pregnancy is contraindicated (ACOG 2012). In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003). Use caution in pregnant women with mild-to-moderate hypertension during labor; severe hypertension may occur.
Naproxen		Naproxen crosses the placenta (Brogden 1975). Birth defects have been observed following in utero NSAID exposure in some studies; however, data is conflicting (Bloor 2013). Nonteratogenic effects, including prenatal constriction of the ductus arteriosus, persistent pulmonary hypertension of the newborn, oligohydramnios, necrotizing enterocolitis, renal dysfunction or failure, and intracranial hemorrhage have been observed in the fetus/neonate following in utero NSAID exposure. In addition, nonclosure of the ductus arteriosus postnatally may occur and be resistant to medical management (Bermas 2014; Bloor 2013). Because NSAIDs may cause premature closure of the ductus arteriosus, product labeling for naproxen specifically states use should be avoided starting at 30-weeks gestation. Use of NSAIDs can be considered for the treatment of mild rheumatoid arthritis flares in pregnant women; however, use should be minimized or avoided early and late in pregnancy (Bermas 2014; Saavedra Salinas 2015). The chronic use of NSAIDs in women of reproductive age may be associated with infertility that is reversible upon discontinuation of the medication. Consider discontinuing use in women having difficulty conceiving or those undergoing investigation of fertility. The use of NSAIDs close to conception may be associated with an increased risk of miscarriage (Bloor 2013; Bermas 2014).
Nelfinavir	B	Nelfinavir has a minimal to low level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Humans Services (HHS) Perinatal HIV Guidelines do not recommended nelfinavir for initial therapy in antiretroviral-naive pregnant females due to lower viral suppression when compared to other regimens. The standard twice daily dose may be used when needed; the three times daily dosing is not recommended during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is

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		effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Neomycin/ Polymyxin B Sulfate/ Dexamethasone Ophthalmic Drop		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Dexamethasone: Adverse events were observed in animal reproduction studies following use of topical ophthalmic dexamethasone. Information related to the use of the intravitreal implant during pregnancy is limited (Concillado 2016; Hodzic-Hadzibegovic 2017). Following use of the intraocular suspension, systemic exposure is below the limit of quantification after 15 days. If ophthalmic drops (eg, dexamethasone 0.1% solution) are needed during pregnancy, the minimum effective dose should be used in combination with punctal occlusion to decrease potential exposure to the fetus (Samples 1988).
Neomycin/ Polymyxin B/ Hydrocortisone		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Hydrocortisone: Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014). The treatment of psoriasis in pregnancy is initiated with conservative treatment as in nonpregnant females. When a topical steroid is needed, low to moderate potency corticosteroids are preferred initially. High potency

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		topical steroids should be used only when clearly needed and after the first trimester (Bae 2012).
Nevirapine		Nevirapine has a high level of transfer across the human placenta. No increased risk of overall birth defects following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. [US Boxed Warning]: Severe, life-threatening hepatotoxicity, sometimes fatal, may occur; risk is greatest in the first 6 weeks of therapy. Female gender and higher CD4+ cell counts at treatment initiation increase risk of hepatotoxicity; women with CD4+ cell counts >250 cells/mm3, including pregnant women, are at greatest risk, although pregnancy itself does not appear to increase this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend nevirapine as an initial NNRTI for use in antiretroviral-naive pregnant patients because of the potential for adverse events, complex dosing, and low barrier to resistance. Pharmacokinetics of the immediate-release formulation are not significantly altered during pregnancy; dose adjustment is not currently recommended (data not available for extended-release formulation). Females who become pregnant while on nevirapine therapy and are tolerating it well may continue. Frequent monitoring is recommended. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Niacin	C	Animal reproduction studies have not been conducted. Water soluble vitamins cross the placenta. When used as a dietary supplement, niacin requirements may be increased in pregnant women compared to nonpregnant women (IOM 1998). It is not known if niacin at lipid-lowering doses is harmful to the developing fetus. If a woman becomes pregnant while receiving niacin for primary hypercholesterolemia, niacin should be discontinued. If a woman becomes pregnant while receiving niacin for hypertriglyceridemia, the benefits and risks of continuing niacin should be assessed on an individual basis.
Nifedipine	C	Adverse events were observed in animal reproduction studies. Nifedipine crosses the placenta (Manninen 1991; Silberschmidt 2008). An increase in perinatal asphyxia, cesarean delivery, prematurity, and intrauterine growth retardation have been reported following maternal use. Untreated chronic maternal hypertension is also associated with adverse events in the fetus, infant, and mother. If treatment for chronic hypertension during pregnancy is needed, nifedipine is one of the preferred agents (ACOG 2013; SOGC [Magee 2014]). Nifedipine is also recommended for the management of acute onset, severe hypertension (systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg) with preeclampsia or eclampsia in pregnant and postpartum women (ACOG 692 2017; Magee 2014). Nifedipine has also been evaluated for the treatment of preterm labor.

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		Tocolytics may be used for the short-term (48 hour) prolongation of pregnancy to allow for the administration of antenatal steroids and should not be used prior to fetal viability or when the risks of use to the fetus or mother are greater than the risk of preterm birth (ACOG 171 2016). Nifedipine is ineffective for maintenance tocolytic therapy (ACOG 171 2016; Roos 2013).
Nitrofurantoin	B (Contra-indicated at term)	Adverse effects have not been observed in animal reproduction studies. Nitrofurantoin crosses the placenta (Perry 1967) and maternal serum concentrations may be lower in pregnancy (Philipson 1979). Current studies evaluating maternal use of nitrofurantoin during pregnancy and the development of birth defects have had mixed results (ACOG 2011). An increased risk of neonatal jaundice was observed following maternal nitrofurantoin use during the last 30 days of pregnancy (Nordeng 2013). Nitrofurantoin may be used to treat infections in pregnant women; use during the first trimester should be limited to situations where no alternative therapies are available. Prescriptions should be written when clinically appropriate and for the shortest effective duration for confirmed infections (ACOG 2011). Nitrofurantoin is contraindicated in pregnant patients at term (38-42 weeks gestation), during labor and delivery, or when the onset of labor is imminent due to the possibility of hemolytic anemia in the neonate. Alternative antibiotics should be considered in pregnant women with G-6-PD deficiency (Nordeng 2013).
Nitroglycerin	B/C	Animal reproduction studies have not been conducted with all products; adverse events were not observed in animal reproduction studies conducted using the ointment. Nitroglycerin crosses the placenta (David 2000). Concentrations following application of a transdermal patch 0.4 mg/hour were low but detectable in the fetal serum (fetal/maternal ratio: 0.23) (Bustard 2003). Nitroglycerin may be used in pregnancy when immediate relaxation of the uterus is needed (ACOG 183 2017; Axemo 1998; Chandraharan 2005). Intravenous nitroglycerin may be used to treat pre-eclampsia with pulmonary edema (ESG 2011).
Norethindrone	X	Use is contraindicated during pregnancy. First trimester exposure of progestins may cause genital abnormalities including hypospadias in male infants and mild virilization of external female genitalia. Changes in external genitalia have been reported in female infants exposed to norethindrone acetate (Fine 1963). Significant adverse events related to growth and development have not been observed following use of oral progestins in contraceptive doses (limited studies). Norethindrone: Progestin-only contraceptives may be started immediately postpartum (Curtis 2016a; Curtis 2016b). A rapid return to fertility occurs when progestin-only contraceptives are discontinued. Norethindrone acetate: The contraceptive dose of norethindrone acetate is not known. Barrier contraception is recommended to prevent unintended pregnancy (eg, when treating endometriosis) (Kaser 2012).
Norethindrone/ Ethinyl Estradiol	X	Use is contraindicated in pregnant women. Combination hormonal contraceptives are used to prevent pregnancy; treatment should be discontinued if pregnancy occurs. In general, the use of combination hormonal contraceptives, when inadvertently used early in pregnancy, have not been associated adverse fetal or maternal effects (Curtis 2016b). The manufacturer states that combination hormonal contraceptives should not be started until ≥4 weeks after delivery in women who choose not to breastfeed. Due to the increased risk of venous thromboembolism (VTE) postpartum, combination hormonal contraceptives should not be started in any woman <21 days following delivery. The risk decreases to baseline by postpartum day 42. Use of combination hormonal contraceptives in women between 21 and 42 days after delivery should take into consideration the individual woman's risk factors for VTE (eg, age ≥35 years, previous VTE, thrombophilia, immobility, preeclampsia, transfusion at delivery, cesarean delivery, peripartum cardiomyopathy, BMI ≥30 kg/m2, postpartum hemorrhage, smoking) (Curtis 2016b).
Norgestimate/ Ethinyl Estradiol		Use is contraindicated in pregnant women. Combination hormonal contraceptives are used to prevent pregnancy; treatment should be discontinued if pregnancy occurs. In general, the use of combination hormonal contraceptives, when inadvertently used early in pregnancy, have not been associated adverse fetal or maternal effects (Curtis 2016b).

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		The manufacturer states that combination hormonal contraceptives should not be started until ≥4 weeks after delivery in women who choose not to breastfeed. Due to the increased risk of venous thromboembolism (VTE) postpartum, combination hormonal contraceptives should not be started in any woman <21 days following delivery. The risk decreases to baseline by postpartum day 42. Use of combination hormonal contraceptives in women between 21 and 42 days after delivery should take into consideration the individual woman's risk factors for VTE (eg, age ≥35 years, previous VTE, thrombophilia, immobility, preeclampsia, transfusion at delivery, cesarean delivery, peripartum cardiomyopathy, BMI ≥30 kg/m2, postpartum hemorrhage, smoking) (Curtis 2016b).
Nystatin	C	Animal reproduction studies have not been conducted. Absorption following oral use is poor and nystatin is not absorbed following application to mucous membranes or intact skin.
Ofloxacin Ophthalmic Drop	C	Adverse events have been observed in some animal reproduction studies. When administered orally, ofloxacin crosses the placenta (Giamarellou 1989). The amount of ofloxacin available systemically following topical application of the ophthalmic drops is significantly less in comparison to oral doses. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion for 3 to 5 minutes after application to decrease potential exposure to the fetus (Samples 1988). The amount of ofloxacin available systemically following topical application of the otic drops is significantly less in comparison to oral doses.
Ofloxacin Otic	C	Adverse events have been observed in some animal reproduction studies. When administered orally, ofloxacin crosses the placenta (Giamarellou 1989). The amount of ofloxacin available systemically following topical application of the ophthalmic drops is significantly less in comparison to oral doses. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion for 3 to 5 minutes after application to decrease potential exposure to the fetus (Samples 1988). The amount of ofloxacin available systemically following topical application of the otic drops is significantly less in comparison to oral doses.
Olanzapine	C	Adverse events were observed in animal reproduction studies. Olanzapine crosses the placenta and can be detected in cord blood at birth (Newport 2007). Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited, as such, routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to an agent that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). If treatment is needed in a woman planning a pregnancy or if treatment is initiated during pregnancy, olanzapine may be used (Larsen 2015). Olanzapine may cause hyperprolactinemia, which may decrease reproductive function in both males and females. Health care providers are encouraged to enroll women 18 to 45 years of age exposed to olanzapine during pregnancy in the Atypical Antipsychotics Pregnancy Registry (1-866-961-2388 or http://www.womensmentalhealth.org/pregnancyregistry).
Omeprazole		Available data have not shown an increased risk of major birth defects following maternal use of omeprazole during pregnancy. Recommendations for the treatment of GERD in pregnancy are available. As in nonpregnant patients, lifestyle modifications followed by other medications are the initial treatments (Body 2016; Huerta-Iga 2016; Katz 2013; van der Woude 2014). Based on available data, PPIs may be used when clinically indicated (Body 2016; Matok 2012; Pasternak 2010; van der Woude 2014).

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Ondansetron	B	Adverse events were not observed in animal reproduction studies. Ondansetron readily crosses the human placenta in the first trimester of pregnancy and can be detected in fetal tissue (Siu 2006). Due to pregnancy-induced physiologic changes, clearance of ondansetron may increase as pregnancy progresses (Lemon 2016). Although ondansetron has been evaluated for the treatment of nausea and vomiting of pregnancy, current guidelines note data related to fetal safety are conflicting (ACOG 2018); ondansetron is generally reserved for use when other agents have failed (Arsenault 2002). Because a dose-dependent QT-interval prolongation occurs with use, the manufacturer recommends ECG monitoring in patients with electrolyte abnormalities (which can be associated with some cases of NVP; Koren 2012). An international consensus panel recommends that 5-HT3 antagonists (including ondansetron) should not be withheld in pregnant patients receiving chemotherapy for the treatment of gynecologic cancers, when chemotherapy is given according to general recommendations for chemotherapy use during pregnancy (Amant 2009).
Oseltamivir	C	Adverse events were observed in some animal reproduction studies. Oseltamivir phosphate and its active metabolite oseltamivir carboxylate cross the placenta (Meijer 2012). An increased risk of adverse neonatal or maternal outcomes has generally not been observed following maternal use of oseltamivir during pregnancy (CDC 60[1] 2011; CDC March 13, 2014). Untreated influenza infection is associated with an increased risk of adverse events to the fetus and an increased risk of complications or death to the mother. Neuraminidase inhibitors are currently recommended for the treatment or prophylaxis of influenza in pregnant women and women up to 2 weeks' postpartum (CDC 60[1] 2011; CDC March 13, 2014).
Oxacillin		Adverse events have not been observed in animal reproduction studies. Oxacillin is distributed into the amniotic fluid and is detected in cord blood. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects.
Oxcarbazepine	C	Adverse events have been observed in animal reproduction studies. Oxcarbazepine, the active metabolite MHD and the inactive metabolite DHD, crosses the placenta and can be detected in the newborn (Myllynen 2001). According to the manufacturer, data from a limited number of pregnancies collected from pregnancy registries suggest congenital malformations associated with oxcarbazepine monotherapy, including craniofacial defects and cardiac malformations. In general, the risk of teratogenic effects is higher with AED polytherapy than monotherapy (Harden 2009). Plasma concentrations of MHD gradually decrease due to physiologic changes which occur during pregnancy; patients should be monitored during pregnancy and postpartum. Oxcarbazepine may decrease plasma concentrations of hormonal contraceptives. Data collection to monitor pregnancy and infant outcomes following exposure to oxcarbazepine is ongoing. Patients exposed to oxcarbazepine during pregnancy are encouraged to enroll themselves into the NAAED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Oxybutynin	B	Adverse events were not observed in animal reproduction studies. Information related to the use of oxybutynin in patients treated for neurogenic bladder during pregnancy is limited (Andretta 2018).
Oxymetazoline		Adverse fetal/neonatal events have been noted in case reports following large doses or extended use of oxymetazoline nasal spray in the first trimester of pregnancy (Baxi 1985; Holm 1985; Menezes 2016). Fetal blood flow was not found to be affected by a one-time dose of oxymetazoline in noncomplicated, third trimester pregnancies (Rayburn 1990). Decongestants are not the preferred agents for the treatment of rhinitis during pregnancy. Short-term (<3 days) use of intranasal oxymetazoline may be beneficial to some patients although its safety during pregnancy has not been studied (Wallace 2008).
Pancrelipase	C	Animal reproduction studies have not been conducted. Nutrition should be optimized in pregnancy; in cystic fibrosis patients with malabsorption, pancreatic enzyme replacement is not considered to cause a risk to the pregnancy.
Pantoprazole		Adverse events have not been observed in animal reproduction studies. Recommendations for the treatment of GERD in pregnancy are available. As in

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		nonpregnant patients, lifestyle modifications followed by other medications are the initial treatments (Body 2016; Huerta-Iga 2016; Katz 2013; van der Woude 2014). Based on available data, PPIs may be used when clinically indicated (Body 2016; Matok 2012; Pasternak 2010; van der Woude 2014).
Papillomavirus (HPV Vaccines)		Adverse events were not observed in animal reproduction studies. In clinical trials, women who were found to be pregnant before the completion of the 3-dose regimen were instructed to defer any remaining dose until pregnancy resolution. In pregnancies detected within 30 days of vaccination, no cases of congenital abnormalities were noted. Pregnancies with onset beyond 30 days of vaccination had a rate of congenital anomalies consistent with the general population. Administration of the vaccine in pregnancy is not recommended. Until additional information is available, the vaccine series (or completion of the series) should be delayed until pregnancy is completed. Pregnancy testing is not required prior to administration of the vaccine (CDC/ACIP [Petrosky 2015]). A registry has been established for women exposed to the Gardasil 9 HPV vaccine during pregnancy (1-800-986-8999). Administration of the human papillomavirus vaccine during pregnancy is not recommended. Although exposure to human papillomavirus vaccine has not been causally associated with adverse pregnancy outcomes, until additional information is available the vaccine series (or completion of the series) should be delayed until pregnancy is completed (NACI 2017). The manufacturer recommend pregnancy be avoided during the vaccination series. Exposures to quadrivalent human papillomavirus vaccine during pregnancy should be reported to the manufacturer (800-267-2594) or Vaccine Safety Section at Public Health Agency of Canada (866-844-0018 or http://www.phac-aspc.gc.ca/im/vssv/index-eng.php).
Paroxetine	D/X	Paroxetine crosses the placenta (Hendrick Stowe 2003). An increased risk of teratogenic effects, including cardiovascular defects, may be associated with maternal use of paroxetine or other SSRIs; however, available information is conflicting. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of paroxetine may be altered. The maternal CYP2D6 genotype also influences paroxetine plasma concentrations during pregnancy (Hostetter 2000; Ververs 2009). The manufacturer suggests discontinuing paroxetine or switching to another antidepressant unless the benefits of therapy justify continuing treatment during pregnancy; consider other treatment options for women who are planning to become pregnant. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. The ACOG also recommends that therapy with paroxetine be avoided during pregnancy if possible and that fetuses exposed in early pregnancy be assessed with a fetal echocardiography (ACOG 2008). Other guidelines note that treatment with paroxetine should not be initiated in pregnant women (Bauer 2013). According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. The use of paroxetine is not recommended as first line therapy during pregnancy. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery (APA 2010). Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (Yonkers 2009). Menopausal vasomotor symptoms do not occur during pregnancy;

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		therefore, the use of paroxetine for the treatment of menopausal vasomotor symptoms is contraindicated in pregnant women. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
PEG (Polyethylene Glycol 3350 + Electrolytes Solution)		Polyethylene glycol (PEG) has minimal systemic absorption and would be unlikely to cause fetal malformations. However, until additional information is available, use to treat constipation in pregnancy should be avoided unless other preferred methods are inadequate (Mahadevan 2006). Use as a bowel preparation prior to colonoscopy in pregnant women may be considered (Wexner 2006).
Penicillin G Benzathine		Penicillin G crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Penicillin G is the drug of choice for treatment of syphilis during pregnancy and penicillin G (parenteral/aqueous) is the drug of choice for the prevention of early-onset Group B Streptococcal (GBS) disease in newborns (consult current guidelines) (CDC (RR-10) 2010; CDC [Workowski 2015]). When IV therapy is required for anthrax infection in pregnant and postpartum women, penicillin G may be used as an alternative agent (Meaney-Delman 2014).
Penicillin G Procaine		Penicillin G crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Penicillin G is the drug of choice for treatment of syphilis during pregnancy and penicillin G (parenteral/aqueous) is the drug of choice for the prevention of early-onset Group B Streptococcal (GBS) disease in newborns (consult current guidelines) (CDC (RR-10) 2010; CDC [Workowski 2015]). When IV therapy is required for anthrax infection in pregnant and postpartum women, penicillin G may be used as an alternative agent (Meaney-Delman 2014).
Penicillin V Potassium		Penicillin crosses the placenta. Maternal use of penicillins has generally not resulted in an increased risk of adverse fetal effects. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of penicillin V may be altered in the second and third trimester (Heikkilä 1993). If treatment for the management of Bacillus anthracis is needed in pregnant women, other agents are preferred (Meaney-Delman 2014)
Pentamidine Isethionate		Animal reproduction studies were not conducted by the manufacturer. Pentamidine crosses the human placenta (Fortunato 1989; Schwebke 1995). Intravenous pentamidine can be used as an alternative treatment in pregnant females with HIV infection for mild to moderate Pneumocystis jirovecii pneumonia (HHS [OI; adult] 2017). Pentamidine may be used to treat stage one trypanosomiasis caused by T. brucei gambiense (CDC 2016); information related to treatment of pregnant females for this indication is limited (Pohlig 2016).
Permethrin	B	Adverse events have not been observed in oral animal reproduction studies. The amount of permethrin available systemically following topical application is ≤2%. The CDC considers the use of permethrin or pyrethrins with piperonyl butoxide the drugs of choice for the treatment of pubic lice during pregnancy; permethrin is the preferred treatment of scabies during pregnancy (CDC [Workowski 2015]).
Perphenazine		Jaundice or hyper- or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. If needed, the minimum effective maternal dose should be used in order to decrease the risk of EPS (ACOG 2008).
Petrolatum		
Phenazopyridine	B	Adverse events have not been observed in animal reproduction studies. Phenazopyridine crosses the placenta and can be detected in amniotic fluid (Meyer 1991).
Phenobarbital	D	Phenobarbital crosses the placenta (Harden 2009b). Barbiturates can be detected in the placenta, fetal liver, and fetal brain. Fetal and maternal blood concentrations may be

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		similar following parenteral administration. An increased incidence of fetal abnormalities may occur following maternal use. When used during the third trimester of pregnancy, withdrawal symptoms may occur in the neonate, including seizures and hyperirritability; symptoms of withdrawal may be delayed in the neonate up to 14 days after birth. Use during labor does not impair uterine activity; however, respiratory depression may occur in the newborn; resuscitation equipment should be available, especially for premature infants. Use for the treatment of epilepsy should be avoided during pregnancy (Harden 2009a). A registry is available for women exposed to phenobarbital during pregnancy: Pregnant women may enroll themselves into the North American Antiepileptic Drug (AED) Pregnancy Registry (888-233-2334 or http://www.aedpregnancyregistry.org).
Phenylephrine	C	Animal reproduction studies have not been conducted. Phenylephrine crosses the placenta at term. Maternal use of phenylephrine during the first trimester of pregnancy is not strongly associated with an increased risk of fetal malformations; maternal dose and duration of therapy were not reported in available publications. Phenylephrine is available over-the-counter (OTC) for the symptomatic relief of nasal congestion. Decongestants are not the preferred agents for the treatment of rhinitis during pregnancy. Oral phenylephrine should be avoided during the first trimester of pregnancy; short-term use (<3 days) of intranasal phenylephrine may be beneficial to some patients although its safety during pregnancy has not been studied. Phenylephrine injection is used at delivery for the prevention and/or treatment of maternal hypotension associated with spinal anesthesia in women undergoing cesarean section. Phenylephrine may be associated with a more favorable fetal acid base status than ephedrine; however, overall fetal outcomes appear to be similar. Nausea or vomiting may be less with phenylephrine than ephedrine but is also dependent upon blood pressure control. Phenylephrine may be preferred in the absence of maternal bradycardia. There is limited information available supporting the use of topical agents for the treatment of hemorrhoids. Products containing phenylephrine should be used with caution in pregnant women, especially patients with hypertension or diabetes.
Phenylephrine/ Mineral Oil/ Petrolatum	C	Animal reproduction studies have not been conducted. Phenylephrine crosses the placenta at term. Maternal use of phenylephrine during the first trimester of pregnancy is not strongly associated with an increased risk of fetal malformations; maternal dose and duration of therapy were not reported in available publications. Phenylephrine is available over-the-counter (OTC) for the symptomatic relief of nasal congestion. Decongestants are not the preferred agents for the treatment of rhinitis during pregnancy. Oral phenylephrine should be avoided during the first trimester of pregnancy; short-term use (<3 days) of intranasal phenylephrine may be beneficial to some patients although its safety during pregnancy has not been studied. Phenylephrine injection is used at delivery for the prevention and/or treatment of maternal hypotension associated with spinal anesthesia in women undergoing cesarean section. Phenylephrine may be associated with a more favorable fetal acid base status than ephedrine; however, overall fetal outcomes appear to be similar. Nausea or vomiting may be less with phenylephrine than ephedrine but is also dependent upon blood pressure control. Phenylephrine may be preferred in the absence of maternal bradycardia. There is limited information available supporting the use of topical agents for the treatment of hemorrhoids. Products containing phenylephrine should be used with caution in pregnant women, especially patients with hypertension or diabetes.
Phenytoin		Phenytoin crosses the placenta (Harden and Pennell 2009). An increased risk of congenital malformations and adverse outcomes may occur following in utero phenytoin exposure. Reported malformations include orofacial clefts, cardiac defects, dysmorphic facial features, nail/digit hypoplasia, growth abnormalities including microcephaly, and mental deficiency. Isolated cases of malignancies (including neuroblastoma) and coagulation defects in the neonate (may be life threatening) following delivery have also been reported. Maternal use of phenytoin should be avoided when possible to decrease the risk of cleft palate and poor cognitive outcomes. Polytherapy may also increase the risk of congenital malformations; monotherapy is

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		recommended (Harden and Meader 2009). The maternal use of folic acid throughout pregnancy is recommended to reduce the risk of major congenital malformations (Harden and Pennell 2009). Potentially life-threatening bleeding disorders in the newborn may also occur due to decreased concentrations of vitamin K-dependent clotting factors following phenytoin exposure in utero; vitamin K administration to the mother prior to delivery and the newborn after birth is recommended. Total plasma concentrations of phenytoin are decreased in the mother during pregnancy; unbound plasma (free) concentrations are also decreased and plasma clearance is increased. Due to pregnancy-induced physiologic changes, women who are pregnant may require dose adjustments of phenytoin in order to maintain clinical response; monitoring during pregnancy should be considered (Harden and Pennell 2009). For women with epilepsy who are planning a pregnancy in advance, baseline serum concentrations should be measured once or twice prior to pregnancy during a period when seizure control is optimal. Monitoring can then be continued once each trimester during pregnancy and postpartum; more frequent monitoring may be needed in some patients. Monitoring of unbound plasma concentrations is recommended (Patsalos 2008). In women taking phenytoin who are trying to avoid pregnancy, potentially significant interactions may exist with hormone-containing contraceptives; consult drug interactions database for more detailed information. Patients exposed to phenytoin during pregnancy are encouraged to enroll themselves into the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling 1-888-233-2334. Additional information is available at https:\\aedpregnancyregistry.org.
Phytonadione		Phytonadione crosses the placenta in limited concentrations (Kazzi 1990). The dietary requirements of vitamin K are the same in pregnant and nonpregnant women (IOM 2000). In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003). Use of preservative free solutions are preferred when the injection is needed during pregnancy.
Pioglitazone		Information related to the use of pioglitazone in pregnant women is limited (Glueck 2003; Ortega-Gonzalez 2005; Ota 2008). Thiazolidinediones may cause ovulation in anovulatory premenopausal women, increasing the risk of unintended pregnancy. In women with diabetes, maternal hyperglycemia can be associated with congenital malformations as well as adverse effects in the fetus, neonate, and the mother (ACOG 2005; ADA 2018c; Metzger 2007). To prevent adverse outcomes, prior to conception and throughout pregnancy maternal blood glucose and HbA1c should be kept as close to target goals as possible but without causing significant hypoglycemia (ADA 2018c; Blumer 2013). Agents other than pioglitazone are currently recommended to treat diabetes in pregnant women (ADA 2018c).
Piperonyl Butoxide/ Pyrethrins		Pregnant women may be treated with pyrethrins and piperonyl butoxide (CDC [Workowski 2015]).
Pneumococcal Vaccine	C	Animal reproduction studies have not been conducted. Vaccination should be considered in pregnant women at high risk for infection. Inactivated vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]).
Podofilox		Teratogenic events have not been observed in animal reproduction studies with topical administration. Podofilox should not be used during pregnancy (CDC [Workowski 2015])
Podophyllin		Use is contraindicated in women who are or may become pregnant. Reports in pregnant women have shown evidence of fetal abnormalities, fetal death, and stillbirth.
Poliovirus Vaccine		Animal reproduction studies have not been conducted. Although adverse effects of IPV have not been documented in pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. Pregnant women at increased risk for infection and requiring immediate protection against polio may be administered the vaccine (CDC/ACIP [Prevots 2000]).
Polyethylene Glycol 3350		Polyethylene glycol (PEG) has minimal systemic absorption and would be unlikely to cause fetal malformations. However, until additional information is available, use to

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		treat constipation in pregnancy should be avoided unless other preferred methods are inadequate (Mahadevan 2006). Use as a bowel preparation prior to colonoscopy in pregnant women may be considered (Wexner 2006).
Polymyxin B/ Neomycin/ Bacitracin		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006).
Polymyxin B/ Neomycin/ Gramicidin Ophthalmic		Neomycin: Animal reproduction studies have not been conducted. Aminoglycosides cross the placenta. Aminoglycosides may cause fetal harm if administered to a pregnant woman. There are several reports of total irreversible bilateral congenital deafness in children whose mothers received another aminoglycoside (streptomycin) during pregnancy. Although serious side effects to the fetus/infant have not been reported following maternal use of all aminoglycosides, a potential for harm exists. Large oral doses may cause malabsorption of some nutrients in the mother. Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Bacitracin: Bacitracin is not absorbed systemically following ophthalmic administration (Robert, 2001). If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples, 1988).
Polymyxin B/ Trimethoprim Ophthalmic		Adverse events have been observed with trimethoprim in animal reproduction studies; animal reproduction studies have not been conducted with polymyxin B. See individual agents. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples 1988). Polymixin B: [US Boxed Warning]: Safety in pregnant women has not been established. Animal reproduction studies are lacking. A teratogenic potential has not been identified for polymyxin b, but very limited data is available (Heinonen 1977; Kazy 2005). Based on the relative toxicity compared to other antibiotics, systemic use in pregnancy is not recommended (Knothe 1985). Due to poor tissue diffusion, topical use would be expected to have only minimal risk to the mother or fetus (Leachman 2006). Trimethoprim: Adverse events have been observed in animal reproduction studies. Trimethoprim crosses the placenta and can be detected in the fetal serum and amniotic fluid (Reid 1975). Adverse events may be associated with trimethoprim use during pregnancy (Andersen 2012; Andersen 2013; Mølgaard-Nielsen 2012). Untreated urinary tract infections may cause adverse pregnancy outcomes (Nicolle 2005); because safer options are available for the treatment of UTIs in pregnant women, use of TMP containing products in the first trimester should be avoided (Lee 2008). Studies evaluating the effects of trimethoprim administration in pregnancy have also been conducted with Sulfamethoxazole and Trimethoprim (see the Sulfamethoxazole and Trimethoprim monograph for details).
Potassium Chloride		Potassium requirements are the same in pregnant and nonpregnant women. Adverse events have not been observed following use of potassium supplements in healthy

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		women with normal pregnancies. Use caution in pregnant women with other medical conditions (eg, preeclampsia; may be more likely to develop hyperkalemia) (IOM 2004). Potassium supplementation (that does not cause maternal hyperkalemia) would not be expected to cause adverse fetal events.
Pramipexole		Adverse events were observed in animal reproduction studies. Information related to the use of pramipexole for the treatment of Parkinson disease (Benbir 2013, Mucchiut 2004) or restless legs syndrome (RLS) (Dostal 2013) in pregnant women is limited. Current guidelines note that the available information is insufficient to make a recommendation for the treatment of RLS in pregnant women (Aurora 2012).
Pravastatin	X	Use of pravastatin is contraindicated in pregnancy. Adverse events were observed in some animal reproduction studies. Pravastatin was found to cross the placenta in an ex vivo study using term human placentas (Nanovskaya 2013). There are reports of congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long term outcomes of primary hypercholesterolemia treatment. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Prazosin		Adverse events were observed in some animal reproduction studies. Prazosin crosses the placenta and its pharmacokinetics may be slightly altered during pregnancy (Bourget 1995; Rubin 1983). Limited use in pregnant women has not demonstrated any fetal abnormalities or adverse effects (Dommisse 1983). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are generally preferred (ACOG 2013).
Prednisolone Ophthalmic	C	Adverse events have been observed in animal reproduction studies. Prednisolone crosses the placenta when administered systemically; the amount of prednisolone available systemically following ophthalmic use is unknown. Refer to the Prednisolone (Systemic) monograph for additional information.
Prednisone	C/D	Adverse events have been observed with corticosteroids in animal reproduction studies. Prednisone and its metabolite, prednisolone, cross the human placenta. In the mother, prednisone is converted to the active metabolite prednisolone by the liver. Prior to reaching the fetus, prednisolone is converted by placental enzymes back to prednisone. As a result, the level of prednisone remaining in the maternal serum and reaching the fetus are similar; however, the amount of prednisolone reaching the fetus is ~8 to 10 times lower than the maternal serum concentration (healthy women at term) (Beitins 1972). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant women, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006). Prednisone

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		is preferred by some guidelines when an oral corticosteroid is needed because placental enzymes limit passage to the embryo (Murase 2014). Pregnant women with poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used medications. Uncontrolled asthma is associated with an increased risk of perinatal mortality, preeclampsia, preterm birth, and low birth weight infants. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; however, systemic corticosteroids, including prednisone, should be used to control acute exacerbations or treat severe persistent asthma (ACOG 2008; GINA 2016; Namazy 2016). Prednisone may be used to treat lupus nephritis in pregnant women who have active nephritis or substantial extrarenal disease activity (Hahn 2012). Prednisone is recommended for use in fetal-neonatal alloimmune thrombocytopenia and pregnancy-associated immune thrombocytopenia (ACOG 2016). Prednisone may be used (alternative agent) to treat primary adrenal insufficiency (PAI) in pregnant women. Pregnant women with PAI should be monitored at least once each trimester (Bornstein 2016). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Primaquine	Primaquine is contraindicated in pregnant women.	Primaquine is contraindicated in pregnant women. Sexually active females should have a pregnancy test prior to treatment with primaquine. Females of reproductive potential should use effective contraception during therapy and until the next menses following discontinuation of treatment. Males with female partners of reproductive potential should use condoms during therapy and for 3 months after treatment is discontinued. Malaria infection in pregnant women may be more severe than in nonpregnant women and has a high risk of maternal and perinatal morbidity and mortality. Therefore, pregnant women and women who are likely to become pregnant are advised to avoid travel to malaria-risk areas. When treatment is needed, other agents are preferred (CDC Yellow Book 2016). Consult current CDC guidelines for the treatment of malaria during pregnancy.
Primidone		Primidone and its metabolites (PEMA, phenobarbital, and p-hydroxyphenobarbital) cross the placenta; neonatal serum concentrations at birth are similar to those in the mother. Withdrawal symptoms may occur in the neonate and may be delayed due to the long half-life of primidone and its metabolites. Use may be associated with birth defects and adverse events; the use of folic acid throughout pregnancy and vitamin K during the last month of pregnancy is recommended. Epilepsy itself, number of medications, genetic factors, or a combination of these probably influence the teratogenicity of anticonvulsant therapy. Patients exposed to primidone during pregnancy are encouraged to enroll themselves into the NAAED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Probenecid		Probenecid crosses the placenta. Based on available data, an increased risk of adverse fetal events have not been reported (Gutman, 2012).
Prochlorperazine		Jaundice or hyper- or hyporeflexia have been reported in newborn infants following maternal use of phenothiazines. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The use of prochlorperazine may be considered for adjunctive treatment of nausea and vomiting in pregnant patients when symptoms persist following initial pharmacologic therapy (ACOG 189 2018). Use may interfere with pregnancy tests, causing false positive results.
Promethazine		Adverse effects have not been observed in animal reproduction studies. Promethazine crosses the placenta (Potts 1961). Platelet aggregation may be inhibited in newborns following maternal use of promethazine within 2 weeks of delivery. Promethazine is approved for use as an antiemetic; however, other agents are recommended as initial

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		therapy for the treatment of nausea and vomiting of pregnancy (ACOG 2015). Promethazine is indicated for use during labor for obstetric sedation and may be used alone or as an adjunct to opioid analgesics. Although promethazine is approved for the treatment of allergic conditions (eg, allergic rhinitis, urticaria), other agents are preferred for use in pregnant women (Scadding 2008; Wallace 2008; Zuberbier 2014).
Proparacaine Hydrochloride		Animal reproduction studies have not been conducted.
Propranolol Hydrochloride	C	Adverse events have been observed in some animal reproduction studies. Propranolol crosses the placenta and is measurable in the newborn serum following maternal use during pregnancy (Taylor 1981). According to the manufacturer, congenital abnormalities have been reported following maternal use of propranolol. Bradycardia, hypoglycemia, and/or respiratory depression have been observed in neonates following in utero exposure to propranolol at parturition. Reduced birth weight has also been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth should be available. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). When treatment of hypertension in pregnancy is indicated, beta-blockers may be used. Specific recommendations vary by guideline. Although other agents are preferred (ACOG 2013), use of propranolol may be considered (Magee 2014). Use of propranolol may be considered for some arrhythmias, including SVT, when use of a beta-blocker is needed during pregnancy (ACC/AHA/HRS [Page 2015]; ESC [Regitz-Zagrosek 2011]). Propranolol is recommended for use in controlling hypermetabolic symptoms of thyrotoxicosis in pregnancy (Stagnaro-Green 2011). Propranolol may be used if prophylaxis of migraine is needed in pregnant women; it should be discontinued 2 to 3 days prior to delivery to decrease the risk of adverse events to the fetus/neonate and potential reductions in uterine contraction (Pringsheim 2012).
Propylthiouracil	D	Propylthiouracil has been found to readily cross the placenta. Teratogenic effects have not been observed; however, nonteratogenic adverse effects, including fetal and neonatal hypothyroidism, goiter, and hyperthyroidism, have been reported following maternal propylthiouracil use. The transfer of thyroid-stimulating immunoglobulins can stimulate the fetal thyroid in utero and transiently after delivery and may increase the risk of fetal or neonatal hyperthyroidism (De Groot 2012; Peleg 2002). Antithyroid treatment is recommended for the control of hyperthyroidism during pregnancy (Casey 2006; De Groot 2012). Uncontrolled maternal hyperthyroidism may result in adverse neonatal outcomes (eg, prematurity, low birth weight) and adverse maternal outcomes (eg, preeclampsia, congestive heart failure, stillbirth, and abortion). To prevent adverse fetal and maternal events, normal maternal thyroid function should be maintained prior to conception and throughout pregnancy (De Groot 2012).
Psyllium		Psyllium is not absorbed systemically. When administered with adequate fluids, use is considered safe for the treatment of occasional constipation during pregnancy (Wald, 2003).
Pyrazinamide	C	Adverse events have not been observed in animal reproduction studies. Due to the risk of tuberculosis to the fetus, treatment is recommended when the probability of maternal disease is moderate to high. Drug-susceptible TB guidelines recommend pyrazinamide as part of the initial treatment regimen; however, risks and benefits of use during pregnancy should be considered for each individual patient (Nahid 2016).
Pyridostigmine	B/C	Adverse events have not been observed in animal reproduction studies. Pyridostigmine may cross the placenta (Buckley 1968). Use of pyridostigmine may be continued during pregnancy for the treatment of myasthenia gravis (Norwood 2014; Skeie 2010) and its use should be continued during labor (Norwood 2014). Transient neonatal myasthenia gravis may occur in 10% to 20% of neonates due to placental transfer of maternal antibodies (Skeie 2010; Varner 2013). In general, medications used as antidotes should take into consideration the health and prognosis of the mother; antidotes should be administered to pregnant women if there is a clear indication for use and should not be withheld because of fears of teratogenicity (Bailey 2003).

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Pyridoxine	A	Water soluble vitamins cross the placenta. Maternal pyridoxine plasma concentrations may decrease as pregnancy progresses and requirements may be increased in pregnant women (IOM 1998). Pyridoxine is used to treat nausea and vomiting of pregnancy (ACOG 189 2018; Neibyl 2010; Campbell [SOGC] 2016).
Pyrimethamine	C	Adverse events have been observed in animal reproduction studies. If administered during pregnancy (ie, for toxoplasmosis), supplementation of folate is strongly recommended. Pregnancy should be avoided during therapy.
Quinidine Sulfate	C	Animal reproduction studies have not been conducted. Quinidine crosses the placenta and can be detected in the amniotic fluid, cord blood, and neonatal serum. Quinidine is indicated for use in the treatment of severe malaria infection in pregnant women (CDC, 2013; Smereck, 2011) and has also been used to treat arrhythmias in pregnancy when other agents are ineffective (European Society of Cardiology, 2003).
Quinine	C	Teratogenic effects have been reported in some animal studies. Quinine crosses the human placenta. Cord plasma to maternal plasma quinine ratios have been reported as 0.18-0.46 and should not be considered therapeutic to the infant. Teratogenic effects, optic nerve hypoplasia, and deafness have been reported in the infant following maternal use of very high doses; however, therapeutic doses used for malaria are generally considered safe. Quinine may also cause significant hypoglycemia when used during pregnancy. Malaria infection in pregnant women may be more severe than in nonpregnant women. Because P. falciparum malaria can cause maternal death and fetal loss, pregnant women traveling to malaria-endemic areas must use personal protection against mosquito bites. Quinine may be used for the treatment of malaria in pregnant women; consult current CDC guidelines. Pregnant women should be advised not to travel to areas of P. falciparum resistance to chloroquine.
Raltegravir Potassium		Raltegravir has high transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. The Health and Human Services (HHS) Perinatal HIV Guidelines consider raltegravir to be the preferred integrase inhibitor for initial use in antiretroviral-naive pregnant patients and is useful when drug interactions with protease inhibitors are a concern. Because of its ability to rapidly suppress viral load, raltegravir may be useful in women who present late in pregnancy with high viral loads. Dose adjustments are not required in pregnant women; however, once daily dosing is not recommended until more data is available. Reversible elevation of liver enzymes occurred in a patient who initiated raltegravir late in pregnancy; monitor liver enzymes if used during pregnancy. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the

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		National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Ranitidine Hydrochloride		Ranitidine crosses the placenta (Armentano 1989). Histamine H2 antagonists have been evaluated for the treatment of gastroesophageal reflux disease (GERD) as well as gastric and duodenal ulcers during pregnancy. If needed, ranitidine is the agent of choice (Cappell 2003; Richter 2003). Histamine H2 antagonists may be used for aspiration prophylaxis prior to cesarean delivery (ASA 2007).
Rifampin	C	Adverse events have been observed in animal reproduction studies. Rifampin crosses the human placenta. Postnatal hemorrhages have been reported in the infant and mother with administration during the last few weeks of pregnancy. Maternal treatment of tuberculosis is recommended when the probability of maternal disease is moderate to high due to the risk of infection to the fetus (ATC/CDC 2003). Rifampin may be considered for use as an alternative agent in pregnant women for the treatment of mild illness due to human anaplasmosis (also known as human granulocytic anaplasmosis [HGA]); case reports have shown favorable maternal and pregnancy outcomes in small numbers of rifampin-treated pregnant women (CDC [Biggs 2016]).
Rilpivirine		Rilpivirine has moderate to high placental transfer. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hypersensitivity reactions (including hepatic toxicity and rash) are more common in women on NNRTI therapy; it is not known if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines recommend rilpivirine as a component in alternative regimens for initial use in antiretroviral-naïve pregnant females with a pretreatment HIV RNA ≤100,000 copies/mL and CD4 cell count ≥200 cells/mm3. The pharmacokinetics are highly variable in pregnancy; data is insufficient to recommend pregnancy specific dosing; however, viral loads should be monitored more frequently when standard doses are used in pregnant females. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Risperidone	C	Adverse events were observed in animal reproduction studies. In human studies, risperidone and its metabolite cross the placenta (Newport 2007). Agenesis of the corpus callosum has been noted in one case report of an infant exposed to risperidone in utero; relationship to risperidone exposure is not known. Antipsychotic use during the third trimester of pregnancy has a risk for extrapyramidal symptoms (EPS) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress,

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		somnolence, and tremor. These effects may be self-limiting and allow recovery within hours or days with no specific treatment, or they may be severe requiring prolonged hospitalization. When using Risperdal Consta, patients should notify health care provider if they become or intend to become pregnant during therapy or within 12 weeks of last injection. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited. As a result, routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to an agent that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). If treatment is needed in a woman planning a pregnancy or if treatment is initiated during pregnancy, use of an agent other than risperidol is preferred (Larsen 2015). Risperidone may cause hyperprolactinemia, which may decrease reproductive function in both males and females. Healthcare providers are encouraged to enroll women 18 to 45 years of age exposed to risperidone during pregnancy in the Atypical Antipsychotics Pregnancy Registry (1-866-961-2388 or http://www.womensmentalhealth.org/pregnancyregistry).
Ritonavir		Ritonavir has a low level of transfer across the human placenta; no increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with protease inhibitors; it is not clear if pregnancy increases this risk. Ritonavir should only be used as a low-dose booster during pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines consider ritonavir, when used as a booster for other PIs, to be a preferred component of regimens for initial use in antiretroviral-naïve pregnant females. A ritonavir-boosted protease inhibitor regimen is also recommended when acute HIV infection is detected during pregnancy. Early studies have shown lower plasma levels during pregnancy compared to postpartum; however, dosage adjustment is not needed when used as a low-dose booster in pregnant females. Ritonavir is not recommended for initial therapy as a single protease inhibitor in ART naive pregnant females due to inferior efficacy and increased toxicity; females should be switched to a preferred or alternative regimen (ritonavir should only be used as a low-dose booster during pregnancy). The oral solution contains alcohol and therefore is not recommended for use in pregnant patients. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the

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		National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Rosuvastatin		Adverse events have been observed in some animal reproduction studies. There are reports of congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long term outcomes of primary hypercholesterolemia treatment. Use of rosuvastatin is contraindicated in pregnancy. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Rotavirus	C	Reproduction studies have not been conducted. Not indicated for use in women of reproductive age. Infants living in households with pregnant women may be vaccinated (CDC/ACIP [Cortese, 2009]).
Salicylic Acid	C	Adverse events have been observed in animal reproduction studies when administered orally. Salicylates cross the placenta (Østensen 1998). Systemic absorption of topical salicylic acid occurs and varies depending on duration and vehicle (~9% to 25%) and is increased with occlusion (Akhavan 2003). Current guidelines do not recommend salicylic acid for the treatment of psoriasis in pregnant women due to limited safety data and the potential for systemic absorption (Bae 2012). For the topical treatment of acne or warts, salicylic acid can be used in pregnant women if the area of exposure and duration of therapy is limited, although other agents may be preferred (Murase, 2014). Consider maternal/fetal adverse events associated with aspirin if significant systemic exposure occurs (Akhavan 2003).
Salmeterol	C	Adverse events were observed in some animal reproduction studies. Beta-agonists have the potential to affect uterine contractility if administered during labor. Uncontrolled asthma is associated with adverse events on pregnancy (increased risk of perinatal mortality, pre-eclampsia, preterm birth, low birth weight infants). Although data related to its use in pregnancy is limited, salmeterol may be used when a long-acting beta agonist is needed to treat moderate persistent or severe persistent asthma in pregnant women (NAEPP, 2005).
Saquinavir	B	Saquinavir has a low level of transfer across the human placenta. Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend ritonavir-boosted saquinavir for initial use in antiretroviral-naive pregnant females due to potential toxicity, twice-daily dosing requirements, and limited data in pregnancy; use of saquinavir without ritonavir is not recommended in any patient. Based on available data, dose adjustments are not required in pregnant patients. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit

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		of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Selenium Sulfide	C	Animal reproduction studies have not been conducted. The manufacturer's labeling for some products recommend against using selenium sulfide in pregnant women.
Sertraline Hydrochloride		Sertraline crosses the human placenta. Available studies evaluating teratogenic effects following maternal use of sertraline in the first trimester have not shown an overall increased risk of major birth defects. Studies evaluating specific birth defects have provided inconsistent results. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypo- or hypertonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SSRIs/SNRIs or a discontinuation syndrome and may be consistent with serotonin syndrome associated with SSRI treatment. Persistent pulmonary hypertension of the newborn (PPHN) has also been reported with SSRI exposure. The long-term effects of in utero SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, women who are pregnant may require adjusted doses of sertraline to achieve euthymia. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Sevelamer	C	Adverse events have been observed in animal reproduction studies. Sevelamer is not absorbed systemically; however, it may cause a reduction in the absorption of fat soluble vitamins and folic acid.
Silver Nitrate Applicator		
Silver Sulfadiazine		Adverse events were not observed in animal reproduction studies. Because of the theoretical increased risk for hyperbilirubinemia and kernicterus, silver sulfadiazine is contraindicated for use near term, on premature infants, or on newborn infants during the first 2 months of life (refer to Sulfadiazine monograph).
Simethicone		Simethicone is not absorbed systemically following oral administration. Systemic absorption would be required in order for simethicone to cross the placenta and reach the fetus (Mahadevan 2006).
Simvastatin	X	Studies in pregnant women have shown evidence of fetal abnormalities and use is contraindicated in women who are or may become pregnant. There are reports of

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		congenital anomalies following maternal use of HMG-CoA reductase inhibitors in pregnancy; however, maternal disease, differences in specific agents used, and the low rates of exposure limit the interpretation of the available data (Godfrey 2012; Lecarpentier 2012). Cholesterol biosynthesis may be important in fetal development; serum cholesterol and triglycerides increase normally during pregnancy. The discontinuation of lipid lowering medications temporarily during pregnancy is not expected to have significant impact on the long-term outcomes of primary hypercholesterolemia treatment. Use of simvastatin is contraindicated in pregnancy. Because they are potentially teratogenic, the ADA Diabetes guidelines recommends avoiding use of HMG-CoA reductase inhibitors in sexually active women of childbearing age who are not using reliable contraception (ADA 2018b). If treatment of dyslipidemias is needed in pregnant women or in women of reproductive age, other agents are preferred (Berglund 2012; Stone 2013). The manufacturer recommends administration to women of childbearing potential only when conception is highly unlikely and patients have been informed of potential hazards.
Sodium Bicarbonate		Animal reproduction studies have not been conducted. Medications used for the treatment of cardiac arrest in pregnancy are the same as in the non-pregnant woman. Doses and indications should follow current Advanced Cardiovascular Life Support guidelines. Appropriate medications should not be withheld due to concerns of fetal teratogenicity (Campbell 2009; Jeejeebhoy [AHA] 2015). Antacids containing sodium bicarbonate should not be used during pregnancy due to their potential to cause metabolic alkalosis and fluid overload (Mahadevan 2007).
Sodium Chloride	C	Animal reproduction studies have not been conducted. Sodium requirements do not change during pregnancy (IOM 2004). Nasal saline rinses may be used for the treatment of pregnancy rhinitis (Wallace, 2008)
Sodium Phosphate, Rectal	C	Reproduction studies have not been conducted with these products. Use with caution in pregnant women.
Sotalol	B	Adverse events were not observed in the initial animal reproduction studies. Sotalol crosses the placenta and is found in amniotic fluid. Adverse events, such as fetal/neonatal bradycardia, hypoglycemia, and reduced birth weight have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth are generally recommended. Sotalol crosses the placenta in concentrations similar to the maternal serum and it is generally preferred for the treatment of fetal atrial flutter (Namouz-Haddad 2013). The clearance of sotalol is increased during the third trimester of pregnancy, but other pharmacokinetic parameters do not significantly differ from nonpregnant values (O'Hare 1983). Use of sotalol may be considered for some cardiac arrhythmias when use of a beta-blocker is needed during pregnancy (ESC [Regitz-Zagrosek 2011]).
Spironolactone		Spironolactone crosses the placenta (Regitz-Zagrosek 2011). Use of diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. The treatment of heart failure is generally the same in pregnant and nonpregnant women; however, spironolactone should be avoided in the first trimester due to its antiandrogenic effects (Regitz-Zagrosek 2011). The use of mineralocorticoid receptor antagonists is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential. When treatment for hypertension in pregnancy is needed, other agents are preferred (ACOG 2013)
Stavudine	C	Stavudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure to stavudine alone according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is

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		limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. [US Boxed Warning]: Fatal lactic acidosis has been reported in pregnant women using didanosine and stavudine in combination with other antiretroviral agents; co-administration with didanosine is contraindicated. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk. In addition to lactic acidosis, the combination of didanosine and stavudine has been shown to increase the risk of neurodevelopmental disability. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend stavudine for initial therapy in antiretroviral-naive pregnant females due to toxicity; do not use in combination with didanosine or zidovudine. Pharmacokinetics of stavudine are not significantly altered during pregnancy; dose adjustments are not needed. In addition, because of the high risk of toxicity, stavudine should be stopped in females who become pregnant during therapy and women should be switched to a preferred or alternative regimen. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Streptomycin	D	Streptomycin crosses the placenta. Streptomycin may cause fetal harm if administered to a pregnant woman. There are multiple reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Streptomycin should never be substituted as first line therapy for the treatment of tuberculosis in pregnant women (Blumberg 2003).
Sucralfate		Adverse events were not observed in animal reproduction studies. Sucralfate is only minimally absorbed following oral administration. Based on available data, use of sucralfate does not appear to increase the risk of adverse fetal events when used during the first trimester (Mahadevan, 2006).
Sulfacetamide	C	Animal reproduction studies have not been conducted. The amount of sulfacetamide available systemically following topical administration is unknown. Use of systemic sulfonamides during pregnancy may cause kernicterus in the newborn.
Sulfacetamide and Prednisolone Ophthalmic	C/D	Sulfacetamide: Animal reproduction studies have not been conducted. The amount of sulfacetamide available systemically following topical administration is unknown. Use of systemic sulfonamides during pregnancy may cause kernicterus in the newborn. Prednisolone: Adverse events have been observed with corticosteroids in animal reproduction studies. Prednisone and its metabolite, prednisolone, cross the human placenta. In the mother, prednisone is converted to the active metabolite prednisolone by the liver. Prior to reaching the fetus, prednisolone is converted by placental enzymes back to prednisone. As a result, the level of prednisone remaining in the maternal serum and reaching the fetus are similar; however, the amount of prednisolone reaching the fetus is ~8 to 10 times lower than the maternal serum concentration (healthy women at term) (Beitins 1972). Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however,

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		information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest effective dose for the shortest duration of time, avoiding high doses during the first trimester (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant women, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006). Prednisone is preferred by some guidelines when an oral corticosteroid is needed because placental enzymes limit passage to the embryo (Murase 2014). Pregnant women with poorly controlled asthma or asthma exacerbations may have a greater fetal/maternal risk than what is associated with appropriately used medications. Uncontrolled asthma is associated with an increased risk of perinatal mortality, preeclampsia, preterm birth, and low birth weight infants. Inhaled corticosteroids are recommended for the treatment of asthma during pregnancy; however, systemic corticosteroids, including prednisone, should be used to control acute exacerbations or treat severe persistent asthma (ACOG 2008; GINA 2016; Namazy 2016). Prednisone may be used to treat lupus nephritis in pregnant women who have active nephritis or substantial extrarenal disease activity (Hahn 2012). Prednisone is recommended for use in fetal-neonatal alloimmune thrombocytopenia and pregnancy-associated immune thrombocytopenia (ACOG 2016). Prednisone may be used (alternative agent) to treat primary adrenal insufficiency (PAI) in pregnant women. Pregnant women with PAI should be monitored at least once each trimester (Bornstein 2016). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Sulfamethoxazole/ Trimethoprim	D	Sulfamethoxazole and trimethoprim cross the placenta. An increased risk of congenital malformations (neural tube defects, cardiovascular malformations, urinary tract defects, oral clefts, club foot) following maternal use of sulfamethoxazole and trimethoprim during pregnancy has been observed in some studies. Folic acid supplementation may decrease this risk (Crider 2009; Czeizel 2001; Hernandez-Diaz 2000; Hernandez-Diaz 2001; Matok 2009). Due to theoretical concerns that sulfonamides pass the placenta and may cause kernicterus in the newborn, neonatal health care providers should be informed if maternal sulfonamide therapy is used near the time of delivery (HHS [OI adult 2017]). The pharmacokinetics of sulfamethoxazole and trimethoprim are similar to nonpregnant values in early pregnancy (Ylikorkala 1973). Sulfamethoxazole and trimethoprim are recommended for the prophylaxis or treatment of Pneumocystis jirovecii pneumonia (PCP), prophylaxis of Toxoplasmic gondii encephalitis (TE), and for the acute and chronic treatment of Q fever in pregnancy (CDC 2013; HHS [OI adult 2017]). Sulfonamides may also be used to treat other infections in pregnant women when clinically appropriate; use during the first trimester should be limited to situations where no alternative therapies are available (ACOG 717 2017).
Sulfasalazine		Sulfasalazine and sulfapyridine cross the placenta. Based on available data, an increase in fetal malformations has not been observed following maternal use of sulfasalazine for the treatment of inflammatory bowel disease. Cases of neural tube defects have been reported (causation undetermined). Agranulocytosis was noted in an infant following maternal use of sulfasalazine during pregnancy. Although sulfapyridine has poor bilirubin-displacing ability, a potential for kernicterus in the newborn exists. Sulfasalazine is known to inhibit the absorption and metabolism of folic acid and may diminish the effects of folic acid supplementation. When treatment for inflammatory bowel disease is needed during pregnancy, sulfasalazine may be used, although supplementation with folic acid is recommended (Flint 2016; Huang 2014; Mahadevan 2015). Sulfasalazine may cause oligospermia and reversible infertility in males (Habal

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		2012). Use is compatible in males with female partners of reproductive potential; however, discontinuing treatment for 3 months may enhance conception (Flint 2016).
Sulfur/ Salicylic Acid	C	Adverse events have been observed in animal reproduction studies when administered orally. Salicylates cross the placenta (Østensen 1998). Systemic absorption of topical salicylic acid occurs and varies depending on duration and vehicle (~9% to 25%) and is increased with occlusion (Akhavan 2003). Current guidelines do not recommend salicylic acid for the treatment of psoriasis in pregnant women due to limited safety data and the potential for systemic absorption (Bae 2012). For the topical treatment of acne or warts, salicylic acid can be used in pregnant women if the area of exposure and duration of therapy is limited, although other agents may be preferred (Murase, 2014). Consider maternal/fetal adverse events associated with aspirin if significant systemic exposure occurs (Akhavan 2003).
Sumatriptan Succinate	C	In a study using full-term, healthy human placentas, limited amounts of sumatriptan were found to cross the placenta (Schenker 1995). Pregnancy outcome information for sumatriptan is available from a pregnancy registry sponsored by GlaxoSmithKline. As of September 2012, data were available for 617 pregnancies (626 infants/fetuses) exposed to sumatriptan (including 7 pregnancies also exposed to naratriptan). Following sumatriptan exposure, the risk of major birth defects following first trimester exposure was 4.2% and no consistent pattern of birth defects was observed. The pregnancy registry was closed to enrollment in January 2012 (Ephross 2014). An analysis of data collected between 1995 and 2008 using the Swedish Medical Birth Register reported pregnancy outcomes following 5-HT1B/1D agonist exposure. An increased risk of major congenital malformations was not observed following sumatriptan exposure (2,229 exposed during the first trimester) (Källén 2011). An increased risk of major congenital malformations was also not observed using data collected from a Norwegian pregnancy registry study. This study included 415 women who used sumatriptan during the first trimester of pregnancy between 2004 and 2007 (Nezvalová-Henriksen 2013). If treatment for cluster headaches is needed during pregnancy, sumatriptan may be used (Jürgens 2009). Other agents are preferred for the initial treatment of migraine in pregnancy (Da Silva 2012; MacGregor 2014; Williams 2012); however, sumatriptan may be considered if first-line agents fail (MacGregor 2014).
Tacrolimus	C	Adverse events were observed in animal reproduction studies. Tacrolimus crosses the human placenta and is measurable in the cord blood, amniotic fluid, and newborn serum. Tacrolimus concentrations in the placenta may be higher than the maternal serum (Jain 1997). Infants with lower birth weights have been found to have higher tacrolimus concentrations (Bramham 2013). Transient neonatal hyperkalemia and renal dysfunction have been reported. Tacrolimus pharmacokinetics are altered during pregnancy. Whole blood concentrations decrease as pregnancy progresses; however, unbound concentrations increase. Measuring unbound concentrations may be preferred, especially in women with anemia or hypoalbuminemia. If unbound concentration measurement is not available, interpretation of whole blood concentrations should account for RBC count and serum albumin concentration (Hebert 2013; Zheng 2012). In general, women who have had a kidney transplant should be instructed that fertility will be restored following the transplant but that pregnancy should be avoided for ~2 years. Tacrolimus may be used as an immunosuppressant during pregnancy. The risk of infection, hypertension, and pre-eclampsia may be increased in pregnant women who have had a kidney transplant (EBPG 2002). The Transplant Pregnancy Registry International (TPR) is a registry that follows pregnancies that occur in maternal transplant recipients or those fathered by male transplant recipients. The TPR encourages reporting of pregnancies following solid organ transplant by contacting them at 1-877-955-6877 or https://www.transplantpregnancyregistry.org.
Tamoxifen	D	Animal reproduction studies have demonstrated fetal adverse effects and fetal loss. There have been reports of vaginal bleeding, birth defects and fetal loss in pregnant women. Tamoxifen use during pregnancy may have a potential long term risk to the fetus of a DES-like syndrome. For sexually-active women of childbearing age, initiate during menstruation (negative β-hCG immediately prior to initiation in women with

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		irregular cycles). Tamoxifen may induce ovulation. Barrier or nonhormonal contraceptives are recommended. Pregnancy should be avoided during treatment and for 2 months after treatment has been discontinued.
Tamsulosin	B	Adverse events were not observed in animal reproduction studies. For pregnant women with kidney stones, other treatments such as stents or ureteroscopy, are recommended if stone removal is needed (Preminger 2007; Tan 2013).
Tar Shampoo		Limited application of coal tar during pregnancy for the treatment of psoriasis appears to be safe in pregnant women (Gelmetti, 2009; Landau, 2011).
Tears, Artificial		
Telbivudine	B	Adverse events were not observed in animal reproduction studies. In hepatitis B-infected women (not coinfected with HIV), the AASLD chronic hepatitis B treatment guidelines suggest antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg-positive pregnant women with an HBV DNA >200,000 units/mL. There are limited data on the level of HBV DNA for when antiviral therapy is routinely recommended (>200,000 units/mL is a conservative recommendation); however, the AASLD recommends against antiviral therapy to reduce the risk of perinatal transmission in HBsAg-positive pregnant women with an HBV DNA ≤200,000 units/mL. Telbivudine is one of the antivirals that has been studied in pregnant women, with most studies initiating antiviral therapy at 28 to 32 weeks gestation and discontinuing antiviral therapy between birth to 3 months postpartum (monitor for ALT flares every 3 months for 6 months following discontinuation). There is insufficient long-term safety data in infants born to mothers who took antiviral agents during pregnancy (AASLD [Terrault 2016]). Health professionals are encouraged to contact the antiretroviral pregnancy registry to monitor outcomes of pregnant women exposed to antiretroviral medications (1-800-258-4263).
Tenofovir Disoproxil Fumarate	B	Tenofovir has a high level of transfer across the human placenta following maternal use of tenofovir disoproxil fumarate. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Intrauterine growth has not been affected following use of tenofovir disoproxil fumarate, but data are conflicting about potential growth effects later in infancy. Clinical studies in children have shown bone demineralization with chronic use. Bone mineral content was also decreased in infants following in utero exposure. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general NRTIs are well tolerated and the benefits of use generally outweigh potential risk. The Health and Human Services (HHS) Perinatal HIV Guidelines consider tenofovir disoproxil fumarate a component in preferred regimens for initial therapy in antiretroviral-naïve pregnant females. The guidelines also consider emtricitabine plus tenofovir disoproxil fumarate, or lamivudine plus tenofovir disoproxil fumarate as recommended dual NRTI backbone for HIV/HBV coinfected pregnant females. Hepatitis B flare may occur if tenofovir disoproxil fumarate is discontinued. Tenofovir disoproxil fumarate is also a recommended component of a regimen when acute HIV infection is detected during pregnancy. Limited data indicate decreased maternal exposure during the third trimester; dose adjustments are not needed. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as

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		possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Tenofovir disoproxil fumarate is one of the agents recommended for pre-exposure prophylaxis in couples with differing HIV status who are planning a pregnancy. The partner without HIV should begin therapy 1 month prior to attempting conception and continue therapy for 1 month after attempting conception. In hepatitis B-infected women (not coinfected with HIV), the AASLD chronic hepatitis B treatment guidelines suggest antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg-positive pregnant women with an HBV DNA >200,000 units/mL. There are limited data on the level of HBV DNA for when antiviral therapy is routinely recommended (>200,000 units/mL is a conservative recommendation); however, the AASLD recommends against antiviral therapy to reduce the risk of perinatal transmission in HBsAg-positive pregnant women with an HBV DNA ≤200,000 units/mL. Tenofovir is one of the antivirals that has been studied in pregnant women (and may b
Terazosin	C	Adverse events have not been observed in animal studies. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed, other agents are generally preferred (ACOG 2013).
Terbinafine	B	Adverse events were not observed in animal reproduction studies with systemic terbinafine. Avoid use in pregnancy since treatment of onychomycosis is postponable. Systemic absorption is limited following topical application.
Testosterone (Depo Injection)	X	Use is contraindicated in pregnant women or women who may become pregnant. Exposure to a fetus may cause virilization of varying degrees. Because of the potential for secondary exposure, all children and women should avoid skin-to-skin contact to areas where testosterone has been applied topically on another person. Some products contain benzyl alcohol, which can cross the placenta. Large doses of testosterone may suppress spermatogenesis. Treatment of hypogonadotropic hypogonadism is not recommended for men desiring fertility (Endocrine Society [Bhasin 2018]).
Tetanus/ Diphtheria	C	Reproduction studies have not been conducted. DT is not recommended for use in persons ≥7 years of age. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (ACIP [Kroger 2017]). The Advisory Committee on Immunization Practices (ACIP) recommends a single Tdap vaccination during each pregnancy; ideally between 27 and 36 weeks gestation. Pregnant women who are not immunized or are only partially immunized should complete the primary series with Td. Tetanus immune globulin and a tetanus toxoid containing vaccine are recommended by the ACIP as part of the standard wound management to prevent tetanus in pregnant women; the use of a tetanus-toxoid containing vaccine during pregnancy is recommended for wound management if ≥5 years have passed since the last Td vaccination (CDC/ACIP 2013).
Tetanus Toxoid	C	Animal studies have not been conducted. Inactivated bacterial vaccines have not been shown to cause increased risks to the fetus (CDC, 2011). The ACIP recommends vaccination in previously unvaccinated women or in women with an incomplete vaccination series, whose child may be born in unhygienic conditions. Tetanus immune globulin and a tetanus toxoid-containing vaccine are recommended by the ACIP as part of the standard wound management to prevent tetanus in pregnant women. Vaccination using Td is preferred.
Tetrahydrozoline Ophthalmic		
Thiamine	A	Water soluble vitamins cross the placenta. Thiamine requirements are increased in during pregnancy (IOM 1998). Pregnant females are at increased risk of thiamine deficiency when prolonged nausea and vomiting (including hyperemesis gravidarum) occurs; deficiency may present as a polyneuropathy or Wernicke encephalopathy (Chiossi 2006; Karjalainen 1965; WHO 1999). Thiamine supplementation is

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		recommended in pregnant females with prolonged vomiting. Initial treatment with IV thiamine is needed when Wernicke encephalopathy is suspected. Oral, IM, or IV therapy may be considered depending on severity of thiamine deficiency (Berdai 2016; Chiossi 2006; Palacios-Marqués 2012). When intravenous hydration is used in the management of hyperemesis gravidarum, thiamine should be administered prior to infusing dextrose to prevent Wernicke encephalopathy (ACOG 189 2018).
Thiothixene		Adverse events were observed in some animal reproduction studies. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician. When treating schizophrenia during pregnancy, atypical antipsychotics may be better tolerated by the mother however more information related to fetal effects may be available for agents considered typical (or first generation) antipsychotics (ACOG 2008). Information related to the use of thiothixene in pregnancy is limited and other agents may be preferred.
Timolol Maleate	C	Adverse events were not observed in the initial animal reproduction studies. Timolol crosses the placenta (Schneider 1988) and decreased fetal heart rate has been observed following maternal use of timolol during pregnancy (Devoe 1986). Adverse events, such as fetal/neonatal hypoglycemia and reduced birth weight, have been observed following in utero exposure to beta-blockers as a class. Adequate facilities for monitoring infants at birth is generally recommended. Untreated chronic maternal hypertension and preeclampsia are also associated with adverse events in the fetus, infant, and mother (ACOG 2015; Magee 2014). Although beta-blockers may be used when treatment of hypertension in pregnancy is indicated, agents other than timolol are preferred (ACOG 2013; Magee 2014). In addition, other agents are preferred when migraine prophylaxis is needed in pregnant women (Pringsheim 2012).
Tipranavir		Tipranavir has a moderate level of transfer across the human placenta (based on one case). Data collected by the antiretroviral pregnancy registry are insufficient to evaluate human teratogenic risk. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Hyperglycemia, new onset of diabetes mellitus, or diabetic ketoacidosis have been reported with PIs; it is not clear if pregnancy increases this risk. The Health and Human Services (HHS) Perinatal HIV Guidelines do not recommend tipranavir for initial use in antiretroviral-naive pregnant patients. Available pharmacokinetic data are insufficient to make dosing recommendations. In general, ART is recommended for all pregnant females with HIV to keep the viral load below the limit of detection and reduce the risk of perinatal transmission. When HIV is diagnosed during pregnancy in a female who has never received antiretroviral therapy, ART should begin as soon as possible after diagnosis. Females who become pregnant on a stable ART regimen may continue that regimen if viral suppression is effective, appropriate drug exposure can be achieved, contraindications for use in pregnancy are not present, and the regimen is well tolerated. Monitoring during pregnancy is more frequent than in nonpregnant adults; ART should be continued postpartum for all females living with HIV. Health care providers are encouraged to enroll pregnant females exposed to antiretroviral medications as early in pregnancy as possible in the Antiretroviral Pregnancy Registry (1-800-258-4263 or

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		http://www.APRegistry.com). Health care providers caring for HIV-infected females and their infants may contact the National Perinatal HIV Hotline (888-448-8765) for clinical consultation (HHS [perinatal] 2017).
Titanium Dioxide		
Tizanidine		Adverse events were observed in some animal reproduction studies.
Tobramycin Ophthalmic	B	Adverse events have not been observed in animal reproduction studies. The amount of tobramycin available systemically following topical application of the ophthalmic drops is undetectable (<0.2 mcg/mL) (Filatov 1994). If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctal occlusion to decrease systemic absorption (Samples 1988).
Tolnaftate		
Topiramate	D	Adverse events have been observed in animal reproduction studies. Based on limited data (n=5), topiramate was found to cross the placenta and could be detected in neonatal serum (Ohman 2002). Topiramate may cause fetal harm if administered to a pregnant woman. An increased risk of oral clefts (cleft lip and/or palate) and for being small for gestational age (SGA) has been observed following in utero exposure. Data from the North American Antiepileptic Drug (NAAED) Pregnancy Registry reported that the prevalence of oral clefts was 1.1% for infants exposed to topiramate during the first trimester of pregnancy, versus 0.36% for infants exposed to a reference antiepileptic drug, and 0.12% for infants with no exposure born to mothers without epilepsy; the relative risk of oral clefts in infants exposed to topiramate was calculated to be 9.6 (95% CI: 4 to 23). Data from the NAAED Pregnancy Registry reported that the prevalence of small for gestational age newborns was 19.7% for newborns exposed to topiramate in utero, versus 7.9% for newborns exposed to a reference antiepileptic drug, and 5.4% for newborns with no exposure born to mothers without epilepsy. Although not evaluated during pregnancy, metabolic acidosis may be induced by topiramate. Metabolic acidosis during pregnancy may result in adverse effects and fetal death. Pregnant women and their newborns should be monitored for metabolic acidosis. In general, maternal polytherapy with antiepileptic drugs may increase the risk of congenital malformations; monotherapy with the lowest effective dose is recommended. Newborns of women taking antiepileptic medications may be at an increased risk of a 1 minute APGAR score <7 (Harden 2009). Maternal serum concentrations may decrease during the second and third trimesters of pregnancy; therefore, therapeutic drug monitoring should be considered during pregnancy and postpartum in patients who require therapy (Ohman 2009; Westin 2009). Effective contraception should be used in women who are not planning a pregnancy; consider use of alternative medications in women who wish to become pregnant. Data collection to monitor pregnancy and infant outcomes following exposure to topiramate is ongoing. Patients may enroll themselves into the AED Pregnancy Registry by calling 1-888-233-2334. Additional information is available at www.aedpregnancyregistry.org.
Tramadol		[US Boxed Warning]: Prolonged maternal use of opioids during pregnancy can cause neonatal withdrawal syndrome in the newborn which may be life-threatening if not recognized and treated according to protocols developed by neonatology experts. If prolonged opioid therapy is required in a pregnant woman, ensure treatment is available and warn patient of risk to the neonate. Tramadol crosses the placenta. Maternal use of opioids may be associated with birth defects, poor fetal growth, stillbirth, and preterm delivery (CDC [Dowell 2016]). If chronic opioid exposure occurs in pregnancy, adverse events in the newborn (including withdrawal) may occur (Chou 2009). Symptoms of neonatal abstinence syndrome (NAS) following opioid exposure may be autonomic (eg, fever, temperature instability), gastrointestinal (eg, diarrhea, vomiting, poor feeding/weight gain), or neurologic (eg, high-pitched crying, hyperactivity, increased muscle tone, increased wakefulness/abnormal sleep pattern, irritability, sneezing, seizure, tremor, yawning) (Dow 2012; Hudak 2012). Mothers who are physically dependent on opioids may give birth to Infants who are also physically dependent. Opioids may cause respiratory depression and psycho-physiologic effects in the neonate; newborns of mothers receiving opioids during labor should be monitored.

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		Agents other than tramadol are commonly used to treat maternal pain during labor and immediately postpartum (ACOG 177 2017) as well as chronic noncancer pain in pregnant women or those who may become pregnant (CDC [Dowell 2016]; Chou 2009; Kahan 2011).
Trazodone	C	Adverse effects were observed in some animal reproduction studies. The ACOG recommends that therapy with antidepressants during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. Consideration should be given to using agents with safety data in pregnancy. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy (ACOG 2008; APA 2010; Yonkers 2009). Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Tretinoin Topical	C	Adverse events were observed in animal reproduction studies following topical application of tretinoin. Teratogenic effects were also observed in pregnant women following topical use; however, a causal association has not been established. When treatment for acne is needed during pregnancy, other agents are preferred (Kong, 2013). These products should not be used for palliation of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in women who are pregnant, attempting to conceive, or at high risk for pregnancy.
Triamcinolone Acetonide	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014).
Triamcinolone Dental Paste	C	Adverse events have been observed in some animal reproduction studies. Systemic bioavailability of topical corticosteroids is variable (integrity of skin, use of occlusion, etc.) and may be further influenced by trimester of pregnancy (Chi 2017). In general, the use of topical corticosteroids is not associated with a significant risk of adverse pregnancy outcomes. However, there may be an increased risk of low birth weight infants following maternal use of potent or very potent topical products, especially in high doses. Use of mild to moderate potency topical corticosteroids is preferred in pregnant females and the use of large amounts or use for prolonged periods of time should be avoided (Chi 2016; Chi 2017; Murase 2014). Also avoid areas of high percutaneous absorption (Chi 2017). The risk of stretch marks may be increased with use of topical corticosteroids (Murase 2014).
Triamcinolone Hexacetonide		Adverse events have been observed with corticosteroids in animal reproduction studies. Some studies have shown an association between first trimester systemic corticosteroid use and oral clefts or decreased birth weight; however, information is conflicting and may be influenced by maternal dose/indication for use (Lunghi 2010; Park-Wyllie 2000; Pradat 2003). Hypoadrenalism may occur in newborns following maternal use of corticosteroids in pregnancy; monitor. When systemic corticosteroids are needed in pregnancy for rheumatic disorders, it is generally recommended to use the lowest

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		effective dose for the shortest duration of time, avoiding high doses during the first trimester. Intra-articular dosing may be used (Götestam Skorpen 2016; Makol 2011; Østensen 2009). For dermatologic disorders in pregnant females, systemic corticosteroids are generally not preferred for initial therapy; should be avoided during the first trimester; and used during the second or third trimester at the lowest effective dose (Bae 2012; Leachman 2006).
Triamterene/ Hydrochlorothiazide		Triamterene: Adverse events have not been observed in animal reproduction studies. Triamterene crosses the placenta and is found in cord blood. Use of triamterene to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Hydrochlorothiazide: Adverse events have not been observed in animal reproduction studies. Hydrochlorothiazide crosses the placenta. Maternal use may cause may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Use of thiazide diuretics to treat edema during normal pregnancies is not appropriate; use may be considered when edema is due to pathologic causes (as in the nonpregnant patient); monitor. Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother (ACOG 2013). Women who required thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use (ACOG 2013).
Trihexyphenidyl	C	Animal reproduction studies have not been conducted. One case report did not show evidence of adverse events after trihexyphenidyl administration during pregnancy (Robottom, 2011).
Trimethobenzamide Hydrochloride		Although use for the treatment of nausea and vomiting in pregnancy has been reported (Milkovich 1976; Pretorius 1961), use of other agents is preferred (ACOG 189 2018).
Tropicamide		Animal reproduction studies have not been conducted. If ophthalmic agents are needed during pregnancy, the minimum effective dose should be used in combination with punctual occlusion to decrease potential exposure to the fetus (Samples, 1988).
Tuberculin Purified Protein Derivative	C	Animal reproduction studies have not been conducted. Pregnancy is not a contraindication to testing (CDC 2005).
Ulipristal		Use is contraindicated during a known or suspected pregnancy. Isolated cases of major malformations have been reported following inadvertent use during pregnancy, however data are not sufficient to determine a causal relationship and no pattern of adverse outcomes has been identified. When used for emergency contraception, exclude pregnancy prior to therapy; ulipristal is not indicated for terminating an existing pregnancy. A rapid return of fertility is expected following use for emergency contraception; routine contraceptive measures should be initiated or continued following use to ensure ongoing prevention of pregnancy. Barrier contraception is recommended immediately following emergency contraception and throughout the same menstrual cycle; efficacy of hormonal contraceptives may be decreased. The manufacturer recommends waiting ≥5 days after taking ulipristal before resuming oral contraceptives. The CDC notes any contraceptive method may be started immediately after taking ulipristal; however, a barrier method should also be used for 14 days following the dose (or until menses occurs, whichever occurs first) (Curtis 2016a). The manufacturer labeling suggests that ulipristal may be less effective in females with BSA >30 kg/m2. When ulipristal is used for treatment of uterine fibroids (Canadian labeling; not in US labeling) a nonhormonal method of contraception is recommended.
Umeclidinium/ Vilanterol	C	Animal reproduction studies have not been conducted with this combination. Beta-agonists have the potential to affect uterine contractility if administered during labor.
Valproic Acid	X (migraine pro-phylaxis)/ D (all other indi-cations)	Adverse events have been observed in animal reproduction studies and in human pregnancies. [US Boxed Warning]: May cause major congenital malformations, such as neural tube defects (eg, spina bifida) and decreased IQ scores following in utero exposure. Use is contraindicated in pregnant women for the prevention of migraine. Use is not recommended in women of childbearing potential for any other condition unless valproate is essential to manage her condition and alternative therapies are not appropriate. Effective contraception should be used during therapy. Valproic acid crosses the placenta (Harden 2009b). Neural tube defects, craniofacial defects,

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Generic Name	Category	Pregnancy Implications
		cardiovascular malformations, hypospadias, and limb malformations have been reported. Information from the North American Antiepileptic Drug Pregnancy Registry notes the rate of major malformations to be 9% to 11% following an average exposure to valproate monotherapy 1,000 mg/day; this is an increase in congenital malformations when compared with monotherapy with other antiepileptic drugs (AED). Based on data from the CDC National Birth Defects Prevention Network, the risk of spinal bifida is approximately 1% to 2% following valproate exposure (general population risk estimated to be 0.06% to 0.07%). Nonteratogenic adverse effects have also been reported. Decreased IQ scores have been noted in children exposed to valproate in utero when compared to children exposed to other antiepileptic medications or no antiepileptic medications; the risk of autism spectrum disorders may also be increased. Fatal hepatic failure and hypoglycemia in infants have been noted in case reports following in utero exposure to valproic acid. Clotting factor abnormalities (hypofibrinogenemia, thrombocytopenia, or decrease in other coagulation factors) may develop in the mother following valproate use during pregnancy; close monitoring of coagulation factors is recommended. Current guidelines recommend complete avoidance of valproic acid and derivatives for the treatment of epilepsy in pregnant women whenever possible (Harden 2009a), especially when used for conditions not associated with permanent injury or risk of death. Effective contraception should be used during treatment. When pregnancy is being planned, consider tapering off of therapy prior to conception if appropriate; abrupt discontinuation of therapy may cause status epilepticus and lead to maternal and fetal hypoxia. Folic acid decreases the risk of neural tube defects in the general population; supplementation with folic acid should be used prior to conception and during pregnancy in all women, including those taking valproate. A pregnancy registry is available for women who have been exposed to valproic acid. Patients may enroll themselves in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling (888) 233-2334. Additional information is available at www.aedpregnancyregistry.org.
Valsartan		[US Boxed Warning]: Drugs that act on the renin-angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. The use of drugs which act on the renin-angiotensin system are associated with oligohydramnios. Oligohydramnios, due to decreased fetal renal function, may lead to fetal lung hypoplasia and skeletal malformations. Use is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate. The exposed fetus should be monitored for fetal growth, amniotic fluid volume, and organ formation. Infants exposed in utero should be monitored for hyperkalemia, hypotension, and oliguria (exchange transfusions or dialysis may be needed). These adverse events are generally associated with maternal use in the second and third trimesters. Untreated chronic maternal hypertension is also associated with adverse events in the fetus, infant, and mother. The use of angiotensin II receptor blockers is not recommended to treat chronic uncomplicated hypertension in pregnant women and should generally be avoided in women of reproductive potential (ACOG, 2013).
Vancomycin		Adverse events have not been observed in animal reproduction studies. Vancomycin crosses the placenta and can be detected in fetal serum, amniotic fluid, and cord blood (Bourget 1991; Reyes 1989). Adverse fetal effects, including sensorineural hearing loss or nephrotoxicity, have not been reported following maternal use during the second or third trimesters of pregnancy. The pharmacokinetics of vancomycin may be altered during pregnancy and pregnant patients may need a higher dose of vancomycin. Maternal half-life is unchanged, but the volume of distribution and the total plasma clearance may be increased (Bourget 1991). Individualization of therapy through serum concentration monitoring may be warranted. Vancomycin is recommended for the treatment of Clostridium difficile infections in pregnant women (ACG [Surawicz 2013]). Vancomycin is recommended as an alternative agent to prevent the transmission of group B streptococcal (GBS) disease from mothers to newborns (ACOG 2011; CDC 2010).

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Generic Name	Category	Pregnancy Implications
Varicella Vaccine		Varicella virus vaccine is contraindicated for use in pregnant females and pregnancy should be avoided for 3 months (per manufacturer labeling; 1 month per ACIP) following vaccination. Information was collected from 1995-2013 using the manufacturer's pregnancy registry, and included 905 women who received a varicella containing vaccine (30% within 3 months prior to conception) and who had known pregnancy outcomes. Among these women, the rates of miscarriage and birth defects was not increased above background rates, and there were no infants born with abnormalities consistent with congenital varicella syndrome. Varicella disease during the 1st or 2nd trimesters may result in congenital varicella syndrome. The onset of maternal varicella infection from 5 days prior to 2 days after delivery may cause varicella infection in the newborn. All women should be assessed for immunity during a prenatal visit; those without evidence of immunity should be vaccinated upon completion or termination of pregnancy (CDC/ACIP [Marin 2007]). Any exposures to the vaccine during pregnancy or within 3 months prior to pregnancy should be reported to the manufacturer (Merck & Co, 877-888-4231) or to VAERS (800-822-7967) as suspected adverse reactions.
Venlafaxine	C	Adverse events have been observed in some animal reproduction studies. Venlafaxine and its active metabolite ODV cross the human placenta. An increased risk of teratogenic effects following venlafaxine exposure during pregnancy has not been observed, based on available data. The risk of spontaneous abortion may be increased. Neonatal seizures and neonatal abstinence syndrome have been noted in case reports following maternal use of venlafaxine during pregnancy. Nonteratogenic effects in the newborn following SSRI/SNRI exposure late in the third trimester include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hyper- or hypotonia, hyper-reflexia, jitteriness, irritability, constant crying, and tremor. Symptoms may be due to the toxicity of the SNRI or a discontinuation syndrome and may be consistent with serotonin syndrome associated with treatment. The long-term effects of in utero SNRI/SSRI exposure on infant development and behavior are not known. Due to pregnancy-induced physiologic changes, some pharmacokinetic parameters of venlafaxine may be altered. Women should be monitored for decreased efficacy. The ACOG recommends that therapy with SSRIs or SNRIs during pregnancy be individualized; treatment of depression during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary health care provider, and pediatrician. According to the American Psychiatric Association (APA), the risks of medication treatment should be weighed against other treatment options and untreated depression. For women who discontinue antidepressant medications during pregnancy and who may be at high risk for postpartum depression, the medications can be restarted following delivery. Treatment algorithms have been developed by the ACOG and the APA for the management of depression in women prior to conception and during pregnancy. Pregnant women exposed to antidepressants during pregnancy are encouraged to enroll in the National Pregnancy Registry for Antidepressants (NPRAD). Women 18 to 45 years of age or their health care providers may contact the registry by calling 844-405-6185. Enrollment should be done as early in pregnancy as possible.
Verapamil	C	Adverse events have been observed in some animal reproduction studies in doses, which also caused maternal toxicity. Verapamil crosses the placenta. Use during pregnancy may cause adverse fetal effects (bradycardia, heart block, hypotension) (Tan 2001). Women with hypertrophic cardiomyopathy who are controlled with verapamil prior to pregnancy may continue therapy, but increased fetal monitoring is recommended (Gersh 2011). Verapamil may be used IV for the acute treatment of supraventricular tachycardia (SVT) in pregnant women when adenosine or beta-blockers are ineffective or contraindicated. Verapamil may also be used for the ongoing management of SVT in highly symptomatic patients. The lowest effective dose is recommended; avoid use during the first trimester if possible (Page [ACC/AHA/HRS 2015]). Untreated chronic maternal hypertension is associated with adverse events in the fetus, infant, and mother. If treatment for hypertension during pregnancy is needed,

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Generic Name	Category	Pregnancy Implications
		other agents are preferred (ACOG 2013). Additional guidelines are available for management of cardiovascular diseases during pregnancy (ESG [Regitz-Zagrosek 2011]).
Vitamin A		Adverse events have been observed in animal reproduction studies. In humans, the critical period of exposure is the first trimester of pregnancy. Excess vitamin A during pregnancy may cause craniofacial malformations, as well as CNS, heart, and thymus abnormalities. Maternal vitamin A deficiency also causes adverse effects in the fetus, and vitamin A requirements are increased in pregnant women (IOM 2000). The manufacturer notes that the safety of doses >6,000 units/day in pregnant women has not been established and doses greater than the RDA are contraindicated in pregnant women or those who may become pregnant. High doses are used in some areas of the world for supplementation where deficiency is a public health problem (eg, to prevent night blindness); however, single doses >25,000 units should be avoided within 60 days of conception. High-dose supplementation is otherwise not recommended as part of routine antenatal care (WHO 2011c).
Vitamin A&D Ointment		
Vitamin D2 & D3		Ergocalciferol: Adverse events were observed in some animal reproduction studies. The ergocalciferol (vitamin D2) metabolite, 25(OH)D, crosses the placenta; maternal serum concentrations correlate with fetal concentrations at birth (Misra, 2008; Wagner, 2008). Vitamin D deficiency in a pregnant woman may lead to a vitamin D deficiency in the neonate (Misra, 2008; Wagner, 2008). Serum 25(OH)D concentrations should be measured in pregnant women considered to be at increased risk of deficiency (ACOG, 2011). The amount of vitamin D contained in prenatal vitamins may not be adequate to treat a deficiency during pregnancy; although larger doses may be needed, current guidelines recommend a total of 1000 to 2000 units/day until more safety data is available (ACOG, 2011; Holick, 2011). In women not at risk for deficiency, doses larger than the RDA should be avoided during pregnancy (ACOG, 2011). Cholecalciferol: The cholecalciferol metabolite, 25(OH)D, crosses the placenta; maternal serum concentrations correlate with fetal concentrations at birth (Misra 2008; Wagner 2008). Vitamin D requirements are the same in pregnant and nonpregnant females (IOM 2011). Vitamin D deficiency in a pregnant woman may lead to a vitamin D deficiency in the neonate (Misra 2008; Wagner 2008). Serum 25(OH)D concentrations should be measured in pregnant women considered to be at increased risk of deficiency (ACOG 2011). The amount of vitamin D contained in prenatal vitamins may not be adequate to treat a deficiency during pregnancy; although larger doses may be needed, current guidelines recommend a total of 1,000 to 2,000 units/day until more safety data is available (ACOG 2011; Holick 2011). In women not at risk for deficiency, doses larger than the RDA should be avoided during pregnancy (ACOG 2011).
Warfarin		Warfarin crosses the placenta; concentrations in the fetal plasma are similar to maternal values. Teratogenic effects have been reported following first trimester exposure and may include coumarin embryopathy (nasal hypoplasia and/or stippled epiphyses; limb hypoplasia may also be present). Adverse CNS events to the fetus have also been observed following exposure during any trimester and may include CNS abnormalities (including ventral midline dysplasia, dorsal midline dysplasia). Spontaneous abortion, fetal hemorrhage, and fetal death may also occur. Use is contraindicated during pregnancy (or in women of reproductive potential) except in women with mechanical heart valves who are at high risk for thromboembolism; use is also contraindicated in women with threatened abortion, eclampsia, or preeclampsia. Frequent pregnancy tests are recommended for women who are planning to become pregnant and adjusted-dose heparin or low molecular weight heparin (LMWH) should be substituted as soon as pregnancy is confirmed or adjusted-dose heparin or LMWH should be used instead of warfarin prior to conception. In pregnant women with high-risk mechanical heart valves, the benefits of warfarin therapy should be discussed with the risks of available treatments (ACCP [Bates 2012]; AHA/ACC [Nishimura 2014]); when possible avoid

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Generic Name	Category	Pregnancy Implications
		warfarin use during the first trimester (ACCP [Bates 2012]) and close to delivery (ACCP [Bates 2012]; AHA/ACC [Nishimura 2014]). Use of warfarin during the first trimester may be considered if the therapeutic INR can be achieved with a dose ≤5 mg/day (AHA/ACC [Nishimura 2014]). Adjusted-dose LMWH or adjusted-dose heparin may be used throughout pregnancy or until week 13 of gestation when therapy can be changed to warfarin. LMWH or heparin should be resumed close to delivery. In women who are at a very high risk for thromboembolism (older generation mechanical prosthesis in mitral position or history of thromboembolism), warfarin can be used throughout pregnancy and replaced with LMWH or heparin near term; the use of low-dose aspirin is also recommended (ACCP [Bates 2012] AHA/ACC [Nishimura 2014]). Women who require long-term anticoagulation with warfarin and who are considering pregnancy, LMWH substitution should be done prior to conception when possible. If anti-Xa monitoring cannot be done, do not use LMWH therapy in pregnant patients with a mechanical prosthetic valve (AHA/ACC [Nishimura 2014]). When choosing therapy, fetal outcomes (ie, pregnancy loss, malformations), maternal outcomes (ie, VTE, hemorrhage), burden of therapy, and maternal preference should be considered (ACCP [Bates 2012]).
Zalcitabine		
Zidovudine		* Zidovudine has a high level of transfer across the human placenta; the placenta also metabolizes zidovudine to the active metabolite. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Zidovudine/Lamivudine		* Zidovudine has a high level of transfer across the human placenta; the placenta also metabolizes zidovudine to the active metabolite. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk. * Lamivudine has a high level of transfer across the human placenta. No increased risk of overall birth defects has been observed following first trimester exposure according to data collected by the antiretroviral pregnancy registry. Maternal antiretroviral therapy (ART) may increase the risk of preterm delivery, although available information is

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Generic Name	Category	Pregnancy Implications
		conflicting possibly due to variability of maternal factors (disease severity; gestational age at initiation of therapy); however, maternal antiretroviral medication should not be withheld due to concerns of preterm birth. Based on data collected by the antiretroviral pregnancy registry, the risk of spontaneous abortions, induced abortions, and preterm birth is less in lamivudine-containing regimens compared with regimens without lamivudine. Information related to stillbirth, low birth weight, and small for gestational age infants is limited. Long-term follow-up is recommended for all infants exposed to antiretroviral medications; children who develop significant organ system abnormalities of unknown etiology (particularly of the CNS or heart) should be evaluated for potential mitochondrial dysfunction. Cases of lactic acidosis and hepatic steatosis related to mitochondrial toxicity have been reported with use of nucleoside reverse transcriptase inhibitors (NRTIs). These adverse events are similar to other rare but life-threatening syndromes that occur during pregnancy (eg, HELLP syndrome). In general, NRTIs are well tolerated and the benefits of use generally outweigh potential risk.
Zinc Oxide		Zinc oxide is not expected to be absorbed systemically following topical administration to healthy skin (Newman, 2009). Systemic absorption would be required in order for zinc oxide to cross the placenta and reach the fetus.
Ziprasidone	C	Adverse events were observed in animal reproduction studies. Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization. Ziprasidone may cause hyperprolactinemia, which may decrease reproductive function in both males and females. The ACOG recommends that therapy during pregnancy be individualized; treatment with psychiatric medications during pregnancy should incorporate the clinical expertise of the mental health clinician, obstetrician, primary healthcare provider, and pediatrician. Safety data related to atypical antipsychotics during pregnancy is limited and routine use is not recommended. However, if a woman is inadvertently exposed to an atypical antipsychotic while pregnant, continuing therapy may be preferable to switching to a typical antipsychotic that the fetus has not yet been exposed to; consider risk:benefit (ACOG 2008). Healthcare providers are encouraged to enroll women 18-45 years of age exposed to ziprasidone during pregnancy in the Atypical Antipsychotics Pregnancy Registry (1-866-961-2388 or http://www.womensmentalhealth.org/pregnancyregistry).

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Formulary Medications with Contact Precautions

Some oral medications carry with them a risk of untoward or deleterious effects due to unintended absorption. These medications can be chemotherapy, immunosuppressants, enzyme inhibitors, as well as other agents. The National Institute of Occupational Safety and Health recommends using single gloved hands for the administration of intact tablets or capsules.

https://www.cdc.gov/niosh/docket/review/docket233a/pdfs/2016-161finalpublication.pdf

Trade Name	Generic Name	Class No.	Therapeutic Class	Formulation	Contact Precautions
Propecia/ Proscar	finasteride	920800	5 Alpha-Reductase Inhibitor	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Hydrea/ Droxia	hydroxyurea	1000000	Antineoplastic Agents	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Methotrexate	methotrexate	1000000	Antineoplastic Agents	Tablet	Teratogenic potential (FDA Category X); avoid direct contact
CellCept/ Myfortic	mycophenolate	924400	Immunosupressive agents	Capsule/ tablet	Teratogenic potential: Skin contact may enhance tumor production; avoid direct contact

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High Alert Medications

High-Alert Medications in Acute Care Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies like improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; standardizing the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent doublechecks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list).

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts, ISMP created and periodically updates a list of potential highalert medications. During May and June 2014, practitioners responded to an ISMP survey designed to identify which medications were most frequently considered highalert drugs by individuals and organizations. Further, to assure relevance and completeness, the clinical staff at ISMP, members of the ISMP advisory board, and safety experts throughout the US were asked to review the potential list. This list of drugs and drug categories reflects the collective thinking of all who provided input.

Classes/Categories of Medications	
adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)	adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
insulin, subcutaneous and IV	parenteral nutrition preparations
anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)	moderate sedation agents, IV (e.g., dexmedetomidine, midazolam)
antiarrhythmics, IV (e.g., lidocaine, amiodarone)	moderate sedation agents, oral, for children (e.g., chloral hydrate)
antithrombotic agents, including: • anticoagulants (e.g., warfarin, low molecular weight heparin, IV unfractionated heparin) • Factor Xa inhibitors (e.g., fondaparinux, apixaban, rivaroxaban) • direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran etexilate) • thrombolytics (e.g., alteplase, reteplase, tenecteplase) • glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)	narcotics/opioids • IV • transdermal • oral (including liquid concentrates, immediate and sustained release formulations)
	neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium)
	liposomal forms of drugs (e.g., liposomal amphotericin B) and conventional counterparts (e.g., amphotericin B desoxycholate)
cardioplegic solutions	radiocontrast agents, IV
chemotherapeutic agents, parenteral and oral	dextrose, hypertonic, 20% or greater
sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more	sodium chloride for injection, hypertonic, greater than 0.9% concentration
dialysis solutions, peritoneal and hemodialysis	hypoglycemics, oral
epidural or intrathecal medications	inotropic medications, IV (e.g., digoxin, milrinone)

Specific Medications	
EPINEPHrine, subcutaneous	oxytocin, IV
epoprostenol (Flolan), IV	nitroprusside sodium for injection
insulin U-500 (special emphasis)*	potassium chloride for injection concentrate
magnesium sulfate injection	potassium phosphates injection
methotrexate, oral, nononcologic use	promethazine, IV
opium tincture	vasopressin, IV or intraosseous

*All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.

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High-Alert Medications in Community and Ambulatory Healthcare Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors and minimize harm. This may include strategies like providing mandatory patient education; improving access to information about these drugs; using auxiliary labels and automated alerts; employing automated or independent double checks when necessary; and standardizing the prescribing, storage, dispensing, and administration of these products.

Background

Based on error reports submitted to the ISMP Medication Errors Reporting Program (ISMP MERP), reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created a list of potential high alert medications. During June-August 2006, 463 practitioners responded to an ISMP survey designed to identify which medications were most frequently considered high alert drugs by individuals and organizations. In 2008, the preliminary list and survey data as well as data about preventable adverse drug events from the ISMP MERP, the Pennsylvania Patient Safety Reporting System, the FDA MedWatch database, databases from participating pharmacies, public litigation data, literature review, and a small focus group of ambulatory care pharmacists and medication safety experts were evaluated as part of a research study funded by an Agency for Healthcare Research and Quality (AHRQ) grant. This list of drugs and drug categories reflects the collective thinking of all who provided input. This list was created as part of the AHRQ funded project "Using risk models to identify and prioritize outpatient high alert medications"

Classes/Categories of Medications	Specific Medications
antiretroviral agents (e.g., efavirenz, lami**VUD**ine, raltegravir, ritonavir, combination antiretroviral products)	car**BAM**azepine
chemotherapeutic agents, oral (excluding hormonal agents) (e.g., cyclophosphamide, mercaptopurine, temozolomide)	heparin, including unfractionated and low molecular weight heparin
hypoglycemic agents, oral	met**FORMIN**
immunosuppressant agents (e.g., aza**THIO**prine, cyclo**SPORINE**, tacrolimus)	methotrexate, non-oncologic use
insulin, all formulations	propylthiouracil
opioids, all formulations	warfarin
pediatric liquid medications that require measurement	
pregnancy category X drugs (e.g., bosentan, **ISO**tretinoin)	

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High-Alert Medications in Long-Term Care Settings

High-alert medications are drugs that bear a heightened risk of causing significant patient or resident harm when they are used in error (e.g., wrong drug, wrong dose, wrong route). Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients or residents. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels and automated alerts; and employing redundancies such as automated or independent double-checks when necessary. (Note: manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list). Please note that long-term acute care (LTAC) facilities, and LTC facilities with subacute units or where a wide variety of intravenous medications are administered, should also use the ISMP List of High-Alert Medications in Acute Care Settings, which can be found at: www.ismp.org/Tools/institutionalhighAlert.asp. Facilities are also encouraged to use other resources, such as the Beers Criteria1 and STOPP and START Criteria,2 to identify and address medications that should be avoided in the elderly population, which are different from high-alert medications.

Background

Based on error reports submitted to the ISMP National Medication Errors Reporting Program, reports of harmful errors in the literature, and input from practitioners and safety experts, ISMP created and will periodically update a list of potential high-alert medications in the long-term care setting. During March 2016, practitioners from LTC facilities responded to an ISMP survey designed to identify which medications were most frequently considered high-alert medications in this setting. Further, to assure relevance and completeness, the clinical staff at ISMP, members of our LTC Advisory Board, and safety experts throughout the US were asked to review the potential list. This list of specific medications and medication classes/categories reflects the collective thinking of all who provided input.

Classes/Categories of Medications
anticoagulants, parenteral and oral. Including warfarin and new agents.
chemotherapeutic agents, parenteral and oral (excluding hormonal agents)
hypoglycemics, oral (including combination products with another drug)
insulins, all formulations and strengths (e.g., U-100, U-200, U-300, U-500)
parenteral nutrition preparations
opioids - parenteral, transdermal, and oral (including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug)

Specific Medications
digoxin, parenteral and oral
EPINEPHrine, parenteral
iron dextran, parenteral
methotrexate, oral, non-oncology use **
concentrated morphine solution, oral ***

** All forms of chemotherapy are considered a class of high-alert medications. Oral methotrexate for non-oncology purposes has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug when used for non-oncology purposes that can result in death.

*** All forms of opioids are considered a class of high-alert medications. Concentrated morphine solution has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent wrong frequency errors that occur with this drug that can result in death.

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Oral Dosage Forms That Should Not Be Crushed

Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Effervescent Potassium	------	Tablet	Effervescent tablet (f)
Tylenol Arthritis	acetaminophen	Tablet	Slow-release
Charcoal Plus	activated charcoal	Tablet	Enteric-coated
VoSpire ER	albuterol	Tablet	Slow-release
Fosamax	alendronate	Tablet	Mucous membrane irritant
Uroxatral	alfuzosin	Tablet	Slow-release
ALPRAZolam ER	ALPRAZolam	Tablet	Slow-release
Xanax XR	ALPRAZolam	Tablet	Slow-release
Letairis	ambrisentan	Tablet	Slow-release
Moxatag	amoxicillin	Tablet	Slow-release
Adderall XR	amphetamine salts	Capsule	Slow-release (a)
Otezla	apremilast	Tablet	Film-coated
Aspirin enteric-coated	aspirin	Caplet; Tablet	Slow-release; Enteric-coated
Bayer EC	aspirin	Caplet	Enteric-coated
Bayer Regular	aspirin	Caplet	Enteric-coated
Durlaza	aspirin	Capsule	Slow-release
Easprin	aspirin	Tablet	Enteric-coated
Ecotrin Adult Low Strength	aspirin	Tablet	Enteric-coated
Ecotrin Maximum Strength	aspirin	Tablet	Enteric-coated
Ecotrin Regular Strength	aspirin	Tablet	Enteric-coated
Halfprin 81	aspirin	Tablet	Enteric-coated
Reyataz	atazanavir	Capsule	Note: an oral powder is available, see prescribing information for administration instructions
Strattera	atomoxetine	Capsule	Note: capsule contents can cause ocular irritation
Tessalon Perles	benzonatate	Capsule	Note: swallow whole; local anesthesia of the oral mucosa; choking could occur
Alophen	bisacodyl	Tablet	Enteric-coated
Bisac-Evac	bisacodyl	Tablet	Enteric-coated (c)
Doxidan	bisacodyl	Tablet	Enteric-coated (c)
Dulcolax	bisacodyl	Capsule; Tablet	Enteric-coated (c); Liquid-filled
Feen-a-mint	bisacodyl	Tablet	Enteric-coated (c)
Fleet Laxative	bisacodyl	Tablet	Enteric-coated (c)
Tracleer	bosentan	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Briviact	brivaracetam	Tablet	Film-coated (b)
Lodrane 24	brompheniramine	Capsule	Slow-release
LoHist 12 Hour	brompheniramine	Tablet	Slow-release
Entocort EC	budesonide	Capsule	Enteric-coated (a)
Uceris	budesonide	Tablet	Slow-release (Note: film coating is designed to break down at or above pH of 7.0)
Aplenzin	buPROPion	Tablet	Slow-release
Budeprion SR	buPROPion	Tablet	Slow-release
Wellbutrin SR, XL	buPROPion	Tablet	Slow-release
Zyban	buPROPion	Tablet	Slow-release
Cabometyx	cabozantinib	Tablet	Film-coated
Rayaldee	calcifediol	Capsule	Slow-release
Carbatrol	carBAMazepine	Capsule	Slow-release (a)
Equetro	carBAMazepine	Capsule	Slow-release (a)
TEGretol-XR	carBAMazepine	Tablet	Slow-release
Coreg CR	carvedilol	Capsule	Slow-release (a) (Note: may add contents of capsule to chilled, not warm, applesauce and consume immediately)
Cefaclor ER	Cefaclor	Tablet	Slow-release (b)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Cefuroxime	cefuroxime	Tablet	Taste (b) (Note: use suspension for children)
Ceftin	cefuroxime	Tablet	Taste (b) (Note: use suspension for children)
Somnote	chloral hydrate	Capsule	Liquid filled
Cholbam	cholic acid	Capsule	Note: capsules may be opened and the contents mixed with food/drink
Sensipar	cinacalcet	Tablet	Note: tablets are not scored and cutting may cause variable dosage accuracy
Cipro XR	ciprofloxacin	Tablet	Slow-release (b)
Proquin XR	ciprofloxacin	Tablet	Slow-release
Biaxin-XL	clarithromycin	Tablet	Slow-release
Kapvay	cloNIDine	Tablet	Slow-release
Colestid	colestipol	Tablet	Slow-release
AeroHist Plus	combination	Tablet	Slow-release (h)
Aggrenox	combination	Capsule	Slow-release
Alavert Allergy (Sinus 12 hour)	combination	Tablet	Slow-release
Allegra-D	combination	Tablet	Slow-release
Amibid DM	combination	Tablet	Slow-release
Aquatab C	combination	Tablet	Slow-release (h)
Aquatab D	combination	Tablet	Slow-release (h)
Augmentin XR	combination	Tablet	Slow-release (b,h)
Bidex A	combination	Tablet	Slow-release
Bidhist-D	combination	Tablet	Slow-release
Biohist LA	combination	Tablet	Slow-release (h)
Bisacodyl	combination	Tablet	Enteric-coated (c)
Bisa-Lax	combination	Tablet	Enteric-coated (c)
Bromfed PD	combination	Capsule	Slow-release
Bunavail	combination	Buccal film	Note: chewing or swallowing may result in lower peak concentrations and bioavailability
Chlor-Trimeton 12-H	combination	Tablet	Slow-release (b)
Claritin-D 12 Hour	combination	Tablet	Slow-release
Claritin-D 24 Hour	combination	Tablet	Slow-release
Contrave	combination	Tablet	Slow-release (Note: chewing, dividing, or crushing tablets may alter release rate)
Diclegis	combination	Tablet	Slow-release
EC-Naprosyn	combination	Tablet	Enteric-coated
Extendryl JR	combination	Capsule	Slow-release
Extendryl SR	combination	Capsule	Slow-release (b)
Fero-Grad 500 mg	combination	Tablet	Slow-release
Ferro-Sequels	combination	Tablet	Slow-release
Guaifed	combination	Capsule	Slow-release
Guaifed-PD	combination	Capsule	Slow-release
Guaifenex DM	combination	Tablet	Slow-release (h)
Guaifenex GP	combination	Tablet	Slow-release
Guaifenex PSE	combination	Tablet	Slow-release (h)
GuaiMAX-D	combination	Tablet	Slow-release
Hista-Vent DA	combination	Tablet	Slow-release (h)
Jalyn	combination	Capsule	Mucous membrane irritant (Note: women who are, or may become, pregnant, should not handle crushed or broken tablets [I])
Janumet XR	combination	Tablet	Slow-release
Jentadueto XR	combination	Tablet	Slow-release
Kaletra	combination	Tablet	Film-coated
Kazano	combination	Tablet	Note: not scored; no studies available from company
Korn biglyze XR	combination	Tablet	Slow-release (Note: tablet matrix may remain in stool)
Liquibid-PD	combination	Tablet	Slow-release (h)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Lodrane 240	combination	Capsule	Slow-release
Lovaza	combination	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
Maxifed DM	combination	Tablet	Slow-release (h)
Maxifed OMX	combination	Tablet	Slow-release (h)
Maxiphen DM	combination	Tablet	Slow-release (h)
Medent-DM	combination	Tablet	Slow-release
Miraphen PSE	combination	Tablet	Slow-release
Mucinex DM	combination	Tablet	Slow-release
Namzaric	combination	Capsule	Slow-release
Pre-Hist-D	combination	Tablet	Slow-release (h)
QDALL	combination	Capsule	Slow-release
QDALL AR	combination	Capsule	Slow-release
Rescon	combination	Tablet	Slow-release (h)
Rescon JR	combination	Tablet	Slow-release (h)
Rescon MX	combination	Tablet	Slow-release (h)
Respahist	combination	Capsule	Slow-release (a)
Respaire SR	combination	Capsule	Slow-release
R-Tanna	combination	Tablet	Slow-release
Rytary	combination	Capsule	Slow-release (a)
SINUvent PE	combination	Tablet	Slow-release (h)
Sudafed 12 hour	combination	Capsule	Slow-release (b)
Sudafed 24 hour	combination	Capsule	Slow-release (b)
Targiniq ER	combination	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose of oxyCODONE)
Touro CC-LD	combination	Tablet	Slow-release (h)
Touro LA-LD	combination	Tablet	Slow-release (h)
Treximet	combination	Tablet	Note: unique drug matrix enhances rapid drug absorption
Viekira XR	combination	Tablet	Slow-release
Vimovo	combination	Tablet	Slow-release
Xart XR	combination	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose)
Xigduo XR	combination	Tablet	Slow-release
Zegerid	combination	Capsule	Slow-release (b)
Amrix	cyclobenzaprine	Capsule	Slow-release
Cytoxan	cyclophosphamide	Tablet	Note: drug may be crushed but company recommends using injection
Pradaxa	dabigatran	Capsule	Note: breaking, chewing, or emptying contents of the capsule can result in increased exposure
Ampyra	dalfampridine	Tablet	Slow-release (Note: formerly fampridine-SR)
Enablex	darifenacin	Tablet	Slow-release
Sprycel	dasatinib	Tablet	Film-coated (Note: active ingredients are surrounded by wax matrix to prevent healthcare exposure; women who are, or may become, pregnant, should not handle crushed or broken tablet)
Exjade	deferasirox	Tablet	Note: do not give as whole tablet, tablets are meant to be given as oral suspension; see company insert
Khedezla	desvenlafaxine	Tablet	Slow-release
Pristiq	desvenlafaxine	Tablet	Slow-release
Dexilant	dexlansoprazole	Capsule	Slow-release (a)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Kapidex	dexlansoprazole	Capsule	Slow-release (a) (Note: name changed to Dexilant)
Focalin XR	dexmethylphenidate	Capsule	Slow-release (a)
Arthrotec	diclofenac	Tablet	Enteric-coated
Voltaren XR	diclofenac	Tablet	Slow-release
Videx EC	didanosine	Capsule	Slow-release
Cardizem	diltiazem	Tablet	Note: although not in the package insert the drug has a coating that is intended to release the drug over approximately 3 hours
Cardizem CD	diltiazem	Capsule	Slow-release
Cardizem LA	diltiazem	Tablet	Slow-release
Cartia XT	diltiazem	Capsule	Slow-release
Dilacor XR	diltiazem	Capsule	Slow-release
DiIt-CD	diltiazem	Capsule	Slow-release
Diltia XT	diltiazem	Capsule	Slow-release
Taztia XT	diltiazem	Capsule	Slow-release (a)
Tiazac	diltiazem	Capsule	Slow-release (a)
Tecfidera	dimethyl fumarate	Capsule	Slow-release
Norpace CR	disopyramide	Capsule	Slow-release form within a special capsule
Depakene	divalproex	Capsule	Slow-release; mucus membrane irritant (b)
Depakote	divalproex	Tablet	Slow-release
Depakote ER	divalproex	Tablet	Slow-release
Divalproex ER	divalproex	Tablet	Slow-release
Colace	docusate	Capsule	Taste (e)
Aricept 23 mg	donepezil	Tablet	Note: crushing the 23 mg tablet may significantly increase the rate of absorption; the 5 mg and 10 mg tablets are not affected
Cardura XL	doxazosin	Tablet	Slow-release
Acticlate	doxycycline	Capsule; Tablet	Film-coated (h) (Note: tablet scored in thirds rather than half)
Oracea	doxycycline	Capsule	Slow-release
Northera	droxidopa	Capsule	Note: no studies available from company
Cymbalta	DULoxetine	Capsule	Slow-release (a) (Note: may add contents of capsule to apple juice or applesauce but NOT chocolate)
Avodart	dutasteride	Capsule	Note: drug may cause fetal abnormalities; women who are, or may become, pregnant, should not handle capsules; all women should use caution in handling capsules, especially leaking capsules
Cerdelga	eliglustat	Capsule	Preferably taken with water
Drisdol	ergocalciferol	Capsule	Liquid filled (d)
Ergomar	ergotamine	Tablet	Sublingual form (g)
NexlUM	esomeprazole	Capsule	Slow-release (a)
lntelence	etravirine	Tablet	Note: tablet should be swallowed whole and not crushed; tablet may be dispersed in water
Afinitor	everolimus	Tablet	Mucous membrane irritant
Zort	everolimus	Tablet	Note: crushed powder may cause mucous membrane irritation
Plendil	felodipine	Tablet	Slow-release
Trilipix	fenofibric acid	Capsule	Slow-release
FentaNYL	fentaNYL	Lozenge	Slow-release (Note: this lollipop delivery system requires the patient to slowly dissolve in mouth)
Actiq	fentaNYL	Lozenge	Slow-release (Note: this lollipop delivery system requires the patient to slowly allow dissolution)
Fentora	fentaNYL	Tablet	Note: buccal tablet; swallow whole

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Fergon	ferrous gluconate	Tablet	Enteric-coated
Feosol	ferrous sulfate	Tablet	Enteric-coated (b)
Feratab	ferrous sulfate	Tablet	Enteric-coated (b)
Toviaz	fesoterodine	Tablet	Slow-release
Propecia	finasteride	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
Proscar	finasteride	Tablet	Note: women who are, or may become, pregnant, should not handle crushed or broken tablets
PROzac Weekly	FLUoxetine	Tablet	Enteric-coated
Lescol XL	fluvastatin	Tablet	Slow-release
Luvox CR	fluvoxaMINE	Capsule	Slow-release
Gralise	gabapentin	Tablet	Slow-release
Horizant	gabapentin	Tablet	Slow-release
Razadyne ER	galantamine	Capsule	Slow-release
Cytovene	ganciclovir	Capsule	Skin irritant
lressa	gefitinib	Tablet	Note: tablet may be dissolved in 4-8 ounces of water
GlipiZIDE XR	glipiZIDE	Tablet	Slow-release
Glucotrol XL	glipiZIDE	Tablet	Slow-release
Mucinex	guaiFENesin	Tablet	Slow-release
GuaifFENesin/Pseudoephedrine	combination	Tablet	Slow-release
lntuniv	guanFACINE	Tablet	Slow-release
Hysingla ER	HYDROcodone	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose of HYDROcodone)
Zohydro ER	HYDROcodone	Capsule	Slow-release (Note: crushing, chewing, or dissolving capsules may result in overdose or death)
Exalgo	HYDROmorphone	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets can cause rapid release and absorption of a potentially fatal dose)
Droxia	hydroxyurea	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Hydrea	hydroxyurea	Capsule	Note: exposure to the powder may cause serious skin toxicities; health care workers should wear gloves to administer
Levbid	hyoscyamine	Tablet	Slow-release (h)
Levsinex Timecaps	hyoscyamine	Capsule	Slow-release
Symax Duotab	hyoscyamine	Tablet	Slow-release
Symax SR	hyoscyamine	Tablet	Slow-release
Boniva	ibandronate	Tablet	Note: chewed, crushed, or sucked tablets may cause oropharyngeal irritation
lmbruvica	ibrutinib	Capsule	Note: not scored; no studies available from company
Motrin	ibuprofen	Tablet	Taste (b,e)
Zydelig	idelalisib	Tablet	Note: not scored; film-coated
Gleevec	imatinib	Tablet	Taste (h) (Note: may be dissolved in water or apple juice)
Crixivan	indinavir	Capsule	Taste (Note: capsule may be opened and mixed with fruit puree [e.g., banana])
lndocin SR	indomethacin	Capsule	Slow-release (a,b)
Dilatrate-SR	isosorbide	Capsule	Slow-release
lmdur	isosorbide	Tablet	Slow-release (h)
lsordil Sublingual	isosorbide	Tablet	Sublingual form (g)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
lsosorbide Dinitrate Sublingual	isosorbide	Tablet	Sublingual form (g)
lsosorbide SR	isosorbide	Tablet	Slow-release
Absorica	isotretinoin	Capsule	Mucous membrane irritant
Accutane	isotretinoin	Capsule	Mucous membrane irritant
DynaCirc CR	isradipine	Tablet	Slow-release
LaMICtal XR	lamoTRlgine	Tablet	Slow-release
Prevacid	lansoprazole	Capsule	Slow-release
Prevacid SoluTab	lansoprazole	Tablet	Note: orally disintegrating do not swallow; dissolve in water only and dispense via dosing syringe of NG tube
Prevacid Suspension	lansoprazole	Suspension	Slow-release (Note: contains enteric-coated granules; mix with water only; not for NG use)
Revlimid	lenalidomide	Capsule	Note: Teratogenic potential; health care workers should avoid contact with capsule contents/body fluids
Lenvima	lenvatinib	Capsule	Note: may be dissolved in a small glass of liquid
Keppra	levETIRAcetam	Tablet	Taste (b) (Note: some extemporaneous formulas are pharmacy prepared)
Keppra XR	levETIRAcetam	Tablet	Slow-release (b)
Sinemet CR	levo/carbidopa	Tablet	Slow-release (h)
Lithobid	lithium	Tablet	Slow-release
Belviq XR	lorcaserin	Tablet	Slow-release
Altoprev	lovastatin	Tablet	Slow-release
Amitiza	lubiprostone	Capsule	Slow-release
Namenda XR	memantine	Capsule	Slow-release (a)
Apriso	mesalamine	Capsule	Slow-release (a) (Note: maintain pH at < 6.0)
Asacol	mesalamine	Tablet	Slow-release
LiaIda	mesalamine	Tablet	Slow-release
Pentasa	mesalamine	Capsule	Slow-release
Fortamet	metFORMIN	Tablet	Slow-release
Glucophage XR	metFORMIN	Tablet	Slow-release
Glumetza	metFORMIN	Tablet	Slow-release
Aptensio XR	methylphenidate	Capsule	Slow-release (a)
Concert	methylphenidate	Tablet	Slow-release
Metadate CD	methylphenidate	Capsule	Slow-release (a)
Metadate ER	methylphenidate	Tablet	Slow-release
Methylin ER	methylphenidate	Tablet	Slow-release
Ritalin LA	methylphenidate	Capsule	Slow-release (a)
Ritalin SR	methylphenidate	Tablet	Slow-release
Metoprolol ER	metoprolol	Tablet	Slow-release
Toprol XL	metoprolol	Tablet	Slow-release (h)
Flagyl ER	metroNIDAZOLE	Tablet	Slow-release
lmpavido	miltefosine	Capsule	Note: not scored; no studies available from company
Solodyn	minocycline	Tablet	Slow-release
Myrbetriq	mirabegron	Tablet	Slow-release
Morphine sulfate extended-release	morphine	Tablet	Slow-release
AVINza	morphine	Capsule	Slow-release (a; not pudding)
Kadian	morphine	Capsule	Slow-release (a) (Note: do not give via NG tubes)
Morphabond	morphine	Tablet	Slow-release (b)
MS Contin	morphine	Tablet	Slow-release (b)
Oramorph SR	morphine	Tablet	Slow-release (b)
Embeda	morphine sulfate	Capsule	Slow-release (a)
CellCept	mycophenolate	Capsule; Tablet	Teratogenic potential (i)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Myfort	mycophenolate	Tablet	Slow-release
Movantik	naloxegol	Tablet	Film-coated
Naprelan	naproxen	Tablet	Slow-release
Viramune XR	nevirapine	Tablet	Slow-release (b)
Afeditab CR	NI FEdipine	Tablet	Slow-release
Cardene SR	niCARdipine	Capsule	Slow-release
Commit	nicotine	Lozenge	Note: integrity compromised by chewing or crushing
Nicotinic Acid	nicotinic acid	Capsule; Tablet	Slow-release (h)
Niaspan	nicotinic acid	Tablet	Slow-release
Slo-Niacin	nicotinic acid	Tablet	Slow-release (h)
Adalat CC	NIFEdipine	Tablet	Slow-release
Nifediac CC	NIFEdipine	Tablet	Slow-release
Nifedical XL	NIFEdipine	Tablet	Slow-release
Procardia XL	NIFEdipine	Tablet	Slow-release
Tasigna	nilotinib	Capsule	Note: disruption of capsule may yield high blood levels causing enhanced toxicity
OFEV	nintedanib	Capsule	Taste
Sular	nisoldipine	Tablet	Slow-release
Nitrostat	nitroglycerin	Tablet	Sublingual form (g)
Omtryg	omega-3-acid ethyl esters A	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
Epanova	omega-3-carboxylic acids	Capsule	Note: contents of capsule may erode walls of Styrofoam or plastic materials
PriLOSEC	omeprazole	Capsule	Slow-release
PriLOSEC OTC	omeprazole	Tablet	Slow-release
Norflex ER	orphenadrine	Tablet	Slow-release
Tagrisso	osimertinib	Tablet	Note: tablet may be dissolved in 2 ounces of water
Ditropan XL	oxybutynin	Tablet	Slow-release
OxyCONTIN	oxyCODONE	Tablet	Slow-release (Note: tablet disruption may cause a potentially fatal overdose of oxyCODONE)
Xtampza ER	oxycodone	Tablet	Slow-release (b)
Opana ER	oxymorphone	Tablets	Slow-release (Note: crushing, chewing, or dissolving tablets may result in overdose or death)
lnvega	paliperidone	Tablet	Slow-release
Cotazym-S	pancrelipase	Capsule	Enteric-coated (a)
Creon 5, 10, 20	pancrelipase	Capsule	Slow-release (a)
Pancreaze	pancrelipase	Capsule	Enteric-coated (a)
Pancrecarb	pancrelipase	Capsule	Enteric-coated (a)
Pert	pancrelipase	Capsule	Slow-release (a)
Ultrase	pancrelipase	Capsule	Enteric-coated
Ultresa	pancrelipase	Capsule	Slow-release (a)
Viokace	pancrelipase	Tablet	Mucous membrane irritant
Zenpep	pancrelipase	Capsule	Slow-release (b)
Farydak	panobinostat	Capsule	Irritant
Protonix	pantoprazole	Tablet	Slow-release
Paxil CR	PARoxetine	Tablet	Slow-release
Votrient	pazopanib	Tablet	Note: crushing significantly increases the AUC and Tmax
TRENtal	pentoxifylline	Tablet	Slow-release
Feldene	piroxicam	Capsule	Mucous membrane irritant
Noxafil	posaconazole	Tablet	Slow-release (b)
Kaon-CL-10	potassium	Tablet	Slow-release (b)
K-Dur	potassium	Tablet	Slow-release
Klor-Con	potassium	Tablet	Slow-release (b)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Klor-Con M	potassium	Tablet	Slow-release (b,h)
Klotrix	potassium	Tablet	Slow-release
K-Lyte	potassium	Tablet	Effervescent tablet (f)
K-Lyte CL	potassium	Tablet	Effervescent tablet (f)
K-Lyte DS	potassium	Tablet	Effervescent tablet (f)
K-Tab	potassium	Tablet	Slow-release (b)
Effer-K	potassium bicarbonate	Tablet	Effervescent tablet (f)
Micro K Extencaps	potassium chloride	Capsule	Slow-release (a,b)
Urocit-K	potassium citrate	Tablet	Wax-coated; prevents upper GI release
Biltricide	praziquantel	Tablet	Taste (h)
Rayos	predniSONE	Tablet	Slow-release (Note: delayed release is dependent on an intact coating)
Rythmol SR	propafenone	Capsule	Slow-release
lnderal LA	propranolol	Capsule	Slow-release
lnnoPran XL	propranolol	Capsule	Slow-release
Mestinon ER	pyridostigmine	Tablet	Slow-release (b)
SEROquel XR	QUEtiapine	Tablet	Slow-release
AcipHex	rabeprazole	Tablet	Slow-release
Evista	raloxifene	Tablet	Taste; teratogenic potential (i)
Ranexa	ranolazine	Tablet	Slow-release
Actonel	risedronate	Tablet	Irritant (Note: chewed, crushed, or sucked tablets may cause oropharyngeal irritation)
Atelvia	risedronate	Tablet	Slow-release (Note: tablet coating is an important part of the slow-release; chewed, cut, or crushed tablets may cause oropharyngeal irritation)
Norvir	ritonavir	Tablet	Note: crushing tablets has resulted in decreased bioavailability of drug (b)
Xarelto	rivaroxaban	Tablet	Note: crushed tablet must be given within 4 hours
Requip XL	ropinirole	Tablet	Slow-release
Jakafi	ruxolitinib	Tablet	Note: see prescribing information for making a suspension
Uptravi	selexipag	Tablet	Film-coated
RenageI	sevelamer	Tablet	Note: tablets expand in liquid if broken or crushed
Renvela	sevelamer carbonate	Tablet	Note: tablets expand in liquid if broken or crushed (b)
Rapamune	sirolimus	Tablet	Note: pharmacokinetic parameters may be affected (b)
VESlcare	solifenacin	Tablet	Enteric-coated
Azulfidine EN-Tabs	sulfasalazine	Tablet	Slow-release (b)
Belsomra	suvorexant	Tablet	Note: not scored; no studies available from company
Envarsus XR	tacrolimus	Tablet	Slow-release
Flomax	tamsulosin	Capsule	Slow-release
Nucynta ER	tapentadole	Tablet	Slow-release (Note: crushing, chewing, or dissolving tablets may result in overdose or death)
Hetlioz	tasimelteon	Capsule	Note: not scored; no studies available from company
Ketek	telithromycin	Tablet	Slow-release (b)
Temodar	temozolomide	Capsule	Slow-release (Note: accidentally opened or damaged capsules require rigorous precautions to avoid inhalation or contact with the skin or mucous membranes [i])
Theo-24	theophylline	Capsule	Slow-release (Note: contains beads that dissolve throughout the GI tract)

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Drug Product	Active Ingredients	Dosage Form(s)	Reasons/Comments
Theochron	theophylline	Tablet	Slow-release
Uniphyl	theophylline	Tablet	Slow-release
Aptivus	tipranavir	Capsule	Note: oil emulsion within spheres; taste
Xeljanz XR	tofacitinib	Tablet	Slow-release
Detrol LA	tolterodine	Capsule	Slow-release
Qudexy XR	topiramate	Capsule	Slow-release (a)
Topamax	topiramate	Capsule; Tablet	Taste; Taste (a)
Ryzolt	traMADol	Tablet	Slow-release (Note: crushing may cause overdose)
Ultram ER	traMADol	Tablet	Slow-release (Note: tablet disruption may cause a potentially fatal overdose of drug)
Oleptro	traZODone	Tablet	Slow-release (h)
Valcyte	valGANCiclovir	Tablet	Teratogenic and irritant potential (i, b)
Effexor XR	venlafaxine	Capsule	Slow-release
Verapamil SR	verapamil	Tablet	Slow-release (h)
Calan SR	verapamil	Tablet	Slow-release (h)
Covera-HS	verapamil	Tablet	Slow-release
Isoptin SR	verapamil	Tablet	Slow-release (h)
VereIan	verapamil	Capsule	Slow-release (a)
Verelan PM	verapamil	Capsule	Slow-release (a)
Erivedge	vismodegib	Capsule	Note: package insert indicates potential teratogenic effects; material safety data sheet warns against skin contact; health care workers should take appropriate precautions
Zolinza	vorinostat	Capsule	Note: irritant; avoid contact with skin or mucous membranes; avoid contact with crushed or broken tablets
Zyflo CR	zileuton	Tablet	Slow-release
Ambien CR	zolpidem	Tablet	Slow-release
Intermezzo	zolpidem	Tablet	Sublingual form (g)
Pancrelipase		Capsule	Enteric-coated (a)

(a) Capsule may be opened and the contents taken without crushing or chewing; soft food such as applesauce or pudding may facilitate administration; contents may generally be administered via nasogastric tube using an appropriate fluid provided entire contents are washed down the tube.
(b) Liquid dosage forms of the product are available; however, dose, frequency of administration and manufacturers may differ from that of the solid dosage form.
(c) Antacids and/or milk may prematurely dissolve the coating of the tablet.
(d) Capsule may be opened and the liquid contents removed for administration.
(e) The taste of this product form would likely be unacceptable to the patient; administration via nasogastric tube should be acceptable.
(f) Effervescent tablets must be dissolved in the amount of diluent recommended by the manufacturer
(g) Tablets are made to disintegrate under the tongue.
(h) Tablet is scored and may be broken in half without affecting release characteristics.
(i) Skin contact may enhance tumor production; avoid direct contact.

Disclaimer: This list is not meant to represent all products, either by generic or trade name. While every effort has been made to ensure the accuracy and completeness of the information presented in this chart the reader is advised that the authors, editor, or publisher cannot be responsible for the currency of the information, for any errors or omissions, or for any consequences that may arise.
Two official USP terms are used to designate special-release medication forms: "extended release" and "delayed release." Others (e.g., sustained release, controlled release) are commonly used on package labeling. The term "Slow-release" is being used here to signify all such drugs with a special-release mechanism.

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Look-Alike Sound-Alike Medication Names

Drug Name	Confused Drug Name
acetaZOLAMIDE	acetoHEXAMIDE
acetoHEXAMIDE	acetaZOLAMIDE
Actonel	Actos
Actos	Actonel
Adacel (Tdap)	Daptacel (DTaP)
Adderall	Inderal
ALPRAZolam	LORazepam
amantadine	amiodarone
aMILoride	amLODIPine
amiodarone	amantadine
amLODIPine	aMILoride
Antivert	Axert
Apresoline	Priscoline
ARIPiprazole	proton pump inhibitors
ARIPiprazole	RABEprazole
atomoxetine	atorvastatin
atorvastatin	atomoxetine
Atrovent	Natru-Vent
Avandia	Coumadin
Axert	Antivert
azaCITIDine	azaTHIOprine
azaTHIOprine	azaCITIDine
Benadryl	benazepril
benazepril	Benadryl
Bidex	Videx
buPROPion	busPIRone
busPIRone	buPROPion
captopril	carvedilol
carBAMazepine	OXcarbazepine
Cardene	Cardizem
Cardizem	Cardene
Cardura	Coumadin
carvedilol	captopril
ceFAZolin	cefTRIAXone
cefTRIAXone	ceFAZolin
CeleBREX	CeleXA
CeleXA	ZyPREXA
CeleXA	CeleBREX
CeleXA	Cerebyx
Cerebyx	CeleXA
cetirizine	sertraline
cetirizine	stavudine
clobazam	clonazePAM
clonazePAM	clobazam
clonazePAM	cloNIDine
clonazePAM	LORazepam
cloNIDine	clonazePAM
cloNIDine	KlonoPIN
Colace	Cozaar
colchicine	Cortrosyn
Comvax	Recombivax HB
Cortrosyn	colchicine
Coumadin	Avandia
Coumadin	Cardura
Cozaar	Colace
Cozaar	Zocor

Drug Name	Confused Drug Name
cyclophosphamide	cycloSPORINE
cycloSERINE	cycloSPORINE
cycloSPORINE	cyclophosphamide
cycloSPORINE	cycloSERINE
Cymbalta	Symbyax
Daptacel (DTaP)	Adacel (Tdap)
Darvocet	Percocet
Darvon	Diovan
Denavir	indinavir
Depakote	Depakote ER
Depakote ER	Depakote
Depo-Medrol	Solu-MEDROL
desipramine	disopyramide
Desyrel	SEROquel
Diabenese	Diamox
Diamox	Diabenese
Diflucan	Diprivan
dimenhyDRINATE	diphenhydrAMINE
Dioval	Diovan
Diovan	Dioval
Diovan	Zyban
Diovan	Darvon
diphenhydrAMINE	dimenhyDRINATE
Diprivan	Diflucan
Diprivan	Ditropan
disopyramide	desipramine
Ditropan	Diprivan
Doribax	Zovirax
Doxil	Paxil
Dulcolax (bisacodyl)	Dulcolax (docusate sodium)
Dulcolax (docusate sodium)	Dulcolax (bisacodyl)
DULoxetine	FLUoxetine
Effexor	Effexor XR
Effexor XR	Enablex
Effexor XR	Effexor
Enablex	Effexor XR
Engerix-B adult	Engerix-B pediatric/adolescent
Engerix-B pediatric/adolescent	Engerix-B adult
ePHEDrine	EPINEPHrine
EPINEPHrine	ePHEDrine
ethambutol	Ethmozine
ethaverine [non-US name]	etravirine
Ethmozine	ethambutol
etravirine	ethaverine [non-US name]
Fanapt	Xanax
Flonase	Flovent
Flovent	Flonase
flumazenil	influenza virus vaccine
FLUoxetine	PARoxetine
FLUoxetine	DULoxetine
FLUoxetine	Loxitane
folic acid	folinic acid (leucovorin calcium)

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Drug Name	Confused Drug Name
folinic acid (leucovorin calcium)	folic acid
fomepizole	omeprazole
Foradil	Toradol
gentamicin	gentian violet
gentian violet	gentamicin
glacial acetic acid	acetic acid for irrigation
glipiZIDE	glyBURIDE
Glucotrol	Glycotrol
glyBURIDE	glipiZIDE
Glycotrol	Glucotrol
guaiFENesin	guanFACINE
guanFACINE	guaiFENesin
HMG-CoA reductase inhibitors ("statins")	nystatin
HumaLOG	HumuLIN
HumaLOG	NovoLOG
HumuLIN	NovoLIN
HumuLIN	HumaLOG
HumuLIN 70/30	HumaLOG Mix 75/25
HumuLIN R U-100	HumuLIN R U-500
HumuLIN R U-500	HumuLIN R U-100
hydrALAZINE	hydrOXYzine
Hydrea	Lyrica
HYDROcodone	oxyCODONE
Hydrogesic	hydrOXYzine
HYDROmorphone	morphine
hydrOXYzine	Hydrogesic
hydrOXYzine	hydrALAZINE
Inderal	Adderall
indinavir	Denavir
influenza virus vaccine	flumazenil
influenza virus vaccine	perflutren lipid microspheres
influenza virus vaccine	tuberculin purified protein derivative (PPD)
Isordil	Plendil
Janumet	Sinemet
Kaletra	Keppra
Keflex	Keppra
Keppra	Kaletra
Keppra	Keflex
Ketalar	ketorolac
ketorolac	Ketalar
ketorolac	methadone
KlonoPIN	cloNIDine
K-Phos Neutral	Neutra-Phos-K
LaMICtal	LamISIL
LamISIL	LaMICtal
lamiVUDine	lamoTRIgine
lamoTRIgine	lamiVUDine
lamoTRIgine	levETIRAcetam
lamoTRIgine	levothyroxine
Lanoxin	levothyroxine
Lanoxin	naloxone
lanthanum carbonate	lithium carbonate
Lantus	Latuda
Lantus	Lente
Lariam	Levaquin

Drug Name	Confused Drug Name
Lasix	Luvox
Latuda	Lantus
Lente	Lantus
leucovorin calcium	Leukeran
leucovorin calcium	levoleucovorin
Leukeran	leucovorin calcium
Levaquin	Lariam
Levemir	Lovenox
levETIRAcetam	lamoTRIgine
levETIRAcetam	levOCARNitine
levETIRAcetam	levofloxacin
levOCARNitine	levETIRAcetam
levofloxacin	levETIRAcetam
levoleucovorin	leucovorin calcium
levothyroxine	lamoTRIgine
levothyroxine	Lanoxin
levothyroxine	liothyronine
Lexapro	Loxitane
Lexiva	Pexeva
liothyronine	levothyroxine
Lipitor	Loniten
Lipitor	ZyrTEC
lithium	Ultram
lithium carbonate	lanthanum carbonate
Lodine	codeine
Lodine	iodine
Loniten	Lipitor
Lopressor	Lyrica
LORazepam	ALPRAZolam
LORazepam	clonazePAM
LORazepam	Lovaza
Lotronex	Protonix
Lovaza	LORazepam
Lovenox	Levemir
Loxitane	Lexapro
Loxitane	FLUoxetine
Luvox	Lasix
Lyrica	Hydrea
Lyrica	Lopressor
Maalox	Maalox Total Stomach Relief
Maalox Total Stomach Relief	Maalox
Maxzide	Microzide
Menactra	Menomune
Menomune	Menactra
metFORMIN	metroNIDAZOLE
methimazole	metolazone
metolazone	methimazole
metoprolol succinate	metoprolol tartrate
metoprolol tartrate	metoprolol succinate
metroNIDAZOLE	metFORMIN
Micronase	Microzide
Microzide	Maxzide
Microzide	Micronase
Miralax	Mirapex
Mirapex	Miralax
morphine	HYDROmorphone

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Drug Name	Confused Drug Name
morphine - non-concentrated oral liquid	morphine - oral liquid concentrate
morphine - oral liquid concentrate	morphine - non-concentrated oral liquid
Motrin	Neurontin
MS Contin	OxyCONTIN
nalbuphine	naloxone
naloxone	Lanoxin
naloxone	nalbuphine
Narcan	Norcuron
Natru-Vent	Atrovent
Navane	Norvasc
Neo-Synephrine (oxymetazoline)	Neo-Synephrine (phenylephrine)
Neo-Synephrine (phenylephrine)	Neo-Synephrine (oxymetazoline)
Neumega	Neupogen
Neupogen	Neumega
Neurontin	Motrin
Neurontin	Noroxin
niCARdipine	NIFEdipine
NIFEdipine	niCARdipine
NIFEdipine	niMODipine
niMODipine	NIFEdipine
Norcuron	Narcan
Normodyne	Norpramin
Noroxin	Neurontin
Norpramin	Normodyne
Norvasc	Navane
NovoLIN	HumuLIN
NovoLIN	NovoLOG
NovoLIN 70/30	NovoLOG Mix 70/30
NovoLOG	HumaLOG
NovoLOG	NovoLIN
NovoLOG Flexpen	NovoLOG Mix 70/30 Flexpen
NovoLOG Mix 70/30	NovoLIN 70/30
NovoLOG Mix 70/30 Flexpen	NovoLOG Flexpen
nystatin	HMG-CoA reductase inhibitors ("statins")
Occlusal-HP	Ocuflox
Ocuflox	Occlusal-HP
OLANZapine	QUEtiapine
omeprazole	fomepizole
oxaprozin	OXcarbazepine
OXcarbazepine	oxaprozin
OXcarbazepine	carBAMazepine
oxyCODONE	HYDROcodone
oxyCODONE	OxyCONTIN
OxyCONTIN	MS Contin
OxyCONTIN	oxyCODONE
PARoxetine	FLUoxetine
PARoxetine	piroxicam
Paxil	Doxil
Paxil	Taxol
Paxil	Plavix
penicillAMINE	penicillin
penicillin	penicillAMINE
PENTobarbital	PHENobarbital
Percocet	Darvocet
Percocet	Procet
perflutren lipid microspheres	influenza virus vaccine
Pexeva	Lexiva
PHENobarbital	PENTobarbital
piroxicam	PARoxetine
Plavix	Paxil
Plavix	Pradax [Non-US Product]
Plavix	Pradaxa
pneumococcal 7-valent vaccine	pneumococcal polyvalent vaccine
pneumococcal polyvalent vaccine	pneumococcal 7-valent vaccine
Pradax [Non-US Product]	Plavix
Pradaxa	Plavix
prednisoLONE	predniSONE
predniSONE	prednisoLONE
PriLOSEC	Pristiq
PriLOSEC	PROzac
Priscoline	Apresoline
Pristiq	PriLOSEC
probenecid	Procanbid
Procanbid	probenecid
Procardia XL	Protain XL
Procet	Percocet
Prograf	PROzac
propylthiouracil	Purinethol
Proscar	Provera
Protain XL	Procardia XL
protamine	Protonix
proton pump inhibitors	ARIPiprazole
Protonix	Lotronex
Protonix	protamine
Provera	Proscar
Provera	PROzac
PROzac	Prograf
PROzac	PriLOSEC
PROzac	Provera
Purinethol	propylthiouracil
Pyridium	pyridoxine
pyridoxine	Pyridium
QUEtiapine	OLANZapine
quiNIDine	quiNINE
quiNINE	quiNIDine
RABEprazole	ARIPiprazole
Renagel	Renvela
Renvela	Renagel
Reprexain	ZyPREXA
Retrovir	ritonavir
Rifadin	Rifater
Rifamate	rifampin
rifampin	Rifamate
rifampin	rifaximin
Rifater	Rifadin
rifaximin	rifampin

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Drug Name	Confused Drug Name
RisperDAL	Restoril
risperiDONE	rOPINIRole
ritonavir	Retrovir
rOPINIRole	risperiDONE
saquinavir	SINEquan
SEROquel	Desyrel
SEROquel	SINEquan
sertraline	cetirizine
sertraline	Soriatane
Sinemet	Janumet
SINEquan	saquinavir
SINEquan	SEROquel
SINEquan	Singulair
SINEquan	Zonegran
Singulair	SINEquan
sitaGLIPtin	SUMAtriptan
Solu-CORTEF	Solu-MEDROL
Solu-MEDROL	Depo-Medrol
Solu-MEDROL	Solu-CORTEF
Soriatane	sertraline
sotalol	Sudafed
stavudine	cetirizine
Sudafed	sotalol
SUFentanil	fentaNYL
sulfADIAZINE	sulfaSALAzine
sulfaSALAzine	sulfADIAZINE
SUMAtriptan	sitaGLIPtin
SUMAtriptan	ZOLMitriptan
Symbyax	Cymbalta
Taxol	Paxil
TEGretol	TEGretol XR
TEGretol	Tequin
TEGretol	TRENtal
TEGretol XR	TEGretol
Tenex	Xanax
Tequin	TEGretol
tetanus diptheria toxoid (Td)	tuberculin purified protein derivative (PPD)
Thalomid	Thiamine
Thiamine	Thalomid
tiaGABine	tiZANidine
tiZANidine	tiaGABine
Tobradex	Tobrex
Tobrex	Tobradex
Topamax	Toprol-XL
Toprol-XL	Topamax
Toradol	Foradil
traMADol	traZODone
traZODone	traMADol
TRENtal	TEGretol
tuberculin purified protein derivative (PPD)	influenza virus vaccine
tuberculin purified protein derivative (PPD)	tetanus diptheria toxoid (Td)

Drug Name	Confused Drug Name
Tylenol	Tylenol PM
Tylenol PM	Tylenol
Ultram	lithium
Varivax	VZIG (varicella-zoster immune globulin)
Viagra	Allegra
Videx	Bidex
Viracept	Viramune
Viramune	Viracept
VZIG (varicella-zoster immune globulin)	Varivax
Wellbutrin SR	Wellbutrin XL
Wellbutrin XL	Wellbutrin SR
Xanax	Fanapt
Xanax	Tenex
Xanax	Zantac
Yasmin	Yaz
Yaz	Yasmin
Zantac	Xanax
Zantac	ZyrTEC
Zerit	ZyrTEC
Zestril	Zegerid
Zestril	Zetia
Zestril	ZyPREXA
Zetia	Zebeta
Zetia	Zestril
Zocor	Cozaar
Zocor	ZyrTEC
ZOLMitriptan	SUMAtriptan
zolpidem	Zyloprim
Zonegran	SINEquan
Zostrix	Zovirax
Zovirax	Doribax
Zovirax	Zyvox
Zovirax	Zostrix
Zyban	Diovan
Zyloprim	zolpidem
ZyPREXA	CeleXA
ZyPREXA	Reprexain
ZyPREXA	Zestril
ZyPREXA	ZyrTEC
ZyPREXA Zydis	Zelapar (Zydis formulation)
ZyrTEC	Lipitor
ZyrTEC	Zantac
ZyrTEC	Zerit
ZyrTEC	Zocor
ZyrTEC	ZyPREXA
ZyrTEC	ZyrTEC-D
ZyrTEC (cetirizine)	ZyrTEC Itchy Eye Drops (ketotifen fumarate)
ZyrTEC Itchy Eye Drops (ketolifen fumarate)	ZyrTEC (cetirizine)
ZyrTEC-D	ZyrTEC
Zyvox	Zovirax

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U.S. Immigration and Customs Enforcement

PANDEMIC WORKFORCE PROTECTION PLAN

Approved May 12, 2017

Original version approved and signed February 21, 2014.

Version 2.2

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RECORD OF CHANGES

Change Number	Change	Date Entered	Posted By
1	Draft document submitted to DHS Ops	01/07/2014	(b)(6); (b)(7)(C)
2	Document signed by (A) Director Sandweg	02/21/2014	
3	Signed Document submitted to DHS Ops	02/25/2014	
4	Update of Annex D to include new OHA documents	07/08/2014	
5	Update to include Annex R	01/12/2015	
6	Update to include Director Saldaña's name, Enterprise Notification System, and checklists	01/04/2016	
7	Edited NEMD to EMU	05/12/2016	
8	Update to ensure plan is compliant with DHS PEIDWPP and include (A) Director Homan's name	01/01/2017	
9	Update Annex E	05/15/2017	
10	Update Foreward and Annex E	08/24/2017	
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FOREWORD

In April 2013, the Secretary of Homeland Security directed Components to update and expand in scope pandemic plans to include all potential pandemic events and emerging infectious diseases. The *DHS Pandemic Workforce Protection Plan* (PWPP) met the Secretary's guidance by providing centralized coordination and decentralized execution of Departmental workforce safety and health measures relative to pandemics and emerging infectious diseases.

The purpose of the DHS PWPP is to prepare DHS Components to maintain essential functions (EFs) better and to ensure that their personnel, critical contractors, working animals, and people in the care and custody of DHS are protected from potential pandemic events and emerging infectious diseases. The U.S. Immigration and Customs Enforcement (ICE) PWPP delineates ICE-centric information to implement the DHS PWPP. ICE will also continue to follow guidance from the DHS Office of Health Affairs and the DHS Directorate for Management regarding personal protective equipment and medical countermeasures programs.

Disease spread is dynamic; consequently, specific actions and associated triggers are exceedingly difficult to determine in advance. The ICE PWPP will allow ICE to develop plans within the context of their specific requirements to mitigate pandemic events and emerging infectious diseases.

The ICE PWPP is to be read in conjunction with the ICE Continuity Plan. Mission planning and operations associated with this Plan will be guided by existing statutes and regulations, as well as directives, instructions, and agreements. Nothing in this plan shall supersede applicable laws, Executive Orders, directives, existing plans, memoranda of agreement, memoranda of understanding, etc.

In 2016, OHA created a Pandemic and Emerging Infectious Disease Workforce Protection Plan (PEIDWPP). The intent of that plan was to have a single plan to promote the health and wellbeing of the DHS workforce and those under DHS care and custody when any biothreat emerged. Components were involved in the creation of the PEIDWPP. While ICE agreed with the concept, ICE has opted to maintain two plans for biothreats until such a time a single plan that satisfies the needs of ICE can be developed. This is the second plan and it focuses on influenza pandemics. The first plan is the ICE Anthrax Operations Plan, and it is designed to be used for anthrax as the major biothreat.

5-12-17

Thomas D. Homan
(A) Director
U.S. Immigration and Customs Enforcement

Date

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PANDEMIC WORKFORCE PROTECTION PLAN

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Annex C – Operations
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Annex G – Acronyms and Glossary
Annex P – Employee Messaging (Public Affairs)
Annex R - Reporting
Annex T – Component Planning Checklist

*Annexes follow the DHS guidelines for subject matter and, therefore, will not follow in sequential order.

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PANDEMIC WORKFORCE PROTECTION PLAN

1. SITUATION.

a. Purpose.

The purpose of the U.S. Immigration and Customs Enforcement (ICE) Pandemic Workforce Protection Plan (PWPP) is to describe how ICE will provide for the continuation of its Government Functions to the greatest extent possible with the goal of maintaining Mission Essential Functions (MEFs) during a pandemic or in the wake of an emerging infectious disease threat.

1) This Plan provides guidance within ICE to decrease illness and death among the ICE workforce[1] and people in the care and custody of ICE while minimizing mission disruption during a pandemic or an emerging infectious disease threat. This Plan is designed to provide for critical mission readiness and protection of the ICE workforce and people in the care and custody of ICE from the adverse effects of a pandemic or emerging infectious disease threat.

2) Mission planning and operations associated with this Plan will be guided by existing statutes and regulations, as well as directives, instructions, and agreements. Nothing in this Plan shall supersede applicable laws, Executive Orders, memoranda of agreement (MOAs), or memoranda of understanding (MOUs).

3) The ICE PWPP takes effect upon signature by the Director of ICE and will remain in effect until superseded or cancelled. The Plan will be reviewed and revised every 2 years or as needed.

b. Scope.

1) This Plan applies to the ICE workforce and those in ICE's care and custody during a pandemic or an emerging infectious disease threat.

2) This Plan is to be read in conjunction with the ICE Continuity Plan and the ICE Anthrax Operations Plan, as appropriate. It supplements the ICE Continuity Plan to address considerations and elements specific to pandemic events and emerging infectious disease threats. The Department of Homeland Security (DHS) will develop supplemental annexes for specific outbreaks.

c. Background.

1) There is a relationship between the terms *emerging infectious disease*, *endemic infectious disease*, *epidemic*, and *pandemic*. Infectious diseases are caused by

[1] Workforce includes: ICE personnel, critical contractors with DHS badges, and working animals. See

(b)(7)(E)

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microscopic organisms that penetrate the body's natural barriers and multiply to create symptoms that can range from mild to deadly. Although progress has been made to eradicate or control many infectious diseases, humans remain vulnerable to a wide array of new and resurgent organisms. Additionally, dangerous bacteria, viruses, fungi, and parasites can evolve to become resistant to available antibiotics and other treatments. In general, an emerging infectious disease is initially confined to a specific geographical area and characterized as a virus, bacteria, or other pathogen against which humans have little or no immunity and can be readily infected. An emerging infectious disease is the root cause of either an epidemic or pandemic, depending on the scope and breadth of the footprint accompanying any specific infectious disease. Infectious disease epidemics occur when there are higher rates of an infectious disease in a given population or region than normal. As an infectious disease epidemic gathers strength and spreads worldwide, or over a very wide area, crossing international boundaries and usually infecting a large number of people, it becomes a pandemic.

2) Pandemics in the 20th century followed a consistent pattern involving waves of illness. A severe pandemic, such as the influenza pandemic that began in 1918, could have a catastrophic impact on the global economy, national security, critical infrastructure, and the basic functions of society.

3) An initial infectious disease outbreak may not be an indicator of illness severity or fatality rate during subsequent waves of an outbreak. For example, every year in the United States 5% to 20% of the population is infected with influenza; more than 200,000 people are hospitalized from influenza complications; and about 36,000 people die from influenza-related causes. In an influenza pandemic, morbidity and mortality are much higher and affect a higher percentage of the population.

4) Control measures against infectious disease transmission include:
   a) Good personal hygiene practices;
   b) Engineering infection control measures;
   c) Medical countermeasures (MCM) (vaccines and medications);
   d) Administrative infection control measures; and
   e) Personal protective equipment (PPE) use.

5) Vaccine production and distribution are primarily private sector activities requiring a significant amount of time. For example, manufacturers start producing seasonal influenza vaccine 6 to 9 months before distribution begins in the late summer or early fall. Vaccine is produced via just-in-time manufacturing; distribution to health care providers takes place in a phased fashion over several months, usually ending in late November or early December. Manufacturers and distributors strive to deliver vaccine to all providers early in the influenza season, because all providers serve high-risk patients and their household contacts. Vaccine for novel strains of influenza may not be available with the seasonal influenza vaccine.

6) The DHS Area of Operations includes all U.S. States, the District of Columbia, and the Commonwealths, Territories, and Possessions of the United States, per the

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Homeland Security Act of 2002, as well as the foreign locations where Department employees are assigned.

d. Key Authorities and References.

1) Authorities.

a) Economy Act
b) *Federal Food, Drug, and Cosmetic Act*, as amended
c) *Homeland Security Act of 2002*, as amended
d) *Immigration and Nationality Act*, as amended
e) Implementing Recommendations of the *9/11 Commission Act of 2007*
f) *National Emergencies Act of 1976*
g) *Occupational Safety and Health Act of 1970*
h) *Pandemic and All-Hazards Preparedness Act of 2006*
i) *Ports and Waterways Safety Act of 1972*
j) *Post-Katrina Emergency Management Reform Act of 2006*
k) *Project BioShield Act of 2004*, as amended
l) *Privacy Act of 1974*, as amended
m) *Public Health Service Act*, as amended
n) *Robert T. Stafford Disaster Relief and Emergency Assistance Act*, as amended
o) *Tariff Act of 1930*, as amended
p) *The Health Insurance Portability and Accountability Act of 1996*
q) Executive Order No. 12196, as amended, Federal Advisory Council on Occupational Safety and Health
r) Executive Order No. 13295, as amended, Revised List of Quarantinable Communicable Diseases
s) Homeland Security Presidential Directive (HSPD) 5, *Management of Domestic Incidents*, as amended
t) HSPD 10, *Biodefense for the 21st Century*
u) HSPD 20/National Security Presidential Directive 51, *National Continuity Policy*
v) HSPD 21, *Public Health and Medical Preparedness*
w) Presidential Policy Directive (PPD) 8, *National Preparedness*
x) ICE Directive 14007.1 (former number: 1-23.0), *National Incident Management System Policy* (February 8, 2007, or as updated)
y) ICE Directive 14008.1 (former number: 9-4.0), *National Response Plan, Emergency Support Function, Mission Assignment Acceptance Policy* (April 18, 2007, or as updated)

2) References.

a) Under Secretary for Management Rafael Borras Memo, *Assuring Necessary Contractor Performance during Emergency Events* (January 25, 2012)
b) DHS *Pandemic Workforce Protection Plan* (November 8, 2013)
c) DHS Delegation No. 00002, *Delegation to the Under Secretary for Management*, May 29, 2012

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d) DHS Delegation No. 5001, *Delegation to the Assistant Secretary for Health Affairs and Chief Medical Officer* (July 24, 2008)
e) DHS Delegation No. 21000, *Delegation to the Director of Operations Coordination and Planning* (May 29, 2012)
f) DHS *Medical Guidance related to Novel Influenza Virus Infection Control* (2013)
g) DHS Directive No. 066-01, *Safety and Health Programs* (July 25, 2008)
h) DHS Directive No. 066-04, *Medical Countermeasures and Medical Requirements for Occupational Health Exposures to Biological, Chemical, and Radiological Health Hazards and Psychosocial Stressors* (October 3, 2011)
i) DHS *Pandemic Medical Guidance* (2013)
j) ICE *Anthrax Operations Plan* (OPLAN) (January 7, 2011)
k) ICE Directive 14001.1 (former number: 9-2.0), *Continuity of Operations Plan Policy* (March 2, 2007)
l) ICE *Infectious Disease Control Program and Standard Operating Procedure* (March 2013)
m) ICE *Occupational Safety and Health (OSH) Program Requirements Handbook* (April 30, 2013, revision 7)
n) ICE *Respiratory Protection Standard Operating Procedure* (version 1, June 30, 2013)
o) MOU Between the Department of Health and Human Services and the Department of Homeland Security (2005)
p) MOU between the Office of the Chief Administrative Officer and Office of Health Affairs, Occupational and Health Program (2009)
q) National Preparedness Goal (2012)
r) *PPD-8 Frameworks (Prevention, Protection, Mitigation, Response, Recovery) and associated Federal Interagency Operational Plan* (2012/2013)

e. Threat.

1) For the purpose of this Plan, the threat is considered to be an emerging infectious disease with pandemic potential.
2) An emerging infectious disease threat or pandemic poses many challenges for the ICE workforce and those in its care and custody.
3) ICE's mission can place personnel in continuous contact with the public or those who are possibly infected.
4) Exposure to the pathogens increases the probability of disease occurrence and may result in ICE workforce absenteeism due to illness.
5) The persistent opportunity for transmission of infection makes any outbreak a formidable threat to the ICE workforce and people in its care and custody, and to mission execution—both domestically and internationally.

f. Critical Considerations.

The following considerations are essential to the successful implementation of this Plan:

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1) The Secretary of Homeland Security is the Principal Federal Official for all domestic incident management per HSPD 5, Management of Domestic Incidents.
2) ICE works in partnership with Federal departments and agencies to provide consistent, balanced support in collaboration with state, tribal, territorial, and local government jurisdictions and private sector partners.
3) ICE operations inherently involve working in close settings, including law enforcement operations that involve holding or housing people in its care and custody in congregate settings.
4) ICE's primary concern is to prioritize its own resources to maintain the safety and health of its workforce and those under its care and custody to perform MEFs.
5) MCM
   a) Antibiotics, antivirals, and vaccinations may be available or recommended by the DHS Assistant Secretary for Health Affairs and the Chief Medical Officer (CMO).
   b) Pre-positioning and use of antiviral, antibiotic, and vaccination MCM must be in accordance with approved medical authorities for a specific infectious disease threat.
      i) Antivirals, antibiotics, and vaccinations centrally stored and managed by DHS Office of Health Affairs (OHA) will not be delivered without a need/request.
      ii) MCM must be stored, monitored, and utilized consistent with the *Federal Food, Drug, and Cosmetic Act*, as amended by the *Pandemic and All-Hazards Preparedness Reauthorization Act of 2013*.
   c) ICE will follow publication of incident specific health and medical guidance developed and published by OHA.
   d) ICE will follow all revised and distributed antibiotic, antiviral, and other MCM dispensing guidance provided by OHA.
   e) ICE will rely heavily on Point of Dispensing (POD) teams associated with the ICE Anthrax OPLAN to support PODs for antivirals or antibiotics for other infectious disease threats.
6) Personal Protective Equipment/Respiratory Protection
   a) ICE will follow guidance and coordination provided by the DHS Directorate for Management (MGMT) to include developing mechanisms to provide adequate PPE based on mission requirements, hazard/risk assessments, and appropriate guidance.
   b) PPE can be pre-positioned or delivered without a need/request.
7) Workplace controls and infection control measures reduce illness and absenteeism and should be included in standard operating procedures (SOPs) for all activities with potential exposure to diseases. New or revised workplace controls/infection control measures will enhance all pandemic and infectious disease response.
8) Implementation of health and medical guidance must employ geographical as well as risk-based efforts to reduce disease occurrence. Health and safety requirements must be assessed in terms of mission.
9) Influenza pandemics historically lasted 12 to 18 months with 2 to 3 month long waves of outbreaks.
10) Emerging infectious disease cycles vary and are dependent upon the specific virus, bacteria, or other pathogen.

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g. Critical Assumptions.

The following assumptions are essential to the successful implementation of this Plan:

1) Emerging infectious diseases with pandemic potential affecting humans will appear with little or no warning.
2) A pandemic will result in high workforce absenteeism.
3) Emerging infectious disease characteristics and duration will be unknown.
4) There will be a delay between the time of the initial emerging infectious disease outbreak and the characterization of the outbreak.
5) The direction or spread and the level of infection will be difficult to determine precisely.
6) Pandemic response will extend across numerous jurisdictions and will involve multiple DHS components and multiple ICE programs.
7) The CMO will issue health and medical advisories and recommendations/guidance to the DHS operational and support components based on the best scientific, health, and medical information.
8) Required Emergency Use Authorizations (EUAs) will be in place during a pandemic to allow dispensing of MCM to the workforce and those under ICE care and custody.
9) A vaccine will not be readily available for immediate dispensing or use.
10) ICE will implement workplace controls and standard precautions to the extent that it is practical during a pandemic and serve as a primary means of infection control to mitigate and reduce exposures and illness.
11) MCM prioritization will be required during shortages.
12) Critical ICE resources will need to be prioritized and redirected, if available, in order to meet evolving demands and maximize mission effectiveness.
13) ICE will have plans that provide continuity of its MEFs, as many of its Government Functions as possible, and measures to protect personnel.
14) Any other catastrophic incident occurring during an outbreak will be addressed by a separate plan and existing policies.
15) ICE will receive MCM such as antivirals and antibiotics within 24 hours of a request to OHA if requests are submitted by noon Eastern Time.
16) ICE will utilize the logistical and management chain established to deliver and dispense MCM, in accordance with U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) recommendations, guidance, and an EUA.
17) ICE will utilize the logistical and management chain established for PPE inventory to maintain and deliver/issue in accordance with DHS MGMT, Occupational Safety and Health Administration (OSHA), and HHS recommendations.

2. MISSION.

ICE will take all necessary actions to prepare itself globally for a pandemic or an emerging infectious disease outbreak that threatens the well-being of its workforce, its MEFs, and

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those in its care and custody, while leveraging all available resources in order to prepare for, respond to, and recover from any pandemic or emerging infectious disease threats.

3. EXECUTION.

a. Director's Intent.

1) Protect the ICE workforce and those held in its care and custody.
2) Maintain ICE Government Functions with the goal of maintaining ICE MEFs at the least.
3) Mitigate suffering and loss of life.
4) Promote the synchronized support and coordination of resources with programs while maintaining the ability to address other threats to the Nation.
5) Promote the synchronized support and coordination of resources with external partners.

b. Concept of Operations.

1) Pre-Incident. This phase addresses all actions taken by ICE prior to pandemics or emerging infectious disease threats.
   a) The Emergency Management Unit (EMU), in Homeland Security Investigations, in collaboration with ICE programs, will continue to develop and refine the ICE PWPP by conducting periodic reviews and training to include occasional exercises.
   b) EMU, in collaboration with OHA, will ensure that adequate training and exercising is provided.
   c) EMU, in collaboration with the ICE Office of the Principal Legal Advisor, will continue to develop partnerships with other DHS components and U.S. Government Departments and Agencies through agreements to promote synergistic responses to a pandemic or emerging infectious disease threats.
   d) Collateral duty safety officers (CDSOs), under the oversight of the ICE Office of Asset and Facilities Management (OAFM) Safety and Health Branch shall ensure that hazard/risk assessments are conducted annually to identify personnel who may have to perform duties in an environment impacted by a pandemic or emerging infectious disease threat.
      i) The ICE OAFM Safety and Health Branch will provide oversight to ensure that CDSOs employ the appropriate workplace controls.
   e) ICE will identify personnel, supplies, and equipment that may be required to be deployed in an infectious disease threat or pandemic.

2) Incident Response. This phase addresses ICE's response actions during a pandemic or an emerging infectious disease threat.

   The Secretary of Homeland Security will activate responses for a pandemic or emerging infectious disease threat. Notification to DHS components likely will be sent via several modes; however, the National Operation Center (NOC) will be the

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primary information center. The ICE Joint Intelligence Operations Center (JIOC) will notify senior leaders and upon direction from the office of the Director, EMU will activate the Crisis Action Team (CAT), which aligns with the Incident Command System structure. The CAT will provide direction from the ICE Director, the NOC, and other sources to ICE directorates, and program offices. Similarly, directorates, and program offices will convey reports and requests through the ICE CAT. The CAT will ensure the Director and NOC receive information and requests as appropriate.

a) ICE programs provide immediate situational awareness to the Office of the Director via the JIOC or the CAT to include the safety and well-being of the workforce and those under its care and custody.
b) The CAT will ensure concurrent information sharing and emergency management coordination. The CAT/CAT Director will be responsible for the information flow during a pandemic event.
c) The ICE directorates, and program offices may terminate annual leave, cancel/postpone lower priority training, curtail lower priority activities, and integrate internal assets.
d) The ICE CAT and POD Managers will ensure that OHA-issued MCM are transported to a designated POD via the most efficient and expeditious means possible. This includes transporting MCM from the closest cache to the designated POD in the area where the incident occurred and transporting rear cache supplies and/or POD personnel forward to a staging area in or near the area where the incident occurred. (Note: Whenever MCM is transported by ICE from one location to another, it must be escorted by an LEO and OHA must be notified. Notifications should be sent to the OHA MCM Program Manager.)
e) ICE will follow instructions from OHA for all guidance concerning antiviral, antibiotic, or vaccination dispensing.
f) ICE will follow any associated medical guidance provided by OHA as it relates to personnel and those under ICE care and custody.
g) Workforce requiring MCM should be instructed to use the following preferentially ordered options to receive antibiotic:
    i) Personal Physician: If possible, personnel are encouraged to see their personal medical provider immediately, if they feel they have been exposed to or have symptoms consistent with the current pandemic, such as influenza-like-symptoms. Prescriptions for MCM should be filled via normal pharmacy channels.
    ii) Community Public Health POD: In the event that a pandemic public health emergency is declared, community public health PODs will open to serve the public. DHS personnel and their family members are encouraged to receive MCM via a community POD.
    iii) Non-Medical POD: ICE non-medical personnel are trained to provide limited screening and dispense the first increment of a pre-defined MCM course to the designated workforce and those in ICE care and custody. An EUA issued by the Secretary of HHS is required to be in place for this option. OHA will publish an SOP and provide guidance for exercising this option. When directed, ICE POD staff(s) in ICE POD(s) will provide initial

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MCM. Then, OHA will provide the necessary guidance regarding the complete course of treatment in coordination with the local jurisdiction, other public health authorities, and the CDC.

iv) Medical PODs: Are similar in operation to the non-medical PODs; however, medical PODs are administered by DHS-credentialed licensed medical providers. Because a medical provider has the authority to prescribe and dispense MCM, an EUA will not be required to stand up and operate a medical POD.

h) DHS OHA will provide MCM upon request.
   i) Delivery will usually occur within 24 hours and must be kept in a controlled environment. Controls include:
      - A controlled chain of custody at all times;
      - Restricted access via two locks within an ICE facility or ICE custody where a second lock is accessible only to a restricted number of key personnel; and
      - A dry environment within a temperature range of 72° F ± 5° F or as directed by OHA.

i) ICE will keep the workforce informed via established communication systems and practices.

j) ICE directorates and program offices may deploy pre-designated personnel and resources to emergency support function (ESF) assignments if it is safe to do so.

k) ICE directorates and program offices will perform rapid hazard/risk assessments based on anticipated potential exposure to emerging infectious disease threats while performing MEFs by:
   i) Modify plans, procedures, and practices based on additional information in response to current disease-related information and rapid hazard/risk assessment findings as well as administrative changes;
   ii) In coordination with the CDC National Institute for Occupational Safety and Health (NIOSH), OSHA and/or appropriate federal authority, determine the protection measures needed while performing each MEF; and
   iii) Ensure that a program is in place to disseminate guidance regarding MCM dispensing and PPE use.

l) ICE POD staff will operate PODs upon activation.

m) ICE will maintain records related to PPE and PODs as required and directed.

3) Recovery.[2] This phase addresses the long-term ICE recovery actions and activities required to mitigate the long-term effects of pandemics or emerging infectious disease threats.
   a) Staffing, transportation, and equipment assets will be demobilized at a rate commensurate with decreases in operational activity.
   b) ICE directorates and program offices will continue to monitor and report activities within the impacted area of responsibility (AOR).
   c) MCM will be returned to the designated storage location(s).

[2] The Recovery phase encompasses the "Demobilization."

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d) EMU will lead the collective review of plans, processes, and actions conducted by ICE personnel and will consolidate information for an after-action report, which will be used to improve ICE incident response practices.

c. Roles and Responsibilities.

1) The Office of the Director

a) Provide leadership and guidance to integrate and/or deploy ICE resources.
b) Interact as necessary with senior-level DHS leaders and other department or agency leaders.
c) Lead and coordinate the overall ICE response.
d) Determine the appropriate level of response to ensure that ICE and national interests are met.
e) Ensure that personnel that require non-pharmacological countermeasures, PPE, and MCM will receive them in the most expeditious and efficient manner possible, including training on appropriate use.
f) Ensure the continuation of ICE Governement Functions or ICE's MEFs during the emergency situation to the greatest extent possible.

2) Emergency Management Unit (EMU)

a) Assumes the role of emergency management for the agency in the National Preparedness Goal mission areas: Prepare, Mitigate, Respond, and Recover for the purposes of a pandemic event.
b) Works with OHA and DHS Ops guidance.
c) Coordinates the deployment of available ICE resources.
d) Interacts with senior-level ICE, DHS, and other department or agency leaders. The Outlook email address group: #ICENEMDREPORTING@fins3.dhs.gov is the best conduit for DHS Headquarters to reach an ICE point of contact.
e) With the ICE directorates and program offices and senior-level management, coordinates the ICE effort via the ICE CAT at headquarters (HQ) and via a command structure at the scene(s) of the incident(s).
f) Via the CAP, constructs, activates, and coordinates the rapid deployment and dispensing of MCM to personnel and detainees in conjunction with representatives from ICE directorates and program offices. These ICE representatives will serve as the focal points for ICE operational and logistical coordination, and will work to address information collection, intelligence analysis, and response coordination.
g) Coordinates with the JIOC to ensure that reporting requirements and requests for information are satisfied.
h) Oversees all pertinent information within the DHS Homeland Security Information Network (HSIN), Common Operational Picture program on behalf of ICE, and trains the appropriate personnel who would access it.
i) If requested, identifies senior-level personnel to staff:

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i. ESF-8 (Public Health Services) and/or ESF-13 (Public Safety and Security) desks at the National Response Coordination Center and/or Regional Response Coordination Center; and

j) Accommodates the Joint Field Office in the impacted area by supporting the ICE personnel delegated to accept, manage, and coordinate ESF-8 and/or ESF-13 mission assignments.

k) Oversees the National POD/MCM Program.

l) Defers workplace control matters to OAFM Safety and Health Branch.

m) Leads the collective review of plans, processes, and actions conducted by ICE personnel and will consolidate information for an after-action report, which will be used to improve ICE incident response practices.

3) POD Managers

a) Are responsible for all aspects of the POD under their auspices, but reports to and receives direction from EMU during steady state operations, and from the ICE CAT and the Incident Commander upon an emergency activation.

b) Promote coordinated and supportive efforts across as many programs as possible.

c) Ensure that notifications will occur primarily via the Emergency Notification System and/or email using the Outlook email group #ICE Antiviral MCM Group. However, additional or alternative forms of communication may be necessary.

d) Ensure that POD staff train and exercise at least once annually. However, upon an emergency activation, ensure that new recruits and established POD staff receive just-in-time training.

e) Ensure POD after action reports with improvement plans are written and acted upon as appropriate.

f) Maintain a roster of personnel, with their current contact information, who are capable of providing access to field cached MCM within 1 hour, 24 hours a day, 7 days a week, 365 days a year.

4) ICE OAFM Safety and Health Branch

a) Works with DHS MGMT.

b) Provides advice and consultation to ICE HQ and field managers, supervisors, and CDSOs concerning pandemic or emerging infectious disease threats, along with advice on the appropriate countermeasures that ensure the protection of the Workforce and those under ICE's care and custody.

c) Ensures that occupational safety and health reports received from ICE directorates and program offices are forwarded to OSHA and other agencies as required.

d) Assists ICE directorates and program offices in the proper selection of PPE/respiratory protection.

5) Collateral Duty Safety Officers or Appointed Personnel

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With oversight from the OAFM Safety and Health Branch:

a) Provide advice and consultation to their ICE HQ directorate or program office and/or field responsible official, managers, and supervisors concerning pandemics or highly infectious disease threats.
b) Ensure that occupational safety and health reports that are received from ICE directorates and program offices are forwarded to the OAFM Safety and Health Branch as required.
c) Assist ICE directorates and program offices in ensuring that proper PPE is purchased and stored for employees.
d) Assist ICE directorates and program offices in ensuring that annual fit testing accommodates any unique respirator requirements for identified personnel.
e) Assist ICE directorates and programs in ensuring that personnel receive training in appropriate use of PPE.
f) Ensure that PPE is maintained and distributed as appropriate.
g) Maintain a roster of personnel, with their current contact information, who are capable of providing access to field cached PPE within 1 hour, 24 hours a day, 7 days a week, 365 days a year.

6) Joint Intelligence and Operations Center

Assists the ICE CAT with information exchange between ICE and DHS, including the NOC and all DHS command centers, to ensure a common operating picture for situational awareness.

7) ICE Directorates and Program Offices

a) Submit reports as requested.
b) Ensure the safety of, and account for, all personnel and those under their care and custody as soon as possible.
c) Provide necessary support and resources as required by the Director.
d) Identify and designate personnel potentially involved or deployable in a response or recovery activity.
e) Identify representatives to participate in the team responsible for coordinating and implementation rapid transport of MCM dispensing.
f) Provide resources dedicated to the rapid and efficient transport and issuance of PPE.
g) Ensure the resumption and continuation of MEFs from the alternate operating facility, if necessary.

8) ICE CAT Director

a) Assumes operational control of the ICE CAT.
b) Provides reports to the NOC as required.
c) Works in close coordination with ICE directorates and programs offices in the affected area(s) to provide any required assistance.

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d) Directs ICE directorates and program offices to assign and move assets required to continue the ICE mission to the greatest extent possible.
e) Designates one ICE CAT Deputy Director per 12-hour shift.
f) Provides Situational Reports to the ICE Director and his or her executive staff members.
g) Coordinates with ICE senior leaders to resolve any issues that cannot be resolved by the ICE CAT.
h) Identifies the type of information and intelligence needed during particular categories of events.
i) Reviews and clears all Requests for Information.
j) Directs changes to the ICE CAT Activation Levels based upon changes to the NOC operational phases or internal ICE requirements.

9) ICE Non-Medical POD Personnel

a) Provide limited screening and dispense the first increment of a pre-defined MCM course to the designated workforce and those in ICE's care[3].
b) Provide limited screening and dispense additional MCM course(s) to the designated workforce and those in ICE's care, as needed and directed.

10) ICE Medical POD Personnel

a) Medical PODs are similar in operation to the non-medical PODs; however, medical PODs are administered by DHS-credentialed licensed medical personnel. Because medical personnel have the authority to dispense MCM an EUA will not be required to stand up and operate a medical POD.
b) These personnel must be credentialed by OHA through the ICE Tactical Medical Coordinator.
c) ICE medical personnel, physicians, and pharmacists are eligible to hold a collateral duty as ICE medical personnel.
d) Each medical personnel shall ensure that his or her contact information is current and up to date in corresponding *Global Outlook* email addresses.
e) Each designated medical personnel shall be assigned to a duty station that is less than or equal to 1 hour travel time of the MCM 24 hours a day, 7 days a week, 365 days a year.
f) It is understood that the designated medical personnel has conflicting responsibilities, takes leave, or has other time off. Therefore, the MCM storage sites must maintain a roster of personnel, with their current contact information, who are capable of providing access to the MCM within 1 hour 24 hours a day, 7 days a week, 365 days a year.
g) Medical personnel will maintain accountability of MCM as required by OHA, reporting the results to the EMU which, in turn, consolidates the data into one complete submission to OHA.

[3] Detainees and residents will be served by the medical authority in the facility in which they are housed.

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h) Medical personnel responsible for an MCM cache that is transported to another location for dispensing must ensure that the chain of custody is transferred to another medical personnel in the affected AOR.
i) Medical personnel located in an AOR that is affected or suspected to be affected by an infectious disease threat or pandemic shall be included as an integral team member of the ICS in POD activation(s).

11) ICE Tactical Medical Personnel

a) ICE has a cadre of tactical medics who fall under the medical oversight of a physician, allowing them the appropriate legal and medical requirements to treat ICE personnel.
b) The ICE Tactical Medical Coordinator is the sole entity responsible for the credentialing of ICE Emergency Medical Technicians and paramedics. All ICE medics participating in the ICE PWPP must meet the minimum requirements defined by ICE and OHA.
c) Any ICE Tactical Medics who have been approved to dispense MCM must be available to deploy to any location in a rapid manner at any time. Their rapid deployment must be facilitated and funded with the most expeditious and supportive means.
d) ICE medical personnel who have been approved to dispense MCM must adhere to the protocols developed and approved by OHA.

12) ICE Health Service Corps Personnel

a) The ICE Health Service Corps (IHSC) will support healthcare operations and provide direct patient care to detainees at IHSC-staffed facilities during a pandemic or emerging infectious disease threat.
b) IHSC medical personnel who are authorized to dispense or administer medications must be available to dispense or administer MCM for detainees housed in facilities with IHSC medical staffing in accordance with the scope of their licenses. IHSC administrative and non-medical personnel must be available to support the logistics of MCM distribution for detainees and health surveillance activities with the approval of the IHSC Assistant Director (AD) or designee.
c) IHSC personnel may participate in ICE personnel PODs if that participation does not conflict with duties required for the care of detainees or their Public Health Service responsibilities and with the approval of the IHSC AD or designee.

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4. ADMINISTRATION, RESOURCES, AND FUNDING.

a. Administration.

1) NOC Phase 1 (Guarded)[4]: ICE will follow internal steady state administrative procedures because the scope is not significant enough to require extra Federal assistance.

2) NOC Phase 2 (Concern)[5]: ICE will modify its internal administrative procedures based on detection and characterization of an emerging infectious disease threat and the approved response plan because Federal assistance becomes increased due to state/local responders becoming overwhelmed, seeking assistance, and/or by order of the DHS Secretary.

   a) During the incident phase, ICE will coordinate and track administrative requirements within the impacted AOR. However, substantive administrative matters shall continue to be handled within existing response-agency channels.
   b) Financial oversight shall be maintained through existing ICE channels. ICE will track expenditures and ensure that all expenditures are within authorized levels and conducted in accordance with existing law.
   c) Deployment of personnel shall be conducted in accordance with existing laws and ICE policy.
   d) ICE directorates and program offices will be responsible for all costs of travel, using existing budgets.

3) NOC Phase 3 (Urgent)[6]: ICE will modify its internal administrative procedures based on an outbreak of a highly pathogenic infectious disease or pandemic that requires Federal assistance, and/or by order of the DHS Secretary.

   a) During the incident phase, ICE will coordinate and track administrative requirements within the impacted AOR(s). However, substantive administrative matters shall continue to be handled within existing response-agency channels.

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[4] NOC Phase 1 (Guarded): is determined by man-made events, natural disasters, and other events that State and local officials will manage with limited Federal assistance; an event that has significant or could have significant impact on critical infrastructure/key resource; suspicious activities, events, incidents or accidents that could become a matter of interest at the National level; and/or an event with a homeland security or public safety nexus that the National Security Staff, the DHS Secretary, and/or senior DHS and/or ICE officials may need to address.

[5] NOC Phase 2 (Concern): is determined by an event meeting any of the four criteria outlined in HSPD-5; incidents causing loss of life and/or large scale evacuations requiring significant Federal commitment of resources and/or possible Stafford Act declarations; an event significantly impacting or potentially impacting critical infrastructure/key resources or densely populated areas with potential public safety or public health impacts; a credible threat with possible/confirmed terror nexus to U.S. homeland security; and/or an event or incident requiring a coordinated Federal response in which two or more DHS Components are substantially involved.

[6] NOC Phase 3 (Urgent): is determined when there is an incident so catastrophic that the Federal Government must assume the highest level of operational posturing and activity.

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b) Financial oversight likely will be managed through existing response-agency channels. ICE will track expenditures and ensure that all expenditures are within authorized levels and conducted in accordance with existing law.
c) Deployment of personnel shall be conducted in accordance with existing laws and ICE policy.
d) When the Stafford Act is invoked, costs associated with the response may be reimbursed.

b. Resources.

1) Phase 1: ICE will follow steady state resource procedures.
2) Phase 2: ICE will modify resource procedures based on detection and characterization of an emerging infectious disease threat and the approved response plan.

a) Each ICE directorate and program office is responsible for identifying deployable personnel and assets that may be used during an emergency situation, to include CAT personnel.
b) All movement of resources into the impacted AOR will be coordinated with EMU and the CAT.
c) Resources will be provided in accordance with existing ICE policies.
d) Requests for critical resources unavailable in time through normal channels will be forwarded by the CAT Director to the Office of the Director.
e) Applicable ICE directorate- or program office-specific plans will cover scalable response levels and will define funding, sustainment, and transportation arrangements.
f) EMU will coordinate all pre-positioning efforts associated with emergency preparedness. Any ICE directorate or program office pre-positioning resources in the impacted AOR during an emergency situation must notify the EMU.

c. Funding.

Funding for this Plan will come from existing budgets. Additional funding and/or supplementals are to be determined based on the situation.

5. OVERSIGHT, COORDINATION, AND COMMUNICATIONS.

a. Oversight. The Director will ensure that the command/coordination organizational structures remain throughout each phase of the plan.

1) The Director is the lead for all ICE operations.
2) The ICE Office of Privacy is the lead for ensuring that all operations comply with applicable privacy laws.
3) EMU is responsible for overseeing the implementation of the ICE PWPP.

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b. Coordination.

1) This Plan is effective upon signature by the Director.
2) ICE will issue plan updates as necessary.
3) EMU, in association with the CAT, will maintain situational awareness on any pandemic or emerging infectious disease threat.
4) To ensure effective and seamless DHS operations, ICE workforce health and safety policies, guidance, and requirements will be coordinated and synchronized with the appropriate DHS HQ offices.
5) When possible, contracts supporting MEFs will be modified as necessary to ensure contract fulfillment with minimal or no interruption throughout the duration of a pandemic event or an emerging infectious disease threat.
6) Working with counterparts at all levels, ICE will leverage existing domestic and international relationships in order to receive, share, and integrate information to prevent, protect, respond, and/or recover from a pandemic or an emerging infectious disease threat.
7) ICE will incorporate additional guidance and lessons learned from any pandemic into current and future operations and plans.
8) ICE will work with employee labor unions in developing and bargaining over such procedures where bargaining unit employees are impacted.
9) ICE will work to review and amend appropriate contracts in order to facilitate continuous contractor support.
10) HSIN is the national mechanism that will be used by all DHS Components to share information, reports, and a common operating picture. Annexes A, C, D, E, G, and P provide additional specific information on coordination, operations, MCM, PPE, lexicon, public affairs, and reporting.
11) ICE will send completed plans to DHS Headquarters when required.

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ANNEX A: COORDINATION AND OVERSIGHT

This is a DHS Annex. The purpose of inserting it into the ICE PWPP is for quick reference concerning Department coordination and oversight.

The purpose of this Annex is to identify and briefly describe the coordination groups DHS would lead or be engaged in during a pandemic. Figures 1 and 2 depict leadership coordination groups and descriptions of these groups. DHS Components will continue to use their existing command/coordination organizational structures throughout each phase of the plan.

DHS Senior Leadership Coordination	
Leadership Group	**Description**
DHS Biodefense Leadership Group (BWG)	Senior-level, intra-Departmental body charged with developing, recommending, and coordinating leadership priorities for biological preparedness, defense, and security issues across the Department. PSC resides as a subset of the BWG. The PSC's role is to make sure the Department is prepared for and has a coordinated response to a pandemic or emerging infectious disease.
DHS Operations Deputies (Ops Deps)	Forum for information sharing, coordination, and issue resolution among DHS Components in the areas of operations, planning, training, exercises, incident management, and resource allocations; during an incident or period of heightened threat will serve as a venue for providing situational awareness, coordinating operations and planning, and working through resource constraint and allocation issues at the strategic level.
DHS Senior Leadership Group (SLG)	Key leadership from the DHS Components convened during an identified threat or incident to provide the Secretary with critical advice related to their respective incident management responsibilities and to communicate the Secretary's decisions.

Figure A-1: Leadership Coordination Chart

DHS Action Officer Coordination	
Working Groups	**Description**
Medical Countermeasure Working Group (MCMWG)	OHA-led forum for coordination among DHS Components and coordination oversight provided by the OHA MCM Program Office.
Biological Working Group (BWG)	Consists of action officers used to develop and implement projects for the BWG.
DHS Continuity Working Group (CWG)	Group for oversight and direction to the DHS Continuity Program. Chaired by the DHS Continuity Manager or designee (OPS). It serves as a forum for information sharing, planning, and operations coordination to facilitate integration of continuity activities within DHS and with other federal, state, local, tribal, territorial, and private sector partners.
Pandemic (or Emerging Infectious Disease Specific) Working Group	Created as required during a potential pandemic event to provide strategic guidance and venue for Departmental coordination.

Figure A-2: Action Officer Coordination Chart

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To maintain Essential Functions (EF), effective DHS operations rely on flexible communications and situational awareness systems that provide a common operating picture. Figure 3, below, lists and describes several communications tools used by DHS.

Communication Tools		
Tool	**Host Organization**	**Description**
National Incident Communications Conference Line (NICCL)	OPA	The NICCL is a standing conference line designated, maintained, and supported by OPA as the primary means for interagency incident communications information sharing during an incident requiring federal coordination. OPA provides guidance to federal interagency public affairs headquarters staffs and affected authorities through the NICCL.
State Incident Communications Conference Line (SICCL)	OPA	The SICCL is a dedicated federal-state incident communications conference line also designated by OPA to facilitate the inclusion, transmission, and exchange of incident management information and messaging to all states and territories to include locals and tribes.
Private Sector Incident Communications Conference Line (PICCL)	OPA and NPPD, Office of Infrastructure and Protection (IP)	The PICCL is a standing line for use by the Critical Infrastructure (CI) incident communications coordinators. Access information will be coordinated and disseminated by NPPD, IP, and OPA to provide timely public information to the CI partners during an incident requiring federal coordination and response.
HSIN	OPS	HSIN facilitates information sharing and collaboration among DHS Components and federal, state, local, tribal, and territorial area partners.

Figure A-3: Communication Tools Chart

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ANNEX C:
OPERATIONS

This is a DHS Annex. The purpose of inserting it into the ICE PWPP is for quick reference concerning Department concerns regarding global operations.

The purpose of Annex C is to provide specific information related to pandemic operations.

A detailed synchronization matrix will be published for any branch plan developed in response to a specific pandemic or emerging infectious disease. This Annex provides information on potential DHS actions in response to a pandemic or emerging infectious disease.

Figure 1 (provided by OHA) identifies indicators; describes the potential impact on DHS mission operations; lists triggers or threshold points for decision making; and displays DHS actions likely to occur at that point.

INDICATOR	MISSION OPERATIONS POTENTIALLY IMPACTED	PROPOSED TRIGGER OR THRESHOLD POINT	DHS ACTIONS
Cases observed at outbreak origin	None	None	- Continued monitoring - Review modify DHS and Component plans - Review MCM and PPE posture for all DHS mission locations - Review update training protocols based on known situation
Regional reporting of confirmed cases	Potentially some impact on DHS operations at regional locations	Reporting of sporadic DHS cases in affected region	- Facilitate provision of MCM and PPE in affected region (distribution and dispensing) - Medically manage cases among DHS personnel in affected area - Assess mission effectiveness in light of cases - Review and alter travel plans as required to minimize disease spread
World Health Organization (WHO) declaration of a pandemic HHS Secretary makes a public health emergency declaration	Potential adjustments to procedures and practices in response to specific guidance from HHS, CDC, and OSHA relating to personal protections	Assessment of reporting from DHS Components that operations are adversely impacted as a result of the disease spread or as a result of adherence to specific guidance from HHS, CDC, or OSHA	- Assess impact of guidance on operations and adjust operations accordingly - Provide specific and localized guidance on personal protections (use of MCM and PPE)
Confirmed cases in North America (Canada, U.S., Mexico)	Assess need to alter baseline work practices to provide for personal protections of DHS personnel while maintaining EFs	Broadly reported cases in North America, either regionally or nationally	- Consider alteration of mission operations to accommodate personal protections while maintaining EFs for all DHS Components

Figure C-1: Triggers and decision points

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ANNEX D: TECHNICAL GUIDANCE FOR ANTIVIRAL MEDICAL COUNTERMEASURES DISTRIBUTION AND DISPENSING

Purpose:

To provide guidance for Medical Countermeasures (MCM) distribution/dispensing plans that protect ICE personnel as well as critical contractors, and those within U.S. Immigration and Customs Enforcement (ICE)'s care and custody who are potentially exposed in a pandemic or other infectious disease threat, in order to sustain essential functions.

MCM Dispensing Objectives and Options:

The objective is to provide personnel and people under the care and custody of ICE with MCM as quickly as possible, using traditional dispensing methods available first. The following options are typically available to the ICE workforce and are preferentially ordered:

1. Personal Physician: If possible, personnel are encouraged to see their personal medical provider immediately if they feel they have been exposed to someone or have symptoms consistent with the current pandemic, such as influenza-like-symptoms. Prescriptions for MCM should be filled via normal pharmacy channels.

   Usual health services for individuals under the custody of ICE: Individuals under the custody of ICE will continue to receive MCM through the usual protocols of the facility where they are housed while supplies are available and accessible.

2. Community Public Health Point of Dispensing (POD): In the event a pandemic public health emergency is declared, community public health PODs will open to serve the public. Department of Homeland Security (DHS) personnel and their family members are encouraged to receive MCM via a community POD.

3. Non-Medical POD: ICE non-medical personnel are trained to provide limited screening and dispense the first increment of a pre-defined MCM course to the designated workforce and those in ICE's care and custody. An Emergency Use Authorization (EUA) issued by the Secretary, U.S. Department of Health and Human Services (HHS) is required to be in place for this option. The DHS Office of Health Affairs (OHA) will publish a Standard Operating Procedure and provide guidance for exercising this option. When directed, ICE POD staff(s) in ICE POD(s) will provide initial MCM. Then, OHA will provide the necessary guidance regarding the complete course of treatment in coordination with the local jurisdiction, other public health authorities, and the Centers for Disease Control and Prevention.

4. Medical POD: Are similar in operation to the non-medical PODs; however, the medical POD is administered by DHS-credentialed licensed medical providers. Because a medical provider has the authority to prescribe and dispense MCM, an EUA will not be required to stand up and operate a medical POD.

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Obtaining MCM and Storage Requirements:

- OHA will provide MCM to DHS components upon request.
- Delivery will usually occur within 24 hours via express shipping. However, some exceptions may apply for weekend, evening, outside of the continental United States deliveries, or infrastructure disruptions.
- ICE will make requests to the OHA MCM Program Manager and provide the following information:
    - Address of the delivery location,
    - A primary point of contact (POC) with a cell phone number,
    - A secondary POC to receive the shipment, and
    - The amount of MCM required.
- MCM must be kept in a secure and controlled environment. Controls include:
    - A controlled chain of custody at all times,
    - Restricted access via two locks within an ICE facility or ICE custody where a second lock is accessible only to a restricted number of key personnel, and
    - A dry environment within a temperature range of 67°-77° Fahrenheit or other temperature range if specifically directed by OHA.
- Antivirals may be co-located with antibiotics in MCM cache locations. However, all MCM must be clearly labeled on the outside containers/cases/over packs to ensure ease of identification and accurate inventory.
- Designated, authorized personnel must be able to access the MCM 24/7/365. It is highly recommended that multiple authorized individuals have access to locked MCM, but those designated personnel be kept to a controlled number. Local leadership and POD Managers shall determine the proper number for their MCM cache(s).
- MCM must be accounted for as required and directed by the Emergency Management Unit (EMU) and OHA.

Point of Dispensing (POD):

- EMU oversees the national POD/MCM Program and will provide as much guidance and support as possible to POD staffs associated with all MCM caches.
- Guidance from OHA should be followed as to whether to dispense antiviral MCM under a medical POD or non-medical POD concept of operations, the former requiring the involvement of DHS-credentialed licensed medical providers.
- POD staffs can exercise their POD plans for either a pandemic or anthrax and get "credit" for meeting their annual exercise obligations.
- ICE POD staff(s) will operate POD(s) upon activation.
    - Activations for influenza pandemics or other infectious disease threats will follow the same implementation as that which was determined for the ICE Anthrax Operations Plan (OPLAN).
    - POD Leads shall promote coordinated and supportive efforts across as many programs as possible.
    - The POD Manager is responsible for ensuring that the correct MCM and associated supporting forms and documents are used for actual POD operations.

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- All POD staff will train and exercise at least once annually. However, upon an emergency activation, new recruits and established POD staff will receive just-in-time training.
    - The mechanism for expeditious and mass dispensing MCM is the same construct regardless of the MCM being dispensed.
    - Training and exercising associated with the ICE Anthrax OPLAN is acceptable.
    - EMU will manage the overall oversight, but local personnel will be responsible for ensuring that local POD personnel complete the task(s).
- The POD Manager is responsible for all aspects of the POD under his or her auspices, but reports through and receives direction from the ICE Crisis Action Team and Incident Commander.
- Operational Checklists may be found at the end of this annex.

MCM CRITICAL ASSUMPTIONS:

- Sufficient risk and threat justifies MCM planning to sustain DHS essential functions.
- The time needed to develop an influenza vaccine is typically 6 months from the time of virus isolation to widespread availability and distribution (vaccination is the best means of protection against a novel virus). Vaccine development for other pandemic threats may take significantly longer.
- As currently developed, the DHS POD plans are for dispensing of antiviral MCM, not of vaccine, which requires a higher level of logistics and planning, including cold chain management.
- Viruses will be susceptible to standard antivirals, including but not limited to Tamiflu (oseltamivir) and Relenza (zanamivir); however, in some cases, resistance to either or both may be observed.
- Recognition that a pandemic has begun may take days to weeks depending on adequacy of biosurveillance situational awareness and information sharing, potentially delaying a determination to stand up PODs to dispense MCM to the workforce and those under ICE's care and custody.

PLANNING REQUIREMENTS:

- The ICE PWPP and the ICE Anthrax OPLAN provide adequate constructs for receiving and dispensing MCM at specific, pre-planned sites or PODs. This will be done in accordance with this guidance, and POD training materials provided by OHA.
- POD staff roles must be identified in advance of emergency activations, to ensure readiness (primary, secondary, and tertiary preferred). Roles include:
    - POD Manager, Team Lead
    - Operations Lead
    - Logistics Lead
    - Communications Lead
    - Administration Lead
    - Security Lead
    - MCM delivery

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- Greeter
- Forms reviewer
- Flow Controller
- Dispensers
- Exit monitor

- After Action Reports will be created and acted upon to continuously improve POD performance and preparedness.
- All necessary administrative means to track which employees have received MCM must be utilized and maintained to ensure privacy.

PROCEDURES AND SEQUENCE OF EVENTS:

Procedures for distribution/dispensing MCM to appropriate workforce will be activated if the following conditions are met:

- The Secretary of Homeland Security directs Components to stand up their PODs to dispense antivirals.
- In the event that Component MCM dispensing plans are executed, OHA will provide specific guidance to facilitate dispensing operations at the time of plan execution.
- OHA will determine whether HHS has issued the requisite EUA for dispensing of MCM by non-medical DHS personnel and activate the dispensing plan.
- PODs will be established and operated in accordance with any applicable plan and any EUA.
- Appropriate screening document(s) will be used in screening/assessing all recipients to identify and document antiviral type.
- A treatment consent/declination form/privacy statement will be used.
- Patient information handouts will be provided for all DHS Personnel for the applicable MCM dispensed.

TRACKING:

Tracking and reporting will be managed in accordance with the *Privacy Act*, other relevant laws, and DHS guidance, and reporting information on recipients receiving MCM to OHA guidelines. In general, the following applies:

- Following POD operations, ICE will keep the hardcopy patient screening forms and consent memorandum (both signed) in secure records locations at the local level.
- ICE will report aggregate data to OHA during and after POD operations, including MCM dispensed, MCM remaining, recipients dispensed to and recipients declined (aggregate data is not Personally Identifiable Information);
- OHA will provide guidance on the long term storage requirements of paper records.

Operational Checklist:
(*Pre-Incident and Post-Incident Checklists may be found at the end of this checklist.*)

Incident—Immediate Crisis Management Checklists

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Executive Policy Group	
	S1 activates Anthrax OPLAN
	Notify HQ leadership
	Activate Incident Commander
	Activate Crisis Action Team - HQ ICS personnel
This space is intentionally left blank.	EMU
	JIOC
	ICE ERG
	Distribute REPORTING battle rhythm
	Personnel accountability
	Detainee accountability
	MEFs
	Mobilize personnel
	ICE Broadcasts
	Prioritize ESF assignments
	Monitor personnel or detainees who received MCM
	Family outreach

Incident Commander	
	Activate local Operations Section Chief
	Select location of Incident Command Center
	Confirm location of POD
	Activate local Logistics Section Chief
	Activate other local ICS personnel
	Mode of MCM transport
	Local REPORTING battle rhythm
	Personnel accountability
	Detainee accountability
	Notify affected personnel
	Notify affected detainees
	MEFs
	Cancel leave
	Strategically move additional MCM from other cache location(s) to forward location(s)
	Monitor POD
	Consider COOP activation
	Counseling for affected people
	Family member outreach/support
	ESF assignments
	Monitor personnel or detainees who received MCM

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POD Manager & Operations Lead	
	Activate POD staff
	Assume command and control of POD
	Oversee POD set up coordination with MCM and accompanying paperwork
	Coordinate security details
	Establish communications site and modes with ICE CAT and DHS HQ as required
	Provide Just-in-Time training to POD staff
	Ensure POD Staff self-medicate
	Consider transport of MCM to other locations
	Consider ground transportation requirements
	Mobilize personnel associated with air transportation if required
	Ensure documentation accountability for received MCM
	Report MCM POD start time
	Monitor and foster efficient POD flow
	Oversee proper processing of recipients, their forms, and correct dispensing of MCM
	Request additional POD personnel if needed
	Ensure communications flow with OHA and DHS
	Keep POD staff informed of changing situations
	Report end time for MCM dispensing
	Provide debriefing at conclusion of POD
	Ensure POD is closed down properly to include safe storage of MCM and completed forms
	Ensure an AAR-IP is written and addressed
	Ensure personnel or detainees who received MCM can be contacted and/or monitored
	Consider recommendation for counseling to be implemented

Security Lead	
	Escort for MCM
	Ensure overall security of POD operations
	Manage entrances and exits, in coordination with Greeter and Exit Monitor
	Work with Greeter and other POD staff to check for proper DHS identification of recipients
	Notify Area Commander and/or ICE CAT of MCM escort progress
	Notify Area Commander and/or ICE CAT of achieved POD security

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Administration Lead	
	Manage all paperwork associated with the POD
	Track in personnel assigned to POD(s)
	Track personnel receiving MCM
	Track detainees receiving MCM
	Collect completed forms packet (screening form, consent memo and Privacy Statement) from dispensing stations and secures them in a locked storage location

Logistics Lead		
	Incident Command Center set up	
This space is intentionally left blank.		Tables and chairs
		Computers
		Communications equipment
		Potable water
		ICS Forms
		Support personnel
		Rest rooms
		Signage
	POD set up coordination	
This space is intentionally left blank.		Tables and chairs
		Potable water
		POD Tool Kit
		Administrative personnel
		Administrative supplies, to include forms
		Rest rooms
		Signage
		Establish secure location for MCM inventory
	Oversees inventory and supply management	
	Food	
	ICE Broadcast for personnel in target area	
	ICE Broadcast for personnel outside of target area	
	Congressional reporting	
	Press release	
	Portable radios	
	Liaise with CAT and/or procurement personnel to replenish supplies as needed	

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Logistic Planning	
	Vehicles and associated personnel
	Coordinate security detail
	Transport of MCM and forms to POD **or** airport or landing zone
	Air asset with crew if required
	Transport of MCM and forms from airport or landing zone to POD if required
	Notify Area Commander and/or ICE CAT of ETA for delivery of MCM to POD
	Notify Area Commander and/or ICE CAT of MCM arrival at POD

Communications Lead	
	Work closely with the POD Lead/Manager to manage incoming and outgoing information
	Coordinate resources such as radios, walkie-talkies, land and cell phone, computers, printers, and fax machines
	Provide dedicated phone lines and computers to receive and transmit requests as appropriate
	Send real time updates to POD Lead and senior management regarding usage of MCM inventory
	Work with Logistics/Supply Lead and Administration Lead to report inventory analysis at the end of each shift to account for all equipment and materials

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Pre-Incident

	ICE ANTHRAX OPLAN CHECKLIST PRE-INCIDENT
	All appropriate personnel are familiar with the ICE Anthrax OPLAN.
	All appropriate personnel are trained adequately to include reviewing the educational information on the EMU Homepage of the Intranet.
	Appropriate personnel account for MCM as required.
	Appropriate personnel exercise POD MCM dispensing.
	Documentation to support the ICE Anthrax OPLAN is updated as often as necessary, but at least annually.
	Annual hazard assessments for personnel are conducted.

Post-Incident

	ICE ANTHRAX OPLAN CHECKLIST POST INCIDENT
	Return to regular operations to the extent possible.
	Monitor personnel and detainees that received MCM.
	Conduct hot wash(es).
	Write and submit an after action report.
	Replenish MCM as needed.

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June 20, 2014

U.S. Department of Homeland Security
Office of Health Affairs
Washington, DC 20528

STANDARD OPERATING PROCEDURE FOR MEDICAL COUNTERMEASURES POINTS OF DISPENSING (POD) OPERATIONS

PURPOSE

This Department of Homeland Security (DHS) Standard Operating Procedure (SOP) sets forth the requirements for the provision of medical countermeasures (MCM) from points of dispensing (PODs) staffed by DHS-designated employees to DHS personnel, critical contractors, and those under DHS care and custody located in areas suspected as having been exposed to biological pathogens. This SOP provides direction for:

- POD setup based on work space;
- Defining responsibilities and responsible parties;
- Forms management;
  - Logistics, such as receipt of MCM, supplies, equipment, and proper storage – to include tracking and inventory of supplies;
- Establishing a documentation mechanism for individuals who have received MCM.

SCOPE

This SOP is directed to Components and DHS-designated employees who have been identified and trained to operate a POD site from within their work site. This SOP outlines general procedures and guidelines for the setup and management of a DHS POD for dispensing of MCM to DHS personnel, critical contractors, and those under DHS care and custody. This SOP is to be used in conjunction with specific MCM SOPs related to the type of threat (anthrax, viral, etc.) and dispensing personnel (medical or non-medical).

This SOP Does not apply to health services provided by, for, or on behalf of the United States Coast Guard (USCG) that are in alignment and compliant with Department of Defense and USCG Commandant Directives and Instructions related to the provision of health services.

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Furthermore, this SOP does not authorize DHS contracted medical service providers to administer or dispense medications outside the scope of their contract.

BACKGROUND

DHS has established a plan to dispense MCM to the workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation such as a biological pathogen exposure or release, pandemic influenza or other national threat.

Mass dispensing is the term used to describe the dispensing of MCM to a large group of people in a short period of time during a health security event. The location where mass dispensing of MCM is conducted is called a POD. In order to achieve successful mass dispensing, a POD must be designed to accommodate a varying number of people, and must be appropriately staffed to perform dispensing and supporting activities. OHA recognizes that each Component's normal business practices should be considered when designing an appropriate POD for that office and/or Component.

There are two types of PODs, medical and non-medical:

Medical PODs are set up and managed by designated DHS personnel who have been identified and trained to operate a POD site in which authorized medical personnel conduct individualized medical assessments then administer/dispense an appropriate MCM.

Non-Medical PODs are staffed by designated non-medical DHS personnel who have been identified and trained to operate a POD site and dispense MCM based on the decision matrix tool in an individual's completed DHS Screening Form for Dispensing, but do not conduct individualized medical assessments.

NOTE: Non-medical PODs may still require availability of a healthcare professional if the terms of the EUA or PAHPRA (Pandemic and All-Hazards Preparedness Reauthorization Act) order so dictate.

Once the DHS Secretary or designee has declared a health security threat, the CMO will make the determination to stand-up PODs, either medical or non-medical.

These types of PODs are oriented toward a "pull" mechanism, a type of dispensing characterized by the exposed and potentially exposed population coming to the POD to pick up MCM. A Component could decide to opt for dispensing in a "push" fashion, which involves actively moving out to the field to distribute medications in unique situations.

I. POD FUNCTIONS AND ACTIVITIES

The DHS workforce PODs will be set up in a pre-identified location. Medication will be rapidly distributed to eligible personnel at the PODs (or from alternative venues specific to Component mission environs). As shown in Figure 1 - Flowchart of POD Deployment Process from Start to Finish, the responding supervisor must determine the best location based on the logistics of moving people in and out of the office and/or facility in an expeditious and seamless manner, minimizing possible disruption to normal mission operations.

Once the operational plan is developed, exercise and training shall be conducted on a routine annual basis, to those staffing, servicing and supporting the DHS workforce POD to ensure its successful operation when needed.

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Upon notification from the DHS Secretary, based on recommendations from the Assistant Secretary of Health Affairs and Chief Medical Officer (ASHA/CMO), the supervisor will activate the workforce POD as appropriate by transforming the designated space within the office or designated location while normal operations continue to the extent possible.
As indicated in Attachment 1, the POD Manager and/or Site Lead will be in contact with the appropriate chain of command regarding the event, status of POD, numbers reported and logistics. The PODs will remain activated until authorized to deactivate by the DHS Secretary based on recommendations from the ASHA/CMO, at which time the POD Manager/Site Lead will provide required reports up the chain, and facilitate tear-down and demobilization of the POD.

II. DHS WORKFORCE POD GUIDE

The POD Manager and/or Site Lead will serve as liaison for all POD planning and response activity. This should be a supervisor or someone who is in the office (or determined location) on a consistent basis. The POD Manager and designated team will follow this SOP and is responsible for:

1. POD Location:

- Plan for the affected facility as well as COOP sites where MCM may be pre-staged or cached.
- Identify the best locations within the Component to establish POD operations. Designate most optimal location for ease of flow (one entry & one exit) within the work environment, adequate space for screening and review of forms, and medication dispensing (conference room, cafeteria, lobby, tent, vehicle, etc.).
- Space utilization, size, number of eligible personnel will affect the flow and operations of the POD (number of staff to support individual stations and dispensing, adjust up or down based on the demand). See Figure 1 - Flowchart of POD Process from Start to Finish.
- Consider signage to direct people to the location and steps throughout the process (taping arrows/lanes/path for individuals to follow and numbering stations)
- For those DHS Components with a smaller number of eligible personnel, determine if there is a need to enter into an MOU with another Component for operation of a shared POD to coordinate mass dispensing activities.

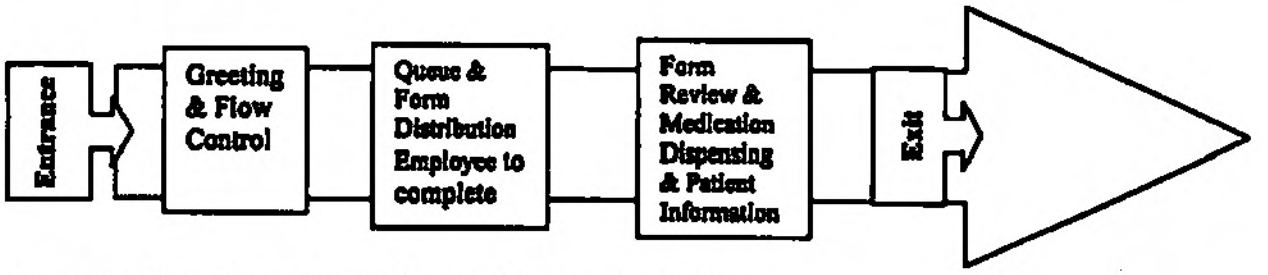

Figure 1 – Flowchart of POD Process from Start to Finish

2. POD Staffing:

Designate employees that will assist in the POD operations. Staffing needs should be based on the size and physical location of the POD.

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The primary difference between a Medical and Non-Medical POD is whether authorized medical personnel conduct individualized medical assessments to administer/dispense an appropriate MCM (Medical POD), or if designated non-medical personnel use an approved DHS Screening Form for Dispensing decision matrix tool to dispense appropriate MCM (Non-medical POD).

Recommend that Component identify personnel to execute the following specific job actions (duties detailed in the Job Action Sheets in Attachments 1 thru 8):

- POD Manager and/or Site Lead
- Operational Logistics
- Operational Job Actions
    - **Greeter:** Dual role of directing people into the POD and screening the crowd (visually and/or through direct questions). Helps individuals in need of assistance.
    - **Forms Distribution:** Most POD plans require data collection. All required pre-screening forms will be completed on site by each individual prior to dispensing.
    - **Dispensing:**
        - Medical POD: Designated DHS medical care providers evaluate individuals for suspected exposure to biological pathogens and may administer/dispense an appropriate MCM. This treatment will be documented on the Standard Form 558 (SF 558), EMERGENCY CARE AND TREATMENT, (Attachment 7) or an equivalent Component-specific form, authorized electronic health record system and/or approved spreadsheet.
        - Non-Medical POD: Designated non-medical personnel review all forms, verify the identity of the person who is receiving the MCM, then dispense the appropriate MCM based on the completed DHS Screening Form for Dispensing decision matrix tool. Staff will include the time, date and signature on forms.
    - Form Collection and Exit: Ensures forms have been collected and directs individuals to the exit. Exit staff provides details to follow-up care, or reinforces compliance messages.
    - Traffic Management: Manages entry and exit points, directs people to available stations and manages crowd control.
    - Security: Responsible for crowd control outside as well as inside the DHS workforce POD site. Establishes a mechanism to secure entry into building or around designated location, checks badges to ensure personal safety of POD staff. Considers securing the perimeter of the POD operation and MCM stock.

NOTE: If possible, provide color-coded vests for ease in recognition of staff. (For example, those wearing a red vest will dispense, and those wearing yellow vests will be responsible for security).

3. POD Operational Logistics (Supply):
Acquisition of all related forms, medical and non-medical supplies, and MCM needed to accomplish the task (identify appropriate workforce numbers).

- Determine the quantity of materials and supplies to be purchased such as signs, clipboards, pens, light, forms, tables, etc.

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- Establish mechanism for receiving inventory and accountability of supplies and equipment. Work with OHA regarding how MCM will be requested, purchased, and distributed to the designated locations and establish a process for the DHS workforce, critical contractors, and those under DHS care and custody to receive MCMs. The following must be considered:
    - MCMs will be shipped in pre-labeled bottles, which will include drug name, strength and quantity, directions for use, lot number. The workforce POD must have the ability to maintain appropriately controlled storage for MCM in accordance with the Standard Operating Procedures For Storage of Medical Countermeasures.
- Forms Management
    - Complete DHS Screening Form and review dispensing matrix tool MCM; forms must include time, date, signature and location of dispensing site.
    - Collect individual's data and dispensing information through use of the DHS Screening Form, an equivalent Component-specific form, authorized electronic health record system and/or approved spreadsheet
    - Complete Privacy Act Statement and Consent-Declination form
    - Distribute patient information sheets from the Centers for Disease Control and Prevention (CDC)
    - Establish a mechanism to prevent individuals from processing more than once (tags, hand stamp, etc.)
    - Maintain all required forms for dispensing and submit them to the appropriate agency as directed. Additional MCM-specific reporting guidance is listed in the Medical Documentation section of SOPs for providing a specific type of MCM from PODs.
- Communication:
    - Identify required number of phone lines and alternate means to communicate should hard lines be disrupted and cell coverage is limited; include emergency radios if feasible.
    - Develop notification protocols for alerting dispensing staff and key employees, and identify how information and communication will flow during the event.
    - Test the system.
    - Establish a reporting mechanism to keep senior leadership informed of status and any logistical requirements.
    - Provide operational logistics (supply) reporting in accordance with the DHS Components guidance for MCM storage.
- Training:
    - Provide training on POD concepts and various roles and responsibilities, and conduct just-in-time training as needed to keep staff refreshed on expectations and specific job tasks. Key content to include are:
        - Chain of command, organizational chart and communication flow
        - POD flow activities and signage.
        - Use of personal protective equipment (PPE) and relevant infection control measures, SOPs, MCM patient information sheets, standard reporting procedures, response to outside requests for information, and patient confidentiality.
        - Proper hand washing or waterless hand sanitizer use and its importance.

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        - Appropriate PPE (preferably disposable) and proper PPE disposal after use.
        - Safety and security.
        - Deactivating and demobilizing a POD.
- Post Event -Stand down or Demobilization
    - Proceed with tear down of POD as directed:
        - Secure and inventory all unused supplies, equipment and MCM (return all unopened supplies as directed).
        - Return supplies to designated locations and/or package supplies for removal and storage if outside workplace.
        - Keep refrigerated items within designated temperature ranges at all times (Document temperature checks at least three times /day).
        - Secure and inventory communication and computer equipment if other than normal office inventory.
        - Clean facility: debris, personal items, medical and non-medical supplies/equipment, bio-hazardous material.
        - Remove equipment brought to site.
        - Notify site point of contact (POC) when the facility is vacated.

III. STORAGE REQUIREMENTS

The following minimum general requirements for the storage and handling of prescription drugs are the responsibility of the DHS Component agency accepting MCM:

- Locations at which prescription drugs are stored, warehoused, and handled, shall be of suitable size and construction to provide adequate space, lighting, temperature, humidity, and security conditions.
- Storage areas shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds, or vermin.
- There should be a designated quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, or adulterated.
- Access to the storage area shall be kept to a minimum and all storage areas shall be secured in a manner that will provide protection against theft and diversion.
- Expanded guidance for MCM storage, tracking, and receiving capabilities is detailed in the Standard Operating Procedure For Storage of Medical Countermeasures.

V. MEDICATION DOCUMENTATION

Prior to any evaluation taking place, eligible personnel requesting evaluation shall acknowledge receipt of the Privacy Act Statement. Upon recommendation and prior to administration/dispensation of MCM, eligible personnel must receive a copy of the MCM-specific Patient Information Sheet and be informed of:

- The potential side effects of the MCM;
- Their right to refuse treatment;
- Their right to refuse the administration/dispensation of these medications; and
- Any other elements required to be communicated to recipients, healthcare professionals, or others under the relevant EUA or PAHPRA order.

Expanded guidance for MCM documentation and reporting is detailed in the Standard Operating Procedures for specific situations (e.g. SOP For Providing Anthrax Medical Countermeasures From

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Points Of Dispensing Staffed By Non-Medical Personnel, SOP For Providing Anthrax Medical Countermeasures From Points Of Dispensing Staffed By Medical Personnel, SOP For Providing Antiviral Medical Countermeasures From Points Of Dispensing Staffed By Medical Personnel, etc.).

VI. MEDICAL OVERSIGHT

The Office of Health Affairs, Workforce Health and Medical Support Division, will provide principal medical oversight of the MCM program for DHS components. The point of contact for this SOP is the Workforce Health and Medical Support Division's MCM Program Manager in the Office of Health Affairs (b)(6); (b)(7)(C)

APPROVED BY:

(b)(6); (b)(7)(C)

Date July 7, 2014

Acting Assistant Secretary for Health Affairs and
Chief Medical Officer

ATTACHMENTS:

Attachment 1: Job Action Sheet: POD Manager
Attachment 2: Job Action Sheet: Operations Lead
Attachment 3: Job Action Sheet: Operational Logistics (Supply) Lead
Attachment 4: Job Action Sheet: Administration Lead (if required)
Attachment 5: Job Action Sheet: Communications Lead (if required)
Attachment 6: Job Action Sheet: Flow Control, Greeter, Forms Review and Exit Monitor
Attachment 7: Job Action Sheet: MCM Delivery
Attachment 8: Job Action Sheet: Security Lead

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Attachment 1 - Job Action Sheets

POD Manager

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: POD Manager and/or Site Lead

Staffing Job Actions:

1. POD Manager is responsible for the command and control activities of the POD. This person(s) will manage and control the total operation of the workforce POD.
2. The POD Manager directly oversees the operations, logistics (supply), planning, and administration by working closely with the identified leads and coordinators for all shifts (if appropriate)
3. Serves as supervisor of the Site and performs the following activities:
   a) Oversees site setup and teardown when informed to deactivate b) Assigns people to leader duties/roles
   c) Provides just-in-time training to staff or delegates duty as appropriate
   d) Establishes a communication site and communicates with HQ DHS leadership (provides update on status, supplies, issues, concerns) as directed
   e) Inventory control, work with assigned logistics leader on setup, security of MCM and supplies and storage
   f) Rectify any safety issues and always enforce SAFETY!
   g) Keep staff informed of changing situations regarding the event h) Debriefing following event

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Attachment 2 - Job Action Sheet

Operations Lead

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation

Role: Operations Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Responsible for all clinical areas of the POD, including:

    a) Screening: meet and greet, flow control, registration, screening form, privacy act and consent, patient education and exit monitor

    b) Dispensing: providing MCM as directed under established protocols and/or decision matrix tool

    c) Special Needs: In pre-planning, identify those individuals who might have difficulties

    d) Resources: Inventory of supplies, medications and any equipment (work closely with logistics lead)

    e) Assess safety and security of the dispensing area

    f) Training: Ensure staff are trained to respective roles and are comfortable in their role

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Attachment 3 - Job Action Sheet

Operational Logistics (Supply) Lead

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: Operational Logistics Lead

Staffing Job Actions:

1. Report directly to POD Manager/Site Lead
2. Manage support personnel as assigned
3. Oversees all support needs of the POD to include acquisition of supplies and equipment
4. Oversees inventory and supply management
5. Establish secure location for MCM inventory in accordance with the Standard Operating Procedure For Storage of Medical Countermeasures
6. Assist in set up of workforce POD, apply signage and directions for individuals to follow as appropriate (depending on size of workspace used and facility location)

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Attachment 4 - Job Action Sheet

Administration Lead (If required)

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: Administration Section Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Manages all paperwork generated at the POD, including but not limited to:
    a) Event documentation
    b) Patient screening forms c)
    Forms management
    d) Documentation, tracking, inventory tools/logs
    e) Maintain security and control of screening forms
3. Report routinely to the POD Manager/supervisor to ensure individuals' status are current and accurate

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Attachment 5 - Job Action Sheet

Communications Lead (if required)

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: Communications Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Work closely with the POD Manager/Site Lead in managing incoming and outgoing information
3. Coordinate resources such as radios, walkie-talkies, land and cell phones, computers, printers, and fax machines (if applicable)
4. Provide for dedicated phone lines and computers to receive and transmit requests as appropriate
5. Inventory analysis at the end of each shift to account for all equipment and materiels

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Attachment 6 - Job Action Sheet

Flow Control, Greeter, Forms Review and Exit Monitor

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: Flow Control, Greeter, Forms Review and Exit Monitor

Report to: Operations Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Maintain awareness for any potential security issue and report immediately to supervisor or security lead
3. Assist in flow control between various stations, ensure that entry points and flow to various stations are clearly identified for individuals to process through
4. Direct individuals to the next station
5. Keep lines moving in an orderly fashion
6. Review individuals' screening forms for completeness, and accuracy (ensure all required fields are complete)
7. Answer non-medical questions about the form s and any other questions related to the process.
8. Provide direction to individuals once they have processed through the stations (event specific). Issues to address include:
   a) Whether or not there is a need to shelter-in-place
   b) Procedures and timing for returning to work
   station c) Communicating situational updates
   d) Providing reassurance

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Attachment 7 - Job Action Sheet

MCM Delivery

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: MCM Delivery

Report to: Operations Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Maintain awareness for any potential security issue and report immediately to supervisor or security lead
3. Set up dispensing table with needed supplies (pens, date stamps, patient information sheets, etc.)
4. Work with Logistics lead on how MCM will be labeled for distribution
5. Review screening forms for completeness and accuracy (ensure all required fields are complete) to include, date, time, signature and POD location
6. Review and understand instructions for MCM delivery; if non-medical POD, review the decision matrix for distributing medication based on individuals' screening form
7. Review and understand instructions for DHS MCM consent-decilination form and privacy act statement
8. Answer non-medical questions about the form and any other questions related to the process
9. Provide patient information sheets to individuals; keep in mind that if this is a non-medical POD, those with medical questions must be referred to their individual provider
10. Direct individuals to the exit station
11. Be supportive to individuals, provide direction and reassurance

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Attachment 8 - Job Action Sheet

Security Lead

Primary Mission: Dispense MCM to the DHS workforce in a safe, timely and secure environment when called upon to do so in the event of an emergent situation.

Role: Security Lead

Staffing Job Actions:

1. Understand the overall POD dispensing concept
2. Maintain crowd control both inside and outside the POD to ensure security of MCM stocks and safety of the workforce
3. Identify additional staff support for security (dependent on the size and location of the POD)

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Homeland Security

June 20, 2014

U.S. Department of Homeland Security
Office of Health Affairs
Washington, DC 20528

STANDARD OPERATING PROCEDURE FOR PROVIDING ANTIVIRAL MEDICAL COUNTERMEASURES FROM POINTS OF DISPENSING STAFFED BY MEDICAL PERSONNEL

PURPOSE

This Department of Homeland Security (DHS) Standard Operating Procedure (SOP) sets forth the requirements for the provision of antiviral Medical Countermeasures (MCM) from points of dispensing (PODs), staffed by designated DHS medical care providers, to the DHS workforce, critical contractors, and those under DHS care and custody who present with symptoms of, or are located in areas suspected as having been exposed to, viral pathogens. This SOP provides direction for:

- Recognizing symptoms of viral exposure;
- Implementing the decision to recommend and/or administer/dispense post-exposure prophylaxis or treatment;
- Activating treatment and post-exposure prophylaxis medication administering/dispensing strategies, dispensing sites, dispensing modalities and other approaches, as necessary, to achieve dispensing goals commensurate with the targeted population;
- Recognizing potential side effects of treatment and post-exposure prophylaxis medications; and,
- Establishing a documentation mechanism for individuals who have received medication from the DHS stockpile.

SCOPE

This SOP is directed to DHS federal employees and detailees whose official duties include the provision of medical care, who are authorized by their Component to provide medical care, and who are also credentialed by the Assistant Secretary for Health Affairs/Chief Medical Officer (ASHA/CMO) in accordance with Delegation 5001 and Directive 248-01 (Medical Quality Management) and any subsequent implementing Instruction on Medical Quality Management

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(hereinafter "designated DHS medical care providers"). This SOP outlines procedures for dispensing of MCM to DHS personnel, critical contractors, and those under DHS care and custody who present with symptoms of, or are located in areas suspected as having been exposed to, viral pathogens.

This SOP Does not apply to health services provided by, for, or on behalf of the United States Coast Guard (USCG) that are in alignment and compliant with Department of Defense and USCG Commandant Directives and Instructions related to the provision of health services. Further, this SOP does not apply to DHS contracted medical service providers to administer or dispense antivirals outside the scope of their contract.

BACKGROUND

DHS has established a plan to dispense MCM to eligible personnel (DHS employees, critical contractors and individuals under care and custody of DHS) in a safe, timely and secure environment in the event of an emergent pandemic situation (DHS Pandemic Workforce Protection Plan_2013:(b)(7)(E)
(b)(7)(E) Based on available evidence, it was determined that providing antiviral MCM such as Tamiflu or Relenza can be safe and effective for treatment or post-exposure prophylaxis. It should be noted that treatment or post-exposure prophylaxis is only partially effective, and prevention is preferred. Inasmuch as pre-planning is possible, managers and supervisors must determine the best way to support administering/dispensing strategies, modalities, and other requirements detailed in this SOP.

Refer to the MCM SOP for Medical Countermeasures Points Of Dispensing (POD) Operations for further information and guidance on the setup and management of a DHS POD.

I. SYMPTOMS OF VIRAL INFECTION:

There is a wide variety of viruses that can cause illness within a population, including influenza (also known as the flu), gastroenteritis, smallpox, hemorrhagic fever, and many others. Viral infections can present with a variety of symptoms, ranging from mild to severe. These symptoms may vary depending on what part of the body is affected, type of viruses, age and overall health of the affected person, and the severity of the illness. The most common types of contagious viral infection, however, involve the respiratory tract, and usually cause one or more of the following "flu-like symptoms":

- Fever (usually high)
- Headache
- Fatigue

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- Chills
- Muscle aches
- Dry cough
- Sore throat
- Runny or stuffy nose
- Rash
- Nausea and vomiting
- Diarrhea

Infectious Period: The length of time someone with a viral infection is infectious depends on the virus that caused the infection. Many people with viral infections are infectious prior to becoming symptomatic, and some remain contagious even after their symptoms resolve. Further information on the symptoms and infectious period of a particular viral agent during an outbreak will be shared as information becomes available.

II. THE DECISION TO RECOMMEND AND/OR ADMINISTER/DISPENSE ANTIVIRAL MCM:

When directed to by the DHS Secretary or the Assistant Secretary for Health Affairs and Chief Medical Officer (ASHA/CMO), MCM will be allocated to Components with directives to set up PODs then commence screening and dispensing antiviral medications to their eligible personnel. Upon request from eligible personnel, designated DHS medical care providers may evaluate the symptoms or potential exposure described by the requestor and in their professional judgment, and pursuant to this SOP, recommend antiviral medication for treatment or post-exposure prophylaxis.

III. TREATMENT AND POST-EXPOSURE PROPHYLAXIS (PEP):

Administration/Dispensation of Antivirals for Treatment or PEP

OHA will continue to monitor the situation regarding any pandemic virus outbreak, and will advise if any changes are to be made as to who may administer these or other medications related to the situation.

Administering/dispensing procedures are the same for post-exposure prophylaxis or treatment although the duration of dosing differs between the two uses.

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The record-keeping requirements noted at the end of this document apply to any antiviral administered or dispensed by a designated DHS medical care provider, regardless of the manner or location of administration/dispensation.

IV. POTENTIAL SIDE EFFECTS OF MEDICATIONS:

All eligible personnel who receive any antiviral medication must be advised of potential side effects and receive a copy of the modified Patient Information Sheet (Attachment 1 for Tamiflu or Attachment 2 for Relenza) prior to medication administration/dispensation.

V. STORAGE REQUIREMENTS

The following minimum general requirements for the storage and handling of prescription drugs are the responsibility of the DHS Component agency accepting MCM:

- Locations at which prescription drugs are stored, warehoused, and handled, shall be of suitable size and construction to provide necessary space, lighting, temperature, humidity, and security conditions.
- Storage areas shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds, or vermin.
- There shall be a designated quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, or adulterated.
- Access from outside the storage area shall be kept to a minimum and all storage areas shall be secured in a manner that will provide protection against theft and diversion.
- MCM-specific storage requirements are listed in the patient information (Attachment 1 for TAMIFLU, Attachment 2 for RELENZA) documents. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements listed on the label of the drug, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
- Additional information for MCM storage, tracking, and receiving capabilities is detailed in the Standard Operating Procedure for Storage of Medical Countermeasures.

VI. MEDICATION DOCUMENTATION

Prior to dispensing any MCM for treatment or PEP, eligible personnel requesting evaluation shall acknowledge receipt of the Privacy Act Statement (Attachment 4) which presents information about:

- The potential side effects of the antiviral medications, as described further in this SOP,
- Their right to refuse treatment,
- Their right to refuse the administration/dispensation of these medications.

Each eligible individual must also sign the DHS Form, Antiviral Medication Consent-Declination (Attachment 3) acknowledging that they have been made aware of the available options prior to

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receiving any antiviral medication. Only upon receipt of the signed consent form may the designated DHS medical care providers administer/dispense antivirals.

For the purposes of this SOP, each DHS Component providing MCM to eligible personnel will document treatment on the Standard Form 558 (SF 558), EMERGENCY CARE AND TREATMENT, (Attachment 7) or an equivalent Component-specific form, authorized electronic health record system and/or approved spreadsheet. The following information will be included:

- Name
- Age
- Location
- Initial signs and symptoms presented
- Treatment modalities
  - Drug given
  - Dosage and schedule
  - Date and time
  - Note potential contraindications
  - Expiration date
- Side effects experienced
- Prevention measures
- Disposition
- Follow-up

Components shall compile a password-protected listing of MCM dispensing data, which includes the above information but has personally identifiable information (e.g., name or SSN) redacted. This listing will be sent to the Workforce Health and Medical Support Division at the Office of Health Affairs (healthaffairs@hq.dhs.gov). Updates shall be provided every 24 hours and shall include any reports of serious suspected adverse effects of administered/dispensed medications.

VII. MEDICAL OVERSIGHT:

The Office of Health Affairs, Workforce Health and Medical Support Division, will provide principal medical oversight of the MCM program for DHS Components. The point of contact for this SOP is the Workforce Health and Medical Support Division's MCM Program Manager in the Office of Health Affairs (healthaffairs@hq.dhs.gov).

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APPROVED BY:

(b)(6); (b)(7)(C)

Date July 7, 2014

Acting Assistant Secretary for Health Affairs and Chief Medical Officer

Attachments:

Attachment 1: TAMIFLU (Oseltamivir) Patient Information Sheet Attachment 2: RELENZA (Zanamivir) Patient Information Sheet Attachment 3: Antiviral Medication Consent – Declination Form Attachment 4: Privacy Act Statement Attachment 5: SF 558, Emergency Care and Treatment Form

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Attachment 1 - TAMIFLU (Oseltamivir) Patient Information Sheet

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Patient Information
TAMIFLU (Oseltamivir) 75-mg *Oral Capsule*
TAMIFLU (Oseltamivir) *Oral Suspension* (6 mg/mL)

Take this medicine as directed.

Adult Dosing (orally):

- Treatment: 75 mg twice daily for 5 days
- Prophylaxis: 75 mg daily for 10 days

Side Effects: Rare but serious skin reactions and allergic reactions have been reported. Stop taking TAMIFLU and call your doctor if you experience any of these reactions, as they could be very serious.

The *most common side effects* of TAMIFLU are mild to moderate nausea and vomiting. TAMIFLU is generally well tolerated.

TAMIFLU can be taken with or without food. As with many medicines, if you take TAMIFLU with a light snack, milk, or a meal, the potential for an upset stomach may be reduced.

People with a viral infection, particularly children and adolescents, may be at an increased risk of self-injury and confusion shortly after taking TAMIFLU, and should be closely monitored for signs of unusual behavior. A healthcare professional should be contacted immediately if the patient taking TAMIFLU shows any signs of unusual behavior.

In addition, take the following precautions when using TAMIFLU:

- You should not take TAMIFLU if you are allergic to Oseltamivir phosphate or any other ingredients in TAMIFLU.
- TAMIFLU is normally not recommended for use during pregnancy or nursing. If you are pregnant, planning to become pregnant or breastfeeding while taking TAMIFLU, talk to your doctor before taking TAMIFLU.
- If you have any type of kidney disease, talk to your doctor before starting TAMIFLU therapy.

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TAMIFLU has been shown to have a minimal chance of negatively interacting with other medications. Your doctor or healthcare professional may recommend taking over-the-counter medications to reduce severity of symptoms while the antiviral action of TAMIFLU takes effect. As with any medication, be sure to discuss with your doctor any over-the-counter or prescription medicines you are currently taking before beginning TAMIFLU therapy. An intranasal flu vaccine, like FluMist, should not be given within two weeks before, or 48 hours after, taking TAMIFLU, unless it is deemed appropriate by your doctor.

If you forget to take your medicine at any time, take the missed dose as soon as you remember, unless it is within two yours of your next scheduled dose. Do not take two doses at a time to make up for a missed dose. You can then continue to take TAMIFLU at the usual times.

TAMIFLU capsules should be stored at room temperature below 77° F (25° C) and kept in a dry place. Refrigerate liquid TAMIFLU at 36° to 46° F (2° to 8° C). Do not freeze.

Storage: TAMIFLU (Oseltamivir) should be kept in a light-resistant container, tightly closed, and out of the reach of children. Store at a controlled room temperature (ideally 68°F to 77°F or 20°C

excess heat and moisture (not in the bathroom). All personnel should be mindful that this is a limited resource, and if used prematurely, may not be available when needed later.

Disclaimer: The below dosing, contraindication, and side effect information was taken from the manufacturer website, www.tamiflu.com. Please see manufacturer insert for dosing instructions and follow-up for questions or concerns.

As with all medications, keep out of the reach of children.

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Attachment 2 - RELENZA (Zanamivir) Patient Information Sheet

Patient Information
RELENZA (Zanamivir) 5-mg blister of *powder for oral inhalation*
via provided DISKHALER.

Take this medicine as directed.

Adult Dosing (oral inhalation):

- Treatment: Two 5-mg inhalations (10-mg total) twice daily, approximately 12 hours apart, for five days (adults and pediatric patients seven years of age and older).
- Prophylaxis: Two 5-mg inhalations (10-mg total) once daily for ten days.

Side Effects: The *most common side effects* with RELENZA have been headaches; diarrhea; nausea; vomiting; nasal irritation; bronchitis; cough; sinusitis; ear, nose, throat infections; and dizziness. Other side effects that have been reported, but were not as common, include rashes and allergic reactions, some of which were severe.

Special Warnings Concerning Relenza

- Some patients have had bronchospasm (wheezing) or serious breathing problems when using RELENZA. Many, but not all, of these patients had previous asthma or chronic obstructive pulmonary disease (COPD). RELENZA has not been shown to shorten the duration of influenza in people with these diseases. Because of the risk of side effects and since it has not been shown to help them, RELENZA is not recommended for people with chronic respiratory disease such as asthma or COPD.
- If you have lung disease, you should have a fast-acting inhaled bronchodilator available while being treated with RELENZA. If your breathing worsens, stop using RELENZA and call your health care provider.

General Precautions with RELENZA

- RELENZA has not been shown to treat flu-like illnesses caused by any virus other than influenza A and B (e.g., stomach flu, common cold, or other reparatory illnesses not caused by influenza).
- RELENZA was not effective in reducing the chance of getting the flu in two studies in nursing home patients.

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- Stop taking RELENZA and contact your health care provider if you experience signs or symptoms of an allergic reaction such as shortness of breath; swelling of eyelids, face or lips; or a skin rash.
- Other kinds of infections can appear like influenza or occur along with influenza, and need different types of treatment. Contact your health care provider if you feel worse or develop new symptoms during or after treatment, or if your influenza symptoms do not start to get better.

Storage: RELENZA (Zanamivir) should be stored in a secure, humidity and temperature controlled environment (56° to 86° F) according to manufacturer's guidance. All personnel should be mindful that this is a limited resource, and if used prematurely, may not be available when needed later.

Disclaimer: The below dosing, contraindication, and side effect information was taken from the manufacturer websites, www.relenza.com . Please see manufacturer insert for dosing instructions and follow-up for questions or concerns.

As with all medications, keep out of the reach of children.

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Attachment 3 - Antiviral Medication Consent – Declination

Print: First Name: _____ MI:____ Last Name:_____

As a DHS employee, critical contractor, or individual under DHS care and custody who has been exposed or has had suspected exposure to a viral pathogen, you are eligible to receive antiviral medications for treatment and post-exposure prophylaxis. Please read the information sheets in reference to the specific antiviral medication being provided, with the generic name of Tamiflu or Relenza. Then complete this form by checking the box preceding the appropriate statement, signing, and dating at the bottom.
(See attached Information Sheets)

_____ CONSENT: As a DHS employee, critical contractor, or individual under DHS care and custody who has been exposed or has had suspected exposure to a viral pathogen, I have been informed about and been offered the opportunity to receive the antiviral medication. I understand that I must take the antiviral medication as directed. I have reviewed the attached information sheets and understand the potential risk of side effects that can be experienced from the antiviral medication. I accept the offer at this time.

_____ DECLINATION: I understand that due to my exposure or suspected exposure to a viral pathogen, I may be at risk of becoming seriously ill. I have been given the opportunity to receive antiviral medication. However, I decline the antiviral medications at this time. I understand that by declining this medication, I continue to be at risk of becoming seriously ill. I understand that if in the future I would like to receive the antiviral medication I must contact my supervisor.

Signature: _____ Date: _____

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Attachment 4 - Privacy Act Statement

Privacy Act Statement: DHS's Use of Your Information

Principal Purposes: When you are assessed and dispensed an antiviral(s) by a designated DHS medical provider for a probable exposure to a viral pathogen, the designated DHS medical provider collects your full name, signature, and details about your medical history based on your completed self-assessment. The designated DHS medical provider may use this information or provide this information to designated DHS medical providers to follow up with you regarding your medical response to the antiviral(s).

Routine Uses and Sharing: In general, the designated DHS medical provider will not use this information for any purpose other than the Principal Purposes. Generally, only de-identified, aggregate data will be shared within the Department and other agencies to track adverse effects to treatment. In addition, in certain circumstances DHS may share this information on a case-by-case basis as described in the OPMIGOVT -10 Employee Medical File System of Records Notice, (75 FR 35099), for example, to share with law enforcement officials to investigate the circumstances surrounding your potential exposure to a viral pathogen.

DHS Authority to Collect This Information: DHS requests that you voluntarily submit this information under the following authorities: Executive Order 12196; 5 U.S.C. Chapters 11, 33, and 63; 5 C.F.R. Subchapter B, Part 293, Subpart E, Employee Medical File System Records.

Effects of Not Providing Information: You may opt not to provide the requested information or to provide only some of the information the designated DHS medical provider requests. If you opt not to provide some or all of the requested information, the designated DHS medical provider may not be able to dispense the antiviral treatment to you.

Accessing and Correcting Information: If for any reason you wish to access or correct the information provided to the designated DHS medical provider, you may go to the designated DHS medical provider or your supervisor to request access. If you are unable to access the information from the designated DHS medical provider, then you may direct your request in writing to the appropriate DHS Freedom of Information Act Officer, whose contact information can be found at http://www.dhs.gov/foia under "Contacts."

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Attachment 5 – SF 558, EMERGENCY CARE AND TREATMENT FORM

NSN 7540-01-075-3796

MEDICAL RECORD	EMERGENCY CARE AND TREATMENT *(Patient)*	LOG NUMBER / TREATMENT FACILITY / RECORDS MAINTAINED AT

PATIENT'S HOME ADDRESS OR DUTY STATION

STREET ADDRESS

CITY | STATE | ZIP CODE

SEX | DUTY/LOCAL PHONE: AREA CODE | NUMBER

AGE | HOME PHONE: AREA CODE | NUMBER

ARRIVAL

DATE (Day, Month, Year) | TIME

TRANSPORTATION TO FACILITY

MILITARY STATUS

ITEM	YES	NO	N/A
PRP			
FLYING STATUS			

MEDICAL HISTORY OBTAINED FROM

THIRD PARTY INSURANCE

ITEM	YES	NO
ADDITIONAL INSURANCE		
DD 2568 IN CHART		

NAME OF INSURANCE COMPANY

CURRENT MEDICATIONS

ALLERGIES

INJURY OR OCCUPATIONAL ILLNESS

ITEM	YES	NO	WHEN (Date)
IS THIS AN INJURY?			WHERE
INJURY/SAFETY FORMS			

HOW

EMERGENCY ROOM VISIT

DATE LAST VISIT | 24 HOUR RETURN ☐ YES ☐ NO

TETANUS

DATE LAST SHOT | COMPLETED INITIAL SERIES ☐ YES ☐ NO

CHIEF COMPLAINT

CATEGORY OF TREATMENT

☐ EMERGENT
☐ URGENT
☐ NON-URGENT

TIME

INITIALS

VITAL SIGNS

TIME					
BP					
PULSE					
RESP					
TEMP					
WT					

LAB ORDERS

☐ CBC/DIFF ☐ ABG ☐ PT/PTT ☐ BHCG/URINE/BLOOD/QUANT
☐ URINE C&S ☐ UA/MSCC/CATH ☐ CHEM:
☐ BLOOD C&S X

X-RAY ORDERS

☐ CXR PA & LAT/PORTABLE ☐ C-SPINE
☐ ACUTE ABDOMEN ☐ LS SPINE
☐ SINUS ☐ HEAD CT
☐ ANKLE R/L

ORDERS

☐ PULSE OX ☐ MONITOR ☐ ECG

TIME	ORDERS	BY	COMPLETED BY	TIME	PATIENT'S RESPONSE

DISPOSITION ☐ HOME ☐ FULL DUTY

DISPOSITION QUARTERS/OFF DUTY ☐ 24 HRS ☐ 48 HRS ☐ 78 HRS

PATIENT/DISCHARGE INSTRUCTIONS

MODIFIED DUTY UNTIL

RETURN TO DUTY

CONDITION UPON RELEASE ☐ IMPROVED ☐ UNCHANGED ☐ DETERIORATED

ADMIT TO UNIT/SERVICE

TIME OF RELEASE

REFERRED ▶ TO | WHEN

I have received and understand these instructions

PATIENT'S SIGNATURE

PATIENT'S IDENTIFICATION *(For typed or written entries, give: Name – last, first, middle, ID no. (SSN or other), hospital or medical facility)*

EMERGENCY CARE AND TREATMENT *(Patient)*
Medical Record

STANDARD FORM 558 (REV. 9-99)
Prescribed by GSA/ICMR
FPMR (41 CFR) 101-11.203(a)(18)

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NSN 7540-01-075-3786

MEDICAL RECORD	EMERGENCY CARE AND TREATMENT *(Doctor)*	TIME SEEN BY PROVIDER

TEST RESULTS

CBC	WBC	SMAC		ABG/PULSE OX			RADIOLOGY	Check if read by radiologist ☐
	HCT			SUP 02	PH	P02	RESULTS	
	PLT			PCO2	SAT	OTHER		
PT				UA	DIP		EKG INTERPRETATION	
APTT		BHCG	ETOH	GLU	MICRO			

PROVIDER HISTORY/PHYSICAL

CONSULT WITH	TIME	ACTION

RESIDENT/MEDICAL STUDENT SIGNATURE AND STAMP

PROVIDER SIGNATURE AND STAMP

DIAGNOSIS

CODES

PATIENT'S CERTIFICATION *(For typed or written entries, give: Name – last, first, middle, ID no. (SSN or other); hospital or medical facility)*

EMERGENCY CARE AND TREATMENT *(Doctor)*
Medical Record
STANDARD FORM 558 (REV. 9/95)
Prescribed by GSA/ICMR
FPMR (41 CFR) 101-11.203-b (10)

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Homeland Security

June 20, 2014

U.S. Department of Homeland Security
Office of Health Affairs
Washington, DC 20528

STANDARD OPERATING PROCEDURE FOR STORAGE OF MEDICAL COUNTERMEASURES

PURPOSE

This Department of Homeland Security (DHS) Standard Operating Procedure (SOP) sets forth the requirements for DHS Component medical countermeasures (MCM) storage, tracking, and receiving capabilities.

SCOPE

This SOP is directed to DHS Components responsible for storing and maintaining MCM in centralized, regional and/or local stockpiles/caches, to ensure rapid access for dispensing to Component personnel regardless of geographic location-including DHS personnel in remote or austere locations.

This SOP does not apply to storing and maintaining MCM by, for, or on behalf of the United States Coast Guard (USCG) that are in alignment and compliant with Department of Defense and USCG Commandant Directives and Instructions related to the provision of health services.

I. STORAGE REQUIREMENTS

General Storage and Security Requirements

The following minimum general requirements for the storage and handling of prescription drugs are the responsibility of the DHS Component agency accepting Medical Countermeasures:

- Locations at which prescription drugs are stored, warehoused, and handled, shall be of suitable size and construction to provide necessary space, lighting, temperature, humidity, and security conditions.
- Storage areas shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds, or vermin.
- There shall be a designated quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, or adulterated.

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- The number of personnel with access from outside the storage area shall be kept to a minimum however, redundancy of personnel with authorized access should be provided.
- Storage areas shall be secured in a manner that will provide protection against theft and diversion. All prescription drugs should be secured and maintained behind locked doors or cabinets.
- All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements on the label of the drug, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

Specific MCM Storage Requirements

Doxycycline - IOOmg Tablets or Capsules (Total 10-day supply)

Doxycycline tablets or capsules shall be kept in a light-resistant, tightly closed container. Store at a controlled room temperature (ideally 68°F to 77°F or 20°C to 25°C, but no lower than 59°F or 15°C and no higher than 86°F or 30°C[?]), away from excess heat and moisture per manufacturer's labeling.

Ciprofloxacin - 500mg Tablets or Capsules (Total 10-day supply)

Ciprofloxacin capsules shall be kept in a light-resistant, tightly closed container. Store at a controlled room temperature (68°F to 77°F or 20°C to 25°C, but no lower than 59°F or 15°C and no higher than 86°F or 30°C[?]), away from excess heat and moisture per manufacturer's labeling.

TAMIFLU (Oseltamivir) - 75-mg Oral Capsule, Oral Suspension (6 mg/mL)

TAMIFLU (Oseltamivir) shall be kept in a light-resistant, tightly closed container. Store at a controlled room temperature (68°F to 77°F or 20°C to 25°C, but no lower than 59°F or 15°C and no higher than 86°F or 30°C[?]), away from excess heat and moisture per manufacturer's labeling. All personnel should be mindful that this is a limited resource, and if used prematurely, may not be available when needed later.

RELENZA (Zanamivir) - 5-mg blister of powder for oral inhalation (via provided DISKHALER)

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* http://www.usp797.org/QA-E9.htm

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RELENZA (Zanamivir) shall be stored in a secure, humidity and temperature controlled environment (56° to 86° F) according to manufacturer's guidance. All personnel should be mindful that this is a limited resource, and if used prematurely, may not be available when needed later.

Potassium Iodide- Store potassium iodide at 77°F (25°C); brief storage at temperatures between 59°F and 86°F (15°C and 30°C) is permitted. Store away from heat, moisture, and light and do not store in the bathroom. Keep potassium iodide solution out of the reach of children and away from pets.

II. LOGISTICS

The DHS Office of Health Affairs (OHA) working in conjunction with each Component will be responsible for determining the quantity of MCM to be stored at each Component MCM cache location.

- MCM will be delivered by commercial carrier to Component locations identified by Component to OHA;
- MCM bottles of 20 pills occupy a volume of approximately 8000 bottles per standard wooden pallet, measuring estimated 40 x 48 inches, not to exceed 52 inches high;
- Each case will hold 100 bottles, each pallet will hold up to 80 cases;
- The total weight for a shipment will not exceed 1200 lbs per fully loaded pallet.

III. TRACKING

For the purposes of this SOP, each DHS Component plan shall ensure the following:

- Maintain inventory records of MCM cache using MCM Quarterly Reporting Template to the OHA Medical Countermeasures Program Manager;
- Verify quantity (# of courses) of MCM stored at facility;
- Confirm expiration date (or dates) for MCM;
- Determine MCM lot number;
- Describe how MCM is stored at each Component facility;
- Maintain MCM in a secured location;
- Verify warehouse owned and operated by Component is accessible 24/7;

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- Identify senior personnel and personnel responsible for 24/7 access at each Component facility

VI. MEDICAL OVERSIGHT

The Office of Health Affairs, Division of Workforce Health & Medical Support will provide principal medical oversight of the MCM program for DHS components. The point of contact for this SOP is the Workforce Health and Medical Support (WHMS) Division MCM Program Manager in the Office of Health Affairs (b)(6); (b)(7)(C)

APPROVED BY:

(b)(6); (b)(7)(C)

Date July 7, 2014

Acting Assistant Secretary for Health Affairs and
Chief Medical Officer

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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

SECTION 1

Applying the Hierarchy of Controls

When planning pandemic and infectious disease workplace readiness and response, workplace controls are defined as processes, procedures, and equipment that are used to reduce/eliminate health hazards/risks to ICE employees. Typically, workplace controls are derived from risk assessments of their duties, work tasks, and the potential hazards/risks. Workplace controls for health hazards/risks will often differ from standard controls for "ordinary" work hazards because the risk of contracting a pandemic type disease is often increased by activities that normally do not usually pose much risk in the workplace.

Hierarchy of Controls. The Occupational Safety and Health Administration (OSHA) regulations and guidance require the use of a "hierarchy of controls" to reduce or eliminate workplace hazards. In controlling the potential hazards during an infectious disease/pandemic event, this hierarchy approach prioritizes controls based on the concept that the best way to control a hazard is to remove it from the workplace, and not rely on employees to take an action to reduce exposure.

The "Hierarchy of Controls" are as follows:

1. Work Practices and Environmental Controls are designed to reduce/eliminate the duration, frequency, or exposure of a recognized workplace hazard/risk(s).

2. Administrative Controls are designed to reduce the hazards/risks by scheduling work tasks in ways that minimize employee exposure to a recognized workplace hazard/risk.

3. Personal Protective Equipment (PPE) is designed to provide an immediate barrier between the employee and a recognized workplace hazard. PPE is normally used in conjunction with Administrative Controls, training, and work practices developed as an effective means in minimizing exposure to infectious diseases and a pandemic event.

During an infectious disease/pandemic event, this hierarchy should be used in concert with OSHA guidance and public health recommendations. As mentioned above, most workplaces within ICE will use a combination of hierarchy control methods. There are advantages and disadvantages to each control measure based on ease of implementation, effectiveness, and cost. For example, hygiene measures and social distancing can be implemented easily and with little expense, but this control method requires employees to modify and maintain their behavior during a stressful situation. On the other hand, installing clear plastic barriers will be more expensive and take longer to implement, but does not require the worker to remember a new procedure and ultimately may be more effective and available for future events.

Applying the Hierarchy Controls in ICE Workplaces. The hierarchy of controls must be included as part of the safety and health risk management planning for pandemic and infectious diseases events. Workplace Practice and Engineering Controls, along with Administrative Control options must be examined for each response phase so that any required items can be can be procured, installed, or implemented in advance. For some ICE facilities/operations and the

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associated work tasks, PPE has been determined to be the only option. However, before PPE is determined to be the only feasible answer, managers/supervisors should be examined ways to reduce exposures to ICE employees and the workplace and still continue to fulfill their missions. The following examples include controls applicable to ICE workplaces.

Work Practice and Environmental Controls. Work practices and engineering controls are often in the hands of local ICE managers, supervisors with consultations from facilities/safety personnel. New technologies that reduce exposure from unavoidable person-to-person contact can also be included in this category. Examples include:

a. Work Practice - Hygiene and Personal Contacts:
   1) Providing resources that promote personal hygiene. For example, provide tissues, hand soap, and hand sanitizer.
   2) Training employees on risk factors and proper behaviors (e.g., cough etiquette and disinfection of shared equipment).
   3) Developing policies and procedures to minimize contacts between employees and between employees and the public.
   4) Conducting interactions at distances of 6 feet or other disease- specific recommendations. In some locations markings can be placed on the floor to indicated 6 feet.
   5) Using the largest available room when conducting long interviews or one-to-one meetings.
   6) If someone in ICE custody or visiting an ICE workplace is displaying symptoms, give them a "procedure mask" to wear and if possible isolate them. If available, consider using a cell designed for potentially ill detainees.
   7) For pandemic influenza, getting a seasonal influenza vaccine. The vaccines can prevent multiple infections (i.e., a pandemic and seasonal strain) and may reduce the severity of a pandemic strain.

b. Environmental Control – Building Ventilation:
   1) Increasing the percentage of fresh air brought into the building by the ventilation system. Increasing fresh air dilutes the hazard. Note that **fresh** air must be supplied; simply increasing the flow of air in the space does not provide the same benefits and may increase risk. Ventilation changes should be discussed with facilities personnel.
   2) Evaluating the ventilation in offices; air moves from supply vents toward returns. If possible, re- position ICE employees closer to the supply vent. If ICE employees conduct interviews with the public, make sure the interviewee is closer to the return vent so the clean air flow moves across the breathing zone of the ICE employee and toward the potentially infectious person.
   3) If ICE employee use a personal fan, make sure it is not blowing air from a potentially contaminated source into their face, e.g., from a detainee or symptomatic person on to them. Fans can also produce disturbance and mixing that can spread germs and disrupt air flow supplied by building systems. During an infectious disease outbreak, it may be best to turn off fans.
   4) Use rooms with the best ventilation supply for meetings or interviews.

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c. Work Practice - Disinfection:
   1) Providing disinfectants for ICE employees to clean their own work surfaces and shared services (copiers, door handles, break rooms). Disinfectants should be EPA listed and that list is available at: www.epa.gov/oppad001/chemregindex.htm . All disinfectants should be used following product directions. Aerosol or spray products can be flammable, so should never be sprayed around flames, heating elements, or electronic equipment. Many sprays cans also damage electronics. Surface disinfectants should not be used on people. Some are very harsh and can seriously damage the skin, respiratory system or eyes.
   2) Working with ICE facility building managers or GSA (if at a GSA leased facility) to conduct additional or special disinfecting cleaning. Janitorial staff can be asked to wipe down surfaces and doors several times per day. This will require additional funding, but allows a potentially severely reduced ICE workforce to concentrate on their work rather than cleaning.

d. Environmental Control - Physical Barriers:
   1) If the task permits, installing physical barriers, such as acrylic plastic barriers between employees and the public.
   2) Isolate symptomatic visitors or detainees by placing them in a separate, closed room.

Administrative Controls. Many administrative controls are related to human capital and guidance is directed by the Office of Personnel Management (OPM). The DHS Office of the Chief Human Capital Officer (OCHCO) develops DHS policies and has information for employees and supervisors available on their Connect intranet pages:

(b)(7)(E)

Many Component human capital offices have additional, Component-specific information also derived from OPM guidance. Examples include:

- Utilizing policies that encourage ill employees to stay at home without fear of any reprisals.
- Encouraging approval of telework for all employees who can perform their function at home or an alternate location.
- Utilizing policies that allow employees who do not serve a critical function to stay at home, similar in concept to a bad weather day.
- Providing supervisors with guidance on asking a symptomatic employee to either go home, or stay at home.
- Restricting face-to-face meetings to only the most critical meetings.
- Staggering work hours or implementing shift plans to reduce the number of individuals in an office at one time.
- Reducing the number of facilities in use. If the workforce is greatly reduced, the remaining critical workers can work from a single location. The location would be selected on the basis of the ventilation system, workspace design, room size, or parking

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facilities that allow employees to avoid public transportation (which may be shut down during a serious infectious disease event).
- Discontinuing unessential travel to locations with high illness transmission rates.
- Developing emergency communications plans that will provide employees with timely and accurate information about their workplace and their risks.
- Developing a method for employees to ask questions and express concerns, ensuring they are provided with accurate answers.

Personal Protective Equipment (PPE). While administrative and engineering controls and proper work practices are considered to be more effective in minimizing exposure to diseases, the use of PPE may still be indicated during certain exposures.

- Selecting PPE based on risk assessment and the hazard to the employee;
- Properly fitting and for respirators, periodically refitting;
- Wearing PPE correctly, following directions and understanding the limits of protection offered by various types of PPE;
- Inspecting regularly and maintain and replace, as necessary;
- Properly removed and disposed of to avoid contamination of self, others or work surfaces.
- The types of PPE recommended for infectious disease events will be based on the mode of transmission (droplet, direct contact, insect bite) and the risk of contracting the disease while working.

NOTE: PPE use may be mandatory or voluntary. When a regulation, hazard level, or an employer requires PPE to perform a task, use is mandatory. If there is no regulation and the hazard level is below OSHA levels for PPE use and the employer does not require PPE be worn, use is voluntary. Voluntary use includes both employer and employee-supplied PPE. If PPE is used voluntarily, the employer must determine that the PPE does not introduce a hazard into the workplace.

Controlling the Spread of Vectorborne Diseases. Many infectious diseases are not spread directly by human-to-human contact, but pass through other animals or plants. These are vectorborne diseases. A vector is an intermediate host where the disease microbe lives and multiples before being passed to human hosts. The most common vectors are insects (e.g., mosquitoes, fleas), arachnids (e.g. spiders, ticks and mites), or rodents (mice, rats). To reduce the hazard of these diseases, you must control the vectors. Malaria is the best known vector disease and is transmitted from person to person by mosquitoes. Dengue Fever is a potentially serious or fatal disease that is also carried by mosquitoes (*In the past, FEMA staff became infected with Dengue infections during disaster responses in the Caribbean and this disease can also be found along the Gulf of Mexico including Florida).* A variety of diseases are carried between horses, mosquitoes and humans, notably equine encephalitis in the south and southeast U.S., and ticks transmit a variety of diseases between mammals and humans (e.g., Rocky Mountain Spotted Fever, Lyme Disease).

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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

Recommended Controls:

- Ensure screens, windows and doors prevent insect entry.
- Eliminate standing water near workplaces or employee housing.
- Keep workplaces free of debris and clutter. Make sure there is no open food, and that food is stored in hard containers (not just plastic bags). This will eliminate places for mice to live and breed.
- Coordinate with the ICE facilities manager to utilize safe and effective pest management strategies. Many pesticides are poisons and should only be handled and used by trained professionals.

Bonus Controls:

Some work methods were never intended to reduce workplace hazards, but still reduce the overall risk to employees. When possible, these should be promoted and optimized. Examples include the following:

- The Global Entry project was designed to assist trusted travelers. This automated passport examination does not directly involve a DHS employee. Use of this system virtually eliminates passport control contacts, thus reducing the contacts experienced by DHS employees. Promotion of this program and increased use would produce a corresponding reduction in DHS employee exposure.



- Many airports have systems that allow the traveler to place their luggage on a belt that moves it past the inspector. These systems were originally designed to prevent lifting injuries, but have the bonus of allowing the traveler to be further from the inspector when they ready their bags for inspection.



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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

Hierarchy of Controls Examples:

1. Your DHS office is located in downtown Washington DC in an older building that houses 250 employees proving mission support. The majority of employees commute via public transportation. Employees have relatively few meetings with the public and these are restricted to meetings with contractors.

A human to human infectious disease is moving into the area that could impact 30% or more of the employees. What actions and controls should management consider BEFORE PPE use?

a) Allow any employees who can telework, to telework.
b) If workloads permit, consider the use of leave.
c) Based on mission, workloads, and telework, determine how many employees must come to your work location.
d) Advise employees who must work in their normal workplace or office, that they should limit their in-person meetings and rely on teleconferences instead.
e) Work with facility and building managers to determine the ventilation control capabilities of your building to see if fresh air circulation can be increased. In this example, you find the system is not adjustable.
f) Look for possible alternative work locations already used by DHS. You find a nearby building with a computer-controlled ventilation system that can provide a variety of fresh air amounts, including full fresh air with no recirculation. The building also has underground parking and you are told that due to teleworking only 10% of the building's normal occupants (DHS employees) will be coming to work. If your personnel are moved to the building, the space will be only 30% occupied and employees will have full access to the DHS network.

Comment: You have several opportunities to reduce risk by reducing the number of people and their office contacts, via the use of teleconferences and telework. You can even consider the feasibility of moving critical employees to a building with better ventilation and the potential to avoid public transportation.

2. Your DHS office conducts interviews with members of the public. Some interviews are conducted in small private offices and others in cubicles. These interviews are critical, cannot be postponed, and cannot be conducted over the phone.

An infectious disease is moving into the area, but your workforce must still conduct interviews. What actions and controls should management consider BEFORE PPE use?

a) Allow any employees who can telework, to telework.
b) If workloads permit, consider the use of leave.
c) Based on mission, workloads, and telework, determine how many employees must come to your work location.
d) Look at the cubicle space. Is there a way to use more cubicles for private interviews, instead of closed small offices? You find that with a reduced workforce, there are several cubicle areas that offer privacy and can be used for interviews.

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e) Can interviews be conducted for more hours per day and your workforce staggered to cover the extra hours? You find you can conduct interviews one hour earlier in the morning and two hours in the afternoon and your employees are willing to shift arrival and departure times.
f) Are some offices larger than others? Can people with larger offices temporarily switch with individuals who conduct interviews? You identify managers' offices and conference rooms that can be temporarily used for interviews.
g) Look at the ventilation supply and returns in private offices. (Safety Officers and facilities managers can assist you.) Do they all have a fresh air supply? If an office doesn't have a supply, don't use it for interviews or meetings. If there is a supply, place the DHS employee closest to it so fresh air will be blowing over them. You find several small offices with no supply. You mark them as unusable for interviews. Offices with supply air are slightly rearranged so that the DHS employee is closest to the supply.
h) You contact the building owner and determine that under the janitorial contract, your space can be wiped down with disinfectants once per day.
i) The building owner also informs you that the fresh air percentage can be increased and you request that he bring in as much fresh air as the system can supply.
j) You provide employees with disinfectant wipes, sprays and cleaners and encourage them to wipe down their areas frequently and between interviewees.

Comment: You continued your mission and reduced risk by managing space utilization, using workforce flexibilities and effective use of the existing ventilation system.

3. Your workforce encounters the public every day, speaking with many people and examining their documents. This activity must continue even though an infectious disease epidemic is moving into the area.

In this situation, some PPE will be necessary because of the exchange of documents that cannot be avoided. Employees should wear non-latex gloves (preferably nitrile). What other, non-PPE actions should be taken?

a) You look at the document examination process. You determine that if both individuals stretch their arms to hand over documents the recommend 6 foot of distance can be maintained for the majority of exchanges. You mark the inspection area floor with lines indicating 6 feet and ask the individual and your employee to both stand behind their line.
b) You may be able to install barriers such as sheets of acrylic material for your employees to stand behind. This prevents direct contacts.
c) You provide hand sanitizer directly in the document inspection area.
d) You supply procedure masks that can be issued to individuals displaying symptoms or to individuals that require closer or extended contact.

Comment: You continued the mission by reducing the hazard of multiple personal contacts and supply ways to continue proper hygiene, even while the employee maintains their station and continues to work.

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4. Your workforce is responding to a disaster in Florida. You find out that due to increased standing water, Dengue Fever is on the rise. Your work most continue and many of your employees must be outside. Since Dengue is carried by mosquitoes, you know you must avoid the insects and prevent bites.

   a) You contact your Safety Officer for more information and find that the mosquito that carries Dengue bites in the day and is most active in early morning and near sunset.
   b) The Safety Officer also provides you with literature to distribute to your employees that explain the disease and how infection can be prevented.
   c) You contact the Office of Health Affairs (OHA) and find they have produced a series of alerts regarding Dengue. You verify your employees are receiving them. You also work with OHA to make sure your employees understand the symptoms and know where to go for medical assistance.
   d) You discuss the Dengue issue during a staff meeting and provide employees with additional information and resources. You also establish procedures to keep them informed of any new information.
   e) You work with supervisors to minimize the time your employees are outside when the mosquitoes are most active.
   f) DEET repellent is effective for mosquitoes and you establish a method of making it available to employees.
   g) You brief employees that wearing long sleeves and pants can help.
   h) You find out that if someone has had Dengue before. A second infection is much worse than the first and can even be fatal. You coordinate with your local human resources representative to develop flexibilities for any employee who has already had Dengue.

Comment: You continued your mission, but reduced the risk by limiting the chance of mosquito bites and ensuring employees are fully informed and understand what they must do to protect themselves. You have also worked to address the needs of those who may be at greater risk.

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SECTION 2

Pandemic and Emerging Infectious Diseases Occupational Safety and Health Risk Assessment Guidance for the Workplace

Protecting the health of the DHS workforce during a Pandemic, infectious disease, or biological incident is essential to ensure the DHS mission. This process begins with risk assessment followed by use of appropriate workplace and medical controls.

This document provides DHS components with guidance and methodology to perform risk assessments and meet other requirements, including mandatory reporting procedures, found in the DHS Pandemic and Emerging Infectious Disease Workforce Protection Plan (PEIDWPP). Specific procedures and requirements are updated in this revised document to address findings by the DHS Office of the Inspector general audits from 2013-2015 of DHS Pandemic readiness and the DHS Ebola response.

A major procedural change developed in response to the audit findings is that the PEIDWPP requires each component to develop their own PEIDWPP following guidance provided in the departmental plan. This guidance also requires each component to conduct risk assessments for all their employees, and that they will submit these risk assessments to DHS Office of Safety and Health (DHS OSH) for review and approval. This applies both to "preparedness risk assessments" as well as those conducted in response to an actual threat.

The risk assessment method described was developed by the Occupational Safety and Health Administration (OSHA) in coordination with the Centers for Disease Control (CDC), National Institute of Occupational Safety and Health (CDC-NIOSH) and is based on the established hazard control principle of control banding.

Components may use this method or another comparable one to assess risk to their workforce; however, for reporting purposes, components must use workplace control levels that parallel those provided by DHS OSH and report their risk assessment and control measures to DHS OSH in the format provided in this guidance. This assures consistency in response, a clear understanding of component protective actions, and assures PPE acquisition is in accordance with the component risk assessment and Office of the Chief Readiness Officer (OCRSO) Logistics guidance.

Components should direct any questions concerning this guidance to the DHS OSH.

Risk Assessment Process

Risk assessment is the tool used by component OSH and medical professionals who develop health risk assessments to evaluate the degree of threat to employees based on various factors. Once the threat is established, they assign each specific position to a protection-level group; when using the method described here the levels are termed "control bands". OSH professionals use control bands to determine the level of protection as provided by workplace controls – to include Personal Protective Equipment (PPE). Representative operational managers will assist by establishing duty/ task- related risk ratings and appropriate control options and responses.

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Operational managers provide the in-depth knowledge of the duties, tasks and methods that personnel perform.

The designation to a band is based on the employee's potential for exposure - as posed by their work task(s) - during the PEID event. Each band includes the appropriate controls and PPE that the employee needs to reduce the risk posed by the specific PEID event. An employee may be designated at different bands on different shifts or even within one shift depending on the tasks they perform. The controls associated with a band will change based on a change in the risk associated with the specific event. Different diseases or events will have different risk factors (e.g. a more transmissible disease has a higher risk for tasks involving human contact) causing the controls associated with each band to change. DHS OSH, in coordination with the OHA will provide specific risk and control band guidance for component use in each PEID incident.

Preparedness Risk Assessment and Employee Protection Report Preparation and Submittal

The DHS PEIDP requires each component to develop a preparedness risk assessment. This process uses a likely disease scenario to identify typical component control measures for influenza and similar diseases, guide procurement of any on-hand PEID PPE stocks, and provide a baseline from which to adjust control measures for other diseases. Components will conduct and document preparedness risk assessments for each position or activity performed by their workforce. The assessment will be based on a disease with a Risk Factor of R-2 (see figure 3), using the attached methods and criteria or a comparable system as part of their PEIDP development. A typical R-2 event is a moderately severe pandemic Influenza or viruses with similar characteristics of human-to-human (HTH) transmission and represents the most likely recurring risk to the DHS workforce. As required by the PEIDWPP, components will submit completed assessments DHS OHS for review with their initial plan and re-evaluate and resubmit it every 2 years.

After DHS OSH and the component agree on the acceptability of a risk assessment, the component will develop an Employee Protection Report (as described in this document) showing estimated numbers of employees in each band and their PEID PPE usage rates per day. DHS OSH and the OCRSO Logistics branch will use these reports to compare to the PPE Acquisition Report (See Annex E of the PEIDWPP) in order to conduct oversight of PEID PPE acquisition and use and report issues such as burn rate and PPE availability to senior management

Pandemic and Infectious Disease Risk Assessment and Coordination Process

During a response, the risk levels/control bands determine who will need and use PPE. PPE use can be mandatory or voluntary based on control band. For facilities, or types of facilities/ operations where more than one DHS Component work (such as airports), working groups comprised of members from each of the components' OSH, medical and operational personnel will be formed to coordinate the DHS response. These groups will work to ensure workforce control band consistency for similar tasks/ positions and maintain inter-component communications for risk assessments, coordination and response. These groups shall form after the individual components make baseline determinations and they will meet to review and revise their plans periodically or as needed for new/different diseases.

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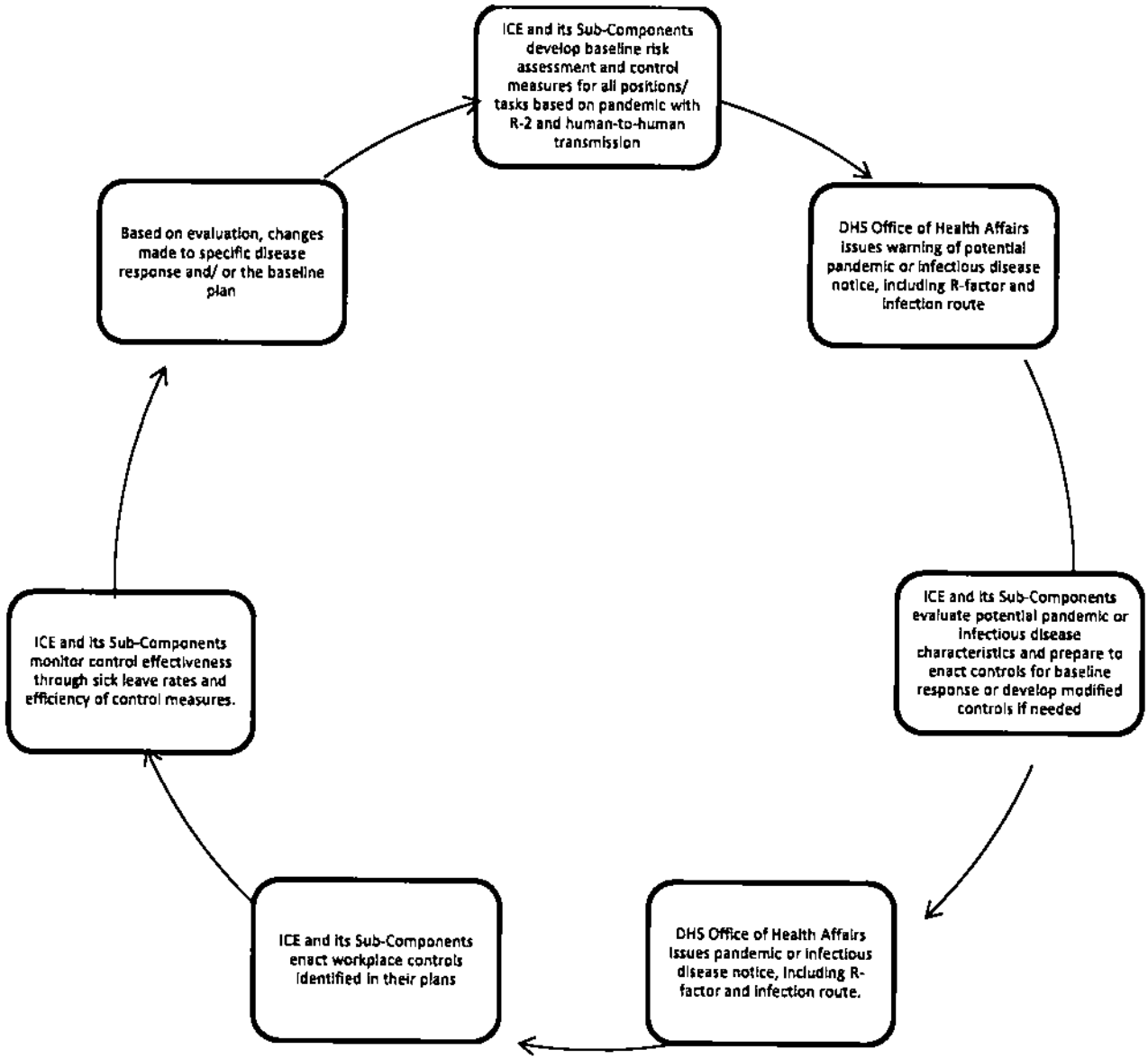
ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

Pandemic and Infectious Disease Risk Assessment and Coordination Process



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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

Basis for Disease Risk Assessment and Control Band Selection

Exposure to a biological agent risk is a function of:

Risk = f [Transmissibility & Virulence, Exposure Time, Exposure Probability, Exposure Intensity]

Transmissibility is a measure of how easily the infection passes from one person to the next, and is often measured in terms of the basic reproduction number, R0. transmissibility varies according to route of transmission, with different pathogens preferentially transmitting disease via different routes, e.g., respirable aerosol, droplet spray, indirect or direct contact (Nicas 2009). For some infectious agents direct contact must be made with an infected surface (fomite transmission) or with discharged matter (e.g., mucous or saliva) from the infected person. Some diseases may be transmitted only over short distances by aerosol and therefore one must be proximate to the infected person, who creates aerosols by sneezing, coughing, talking, etc. (short distances are usually taken as within about 6 feet). Other infectious agents may be airborne transmissible over long distances by small particles.

While diseases are often thought to be transmitted primarily by one route, it is possible for diseases to be transmitted via multiple routes (e.g., even if a disease is thought to be primarily spread via droplet transmission, airborne transmission may also be a route of concern). Transmissibility is also affected by environmental conditions such as temperature, humidity and exposure to UV radiation.

Virulence is related to the probability that once infected a person will suffer serious disease or death/. This is measured by clinical severity parameters including case fatality ratio, case hospitalizations ratio, and/or hospital death ratio.

Exposure time is a combination of the frequency, or number of contacts that a person has with the agent source such as an infected individual or the public and the duration of each contact with the potential for exposure. Duration is estimated or measured by analyzing the task or job functions. Frequency is estimated by considering total number of contacts a worker has in an average day and then reducing the total number of contacts by the probability that a contact could result in an exposure (i.e., the *exposure probability*).

Exposure probability is a measure related to the *prevalence* of disease in the population and the exposure setting. For a given community or locale the prevalence (percent of the population who are actively infected) will vary as the epidemic wave crests in the community increasing the chance for contact with an infected individual compared to national and/or seasonal average prevalence rates. A higher exposure probability exists for certain exposure settings, such as hospitals, clinics, and pharmacies where ill individuals will preferentially congregate as they seek treatment for their symptoms. In these settings the chance for contact with an infected individual will be greater than the general population exposure probability. The highest exposure probability occurs in emergency departments and other emergency management and urgent care settings, patient rooms, hospital wards, and clinics where highly probable and diagnosis-confirmed cases are received, transported, housed, and treated. Pre-diagnosis confirmation, symptomatic persons are sometimes described as having, "influenza like illness (ILI)." These

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situations represent *exposure certainty* for the workers who are providing care or otherwise working with these patients.

Exposure intensity is a measure of infectious dose that the person receives during the contact with an infected individual. Several factors affect intensity including the primary transmission mode of the infectious agent, the employee's proximity to the infected individual, and the condition of the infected individual. For example, intensity will be high if primary transmission mode is airborne, the contact(s) are coughing, sneezing, and otherwise emitting biologically active particles, and the worker is close to the contact without the presence of local ventilation controls or respiratory protection.

Risk Analysis: Risk Assessment and Risk Management

Most of the key factors listed previously will be difficult to establish precisely, so broad groups of controls, grouped into "bands," based on relative assumed risk or probability must be applied. During a disease event (pandemic, epidemic or local outbreak), the health of the workforce must be monitored regularly by OSH and medical management to identify changes in risk and judge the effectiveness of controls.

Control Banding Approach

Control banding is a system for organizing disease and task information that provides decision logic for identifying relative risk to employees and the selection of appropriate control measures. Control banding is the commonly used method when no quantitative exposure limits exist.

This control banding approach was proposed for pandemic influenza by the (OSHA and the Department of Health and Human Services (HHS) in their "Guidance on Preparing Workplaces for an Influenza Pandemic" (OSHA 2007). In this example, words designate and describe the bands. Letters or numbers are also used. The DHS process uses letters A-E, with A representing the least hazardous situation and E the most hazardous.

The control bands from OSHA Pandemic Influenza guidance are shown in the four-level "risk pyramid" in Figure 1.

Figure 1: Occupational Risk Pyramid for Pandemic Influenza



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Very High Exposure Risk:

- Healthcare employees (for example, doctors, nurses, medics) performing aerosol-generating procedures on known or suspected pandemic patients (for example, cough induction procedures, bronchoscopies, or invasive specimen collection).
- Healthcare or laboratory personnel collecting or handling specimens from known or suspected pandemic patients (for example, manipulating cultures from known or suspected pandemic influenza patients).

High Exposure Risk:

- Healthcare delivery and support staff exposed to known or suspected pandemic patients (for example, doctors, nurses, and other hospital staff that must enter patients' rooms).
- Medical transport of known or suspected pandemic patients in enclosed vehicles (for example, emergency medical technicians).
- Performing autopsies on known or suspected pandemic patients (for example, morgue and mortuary employees).

Medium Exposure Risk:

- Employees with high-frequency contact with the general population (such as schools, high population density work environments, and some high volume retail).

Lower Exposure Risk (Caution):

- Employees who have minimal occupational contact with the general public and other coworkers (for example, office employees).

The bands of risk in the Risk Pyramid are based on the risk factors in the risk equation, (e.g., transmissibility, virulence, frequency, duration and exposure intensity) and broadly classify jobs or tasks. The following should be used by component OSH, medical and Operations personnel in a job-hazard analysis so that the control banding approach can be applied to specific jobs and tasks if they do not easily fall into the OSHA pandemic influenza risk band definitions – or if a disease is identified by DHS OSH and OHA as having different or greater risk factors than Pandemic Influenza (for instance, if a disease is more lethal, or is transmitted by vectors such as insects).

DHS Control Band Procedure

In order to develop the most detailed analysis or for non-influenza diseases, component OSH, medical and Operations personnel should assess the risk factors separately and combine them in a risk characterization to identify the appropriate control band. Regardless of whether this separate approach is used or a single evaluation is done, selection of the level for each of the risk components may be done numerically if data are provided, or it may be done by comparing the current situation or job being assessed to established descriptions of the risk factor.

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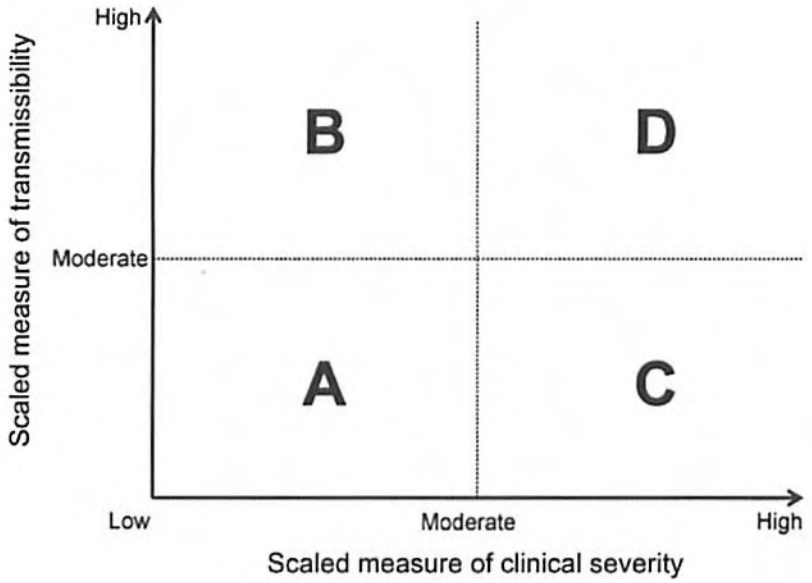
These descriptions and techniques are described below.

Risk Phrases (R)

OHA, in coordination with component medical personnel, will publish the Risk Phrase for each identified pandemic and emerging infectious disease or PEID event. Risk Phrases are based on the transmissibility and severity of the disease using information from Health and Human Services and the Centers for Disease control (HHS/CDC). In the case of infectious agents such as pandemic influenza, Figure 2 (Reed 2013) shows a method for creating *R-phrases* for an initial assessment and subsequent refined assessment of an emerging pandemic. For comparison purposes, the 2009 H1N1 virus was considered an R-2. Appendix 1 includes tables useful for categorizing R-phrases based on data.

Figure 2: Severity and Transmissibility Matrix



R-1 (Quadrant A) = Low transmissibility (infectivity) and low clinical severity (virulence) at the level of routine seasonal influenza;

R-2 (Quadrant B) = Moderate transmissibility and low-moderate clinical severity; similar to the pandemics occurring in 1957 and 1968;

R-3 (Quadrant C) = Low transmissibility but high clinical severity; like avian influenza;

R-4 (Quadrant D) = High transmissibility and high clinical severity; like the 1918 influenza pandemic.

Figure 3: R-Factor Classification Scale

R-1	R-2	R-3	R-4
Least Hazardous			Most Hazardous

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Exposure Time (T)

The longer workers are exposed to source of infection (infected individuals, insect vectors, contaminated air, etc.) the more likely it is that the workers will acquire the infection, other factors being equal. Exposure time is a combination of frequency of exposure and duration of exposure. Both of these time-related variables may be controllable by administrative changes. For example by setting and enforcing minimum contact procedures for employees who may contact infected or potentially infected persons, one can limit the number of persons who have any contact with confirmed or probable infectious people. In this case, the risk is assigned to a decreased number of specialized employees who are better protected by increased controls, including PPE and training. Alternatively, contact tasks could be re-designed or planned to minimize the amount of time the employee is in close proximity to the potentially infected person.

The following table could be used to classify frequency of exposure for a particular job by group:

Figure 4: Exposure Time Matrix

	Frequency (infectious contacts per day)		
Duration of individual interactions within close distance	< 3	3-6	> 6
<5 min	T-1	T-2	T-2
5-30 min	T-2	T-3	T-3
>30 min	T-3	T-4	T-4

The variables can be described qualitatively as the time variable T:

T-1 = Occupational situations with *infrequent* and *very brief* durations

T-2 = Occupational situations with *regular* contacts for *brief* durations

T-3 = Occupational situations with *frequent* contacts *short* durations

T-4 = Occupational situations with *frequent* and regular contact for *extended* duration

The assessment from using this table will depend in part on surveillance data collected by the CDC to determine the public prevalence of the disease to determine the likelihood of encountering infected individuals (Hearl 2009). There is also a cross-relationship with the nature of the disease (R-phrase) that must be considered, and the exposure probability. For example, if the number of different people that a worker encounters in a day can be estimated, and the prevalence of the disease (percent of population infected) is known, the number of potentially infected contacts per day can be computed.

If the disease is R-1 or R-3 (low transmissibility) there will be few infected persons in the general public. Therefore the number of expected contacts by the nonworking public, office workers, and factory workers with a confirmed or probable infected patient is low.

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For an R-3 or R-4 disease (high severity), hospital and clinic workers would be expected to have more frequent contacts because the high severity of disease would increase the number of confirmed or probable infectious patients coming to hospitals and clinics seeking treatment or to pharmacies for prescription and OTC drugs; though the number and chance of contacting infected individuals may remain low for the general public for an R-3 (low transmissible) disease.

For an R-2 or R-4 disease (high transmissibility) occupations that required a high degree of public contact would be expected to have frequent contacts with infected persons, however if the disease is R-4 (severe) those contacts would be expected to be of short duration except for those providing health care.

This type of analysis can assist planners to categorize the overall risk into an appropriate health band. The analysis also suggests administrative strategies to minimize time and duration of potential exposure.

Determining Frequency:

For a particular job, the risk assessor may estimate with some degree of accuracy the number of different persons that the worker will contact each day in the course of the job. For example, if it takes 10-minutes for a hotel receptionist to check-in a guest, that worker would encounter 6 customers per hour and 48 customers per day. If an airport security screener, e.g. CBP, or TSA, spends 2 minutes with each traveler, over an 8-hour shift the screener would encounter 240 travelers per day.

Not all persons contacted will be infectious. When contacting the public during a non-epidemic period, it would generally be considered "unlikely" that a contact will be infectious. During a severe outbreak, persons contacting the general public would normally move into the "possible" exposure range. Workers who are employed in pharmacies, clinics, or hospitals where symptomatic persons may preferentially congregate to seek treatment or remedies would have "probable" exposure to infected persons. Others who provide treatment directly to symptomatic persons have "likely" exposure; though not all symptomatic patients will ultimately have the disease in question. Exposure to a diagnosis-confirmed case are 100% certain to be an exposure contact. The scale in Figure 5 can be used to determine the number of contacts that a person might have with a truly infected and infectious individual. Alternate percentages from those shown in Figure 5 may be used by the risk assessor if specific disease prevalence data are available or otherwise, based on professional judgment by safety, health, and medical personnel.

Figure 5: Exposure Probability Scale

Unlikely	Possible	Probable	Likely
0.1%	1%	5%	50%

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Exposure Intensity (I)

Based on the nature of a person's job, or tasks performed, the risk assessor should categorize the intensity of exposure. The *most intense* exposures would likely occur for workers who are involved in aerosol-generating procedures for direct patient care such as performing bronchoscopies. *High intensity* exposures would occur for physicians and nurses and other clinical personnel involved in direct patient care for individuals who have or are suspected of having active disease. These individuals would likely have exposures within 6 feet or less of the potentially infected patient. *Medium intensity* exposures would occur for teachers, retail workers, and workers at ports of entry. Another medium-low intensity exposure setting might be hospital workers whose jobs did not require direct access to the patients in a hospital or clinical room setting such as receptionists, janitors, and others who work in or around infected individuals. *Less intense* exposure would occur for office workers with only casual contact with other persons. The *lowest intensity* exposures would be for individuals with little to no direct person-person contact, e.g., walk-by scenarios. The intensity variable can be weighted by considering *the condition of the contacts* encountered by the workers. For example a higher I- level may be selected if the contacts are encountered routinely and are violently coughing, sneezing, vomiting, or otherwise disseminating body fluids.

I-1 = Casual *walk-by* contact with symptomatic persons, such as at a mall or shopping center.

I-2 = Contact with symptomatic persons in a ventilated room; but not having close person-to-person contact as with providing direct care or treatment.

I-3 = Close contact with symptomatic persons, such as in settings providing direct patient care in a hospital room, clinical suite, home infirmary, in a confined space, or during ambulance transport.

I-4 = Exposure to aerosol-generating procedures (e.g., bronchoscopy) on symptomatic persons. Because the procedure generates aerosols of both small and large particles, splatter material, and so forth, this represents the highest degree of exposure.

Figure 6: Intensity of Exposure Scale

I-1	I-2	I-3	I-4
Low intensity			**High intensity**

Control Band Selection

Based on the assessments above, components will find the appropriate control band by examining the level/color in the matrix below. There would be a separate matrix created depending on the R-phrase category based on disease severity. There is a possibility that during the course of a pandemic, the determination of the R-phrase may change depending on the biological agent and epidemiologic information that is known. The control banding approach presented here is meant to apply to workers in good health and with normal host defenses.

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Special accommodations in the form of protections that exceed those offered to healthy workers will sometimes need to be made for workers with impaired host defenses or at increased risk for complications of disease. During a pandemic or disease response, HS Components will notify employees that those with these potential increased health risks should consult their physician and Component medical personnel (including Federal Occupational Health if they provide this service) to determine any special precautions are needed for them. Specific employee medical information cannot be openly shared with supervisors without employee consent under HIPPA, but special preventive measures from medical personnel can be.

Figure 7: Control Band Selection Matrices

R-1 – Low transmissibility (infectivity) and low clinical severity (virulence); e.g., seasonal influenza

	T-1	T-2	T-3	T-4
I-1	Band A	Band A	Band B	Band B
I-2	Band A	Band A	Band B	Band B
I-3	Band A	Band A	Band B	Band C
I-4	Band B	Band B	Band C	Band C

R-2 – Moderate transmissibility and low-moderate clinical severity; e.g., 2009 pH1N1

	T-1	T-2	T-3	T-4
I-1	Band A	Band A	Band B	Band B
I-2	Band A	Band B	Band B	Band B
I-3	Band A	Band B	Band C	Band C
I-4	Band B	Band B	Band C	Band D

R-3 – Low transmissibility but high clinical severity; e.g., avian influenza

	T-1	T-2	T-3	T-4
I-1	Band A	Band A	Band B	Band B
I-2	Band A	Band B	Band C	Band C
I-3	Band B	Band C	Band C	Band D
I-4	Band C	Band D	Band D	Band E

R-4 – High transmissibility and high clinical severity; e.g., the severe 1918 influenza pandemic

	T-1	T-2	T-3	T-4
I-1	Band A	Band B	Band C	Band C
I-2	Band B	Band C	Band C	Band D
I-3	Band C	Band C	Band D	Band E
I-4	Band D	Band D	Band E	Band E

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Control Options

The control options for each of the control bands are described qualitatively below. Control strategies should follow the hierarchy of controls for risk management; evaluating and applying, as feasible, workplace and engineering controls (e.g. ventilation, barriers, providing tissues, hand washing facilities/hand soap, hand sanitizer, disinfectants and disposable towels for employees to clean their work surfaces, etc.) first, then administrative controls (such as social distancing, telework, shift modifications, encouraging employees to receive the seasonal flu vaccine, employee training including sneeze and cough etiquette, etc.), and finally Personal Protective Equipment (PPE). See the DHS Pandemic Workplace Control Guidance issued by the DHS Occupational Safety and Health Office for details.

Band A: This level requires no engineering controls or use of PPE. During a pandemic or disease outbreak, persons in occupations with a Band A assessment should be counseled to practice basic hygiene: sneeze and cough etiquette, frequent hand washing, social distancing, and staying home if ill. Workplace controls such as disinfectant supplies should be considered for this level during a pandemic or disease outbreak.

Band B: This level of control is used to address ordinary situations during commonly expected influenza season. The level of protection required depends somewhat on the exposure setting, the degree of susceptibility of the individual, and the degree of risk aversion of the individual worker. Band B includes all of the requirements of Band A. In addition, consideration should be placed on using source controls when encountering symptomatic persons with disease; e.g., coughing, sneezing persons should be asked to wear a surgical/ procedure mask to limit their emissions to the environment. In health care settings, administrative controls such as rapid identification and segregation of symptomatic persons with disease and cohorting, i.e., putting symptomatic persons with disease in one ward (preferably one with at least dilution ventilation) and providing additional protection to workers.

Band C: This level of control is used for workers who are likely to be in frequent close contact with symptomatic persons with disease. Band C controls address scenarios when the disease is easily spread between individuals, when infected persons have obvious symptoms such as coughing and sneezing, and are therefore spreading infectious particles proximate to the workers, and when there is uncertainty of availability of anti-viral drugs and vaccines. Controls which should be used for Band C situations include one of the following as appropriate for the physical configuration: exhaust ventilation, airborne infection isolation rooms, and/or physical isolation shields. The use of N95 respirators by individuals with frequent and extended close contact with confirmed and suspect cases should be required.

Band D: This level of control is used to provide enhanced exposure control for potentially life-threatening diseases, and where exposure to the infectious agent is relatively certain if not for engineering controls to isolate known infected people or provide enhanced types of personal protective equipment. Band D should be considered in situations where the fatality rate among hospitalized cases is high, and where there is limited availability of anti-viral drugs and/or vaccines. Band D controls should include no less than N95 filtering face piece respirators.

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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

Band E: This situation requires expert consultation and coordination with DHS OSH and OHA. Requirements would be Band D level or greater. The control recommendations associated with the selected Control Bands are summarized in Figure 8.

Figure 8: Control Options

Control Band	Administrative	Environmental	Personal Protective Equipment
Band A	-Basic hygiene training -Provide sick-leave option (if sick, stay home) -Encourage vaccination	-Hand washing / sanitizer stations	- None
Band B	- Band A options plus: - Early ID and isolation of symptomatic persons - Signage to warn workers - Masking symptomatic persons - Prompt use of anti-viral drugs	- Hand washing / sanitizer stations - Physical barriers - Dilution ventilation	- Surgical masks for droplet and contact - Gloves - Voluntary N95
Band C	- Band B options	- Hand washing / sanitizer stations - Exhaust ventilation - UVGI, HEPA Filtration	- N95 required - Gloves
Band D	-Band B options	- Band C Options plus: - Airborne infection isolation room	- N95 required - Gloves - PAPR for aerosol-generating procedures
Band E	Seek Expert Advice	Seek Expert Advice	Seek Expert Advice

Mitigating Factors:

There are several mitigating factors that determine which controls to apply within the selected control band, and there may be additional considerations which may cause the component to modify the Control Band selected by application of this method.

1. Transmission Mode
   a. Unknown transmission mode: If there is no or little information available on the transmission mode one should assume fine particle aerosol transmission until data indicate otherwise. Controls for fine particle aerosol will mitigate exposure from the other modes of transmission.
   b. Fine particle aerosol: If the transmission mode is fine particle aerosol transmission, the infectious particles may remain airborne for extended periods of time, and may be carried by Heating, Ventilation and Air Conditioning (HVAC) systems far from the infected persons who are the source. Respirable size particles (generally < 10 μm aerodynamic

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diameter) are not filtered by surgical masks but are efficiently removed by N95 respirators or HEPA filters. These should be selected for fine particle aerosol control along with the droplet and contact measures described below.

c. Droplet Spray: If the transmission mode is determined to be by droplet spray to the exclusion of other transmission routes, there is no need to consider using respiratory protection such as N95 or HEPA filters. For droplet spray modes: barriers, shields, FDA-approved surgical masks and social distancing may be the most appropriate controls.
d. Person-to-Person contact: If the transmission does not include fine particle aerosol or droplet spray, control measures should focus on prevention of direct contact such as but not limited to: social distancing, barriers, use of gloves, hand washing, and surface disinfection.

2. Immune-compromised individuals: If a worker is known to be immune-compromised or individually sensitive to the disease in question, consideration should be given to excluding the worker from exposure or by selecting control options from a Control Band higher than that which results from the job analysis.
3. Essential functions: Persons serving essential functions may require protection above the control band selected based on their exposure risk. Individuals with mission critical skills (e.g., nuclear power plant operators) may require enhanced protective measures to assure public safety and health.
4. Shortages of Protective Equipment: In the event of a shortage of N95 filtering facepiece respirators the following are options, in order of precedence:
   a. Use of any half - or full-face piece mask with any particulate filter cartridge;[1]
   b. Use of a PAPR with a HEPA filter;
   c. Extended use of N95 respirators (single use for multiple encounters with potentially infected people);
   d. Use a surgical mask (not a NIOSH certified product).

Other Sources of Transmission

This control banding technique will also be used for assessing risks and developing controls for non-human-to-human transmission diseases when in pandemic or epidemic stages. Sources of alternate transmission commonly include insect or animal vectors that pass infection through bites, droppings, and other means. Less common in the U.S., but often in developing countries, are water-borne diseases; although these may reach epidemic levels locally, they are unlikely to reach pandemic levels. OHA and DSH OSH will distribute specific risk and precaution notices to components for these diseases as well; unless a component has regular operations in areas impacted by such diseases, specific control banding strategies are not required to be created until notice of a disease outbreak.

[1] The cartridge can be N-, R- or P- type with ratings of 95, 99, or 100.

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Plan Development

Some sample scenarios are included in Appendix 2 of this guidance to illustrate the use of the method.

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Appendix 1

Tables to inform Categorization of R-Phrase based on available data (from Reed, 2013)

Table 1. Scaled measures of transmissibility and clinical severity for the initial assessment of pandemic influenza effects

Parameter no. and description	Scale: Low-moderate	Scale: Moderate-high
Transmissibility		
1. Secondary attack rate, household, %	≤20	>20
2. Attack rate, school or university, %	≤30	>30
3. Attack rate, workplace or community, %	≤20	>20
4. R_0: basic reproductive no.	1.0–1.7	≥1.8
5. Underlying population immunity	Some underlying population immunity present	No underlying population immunity present
6. Emergency department or other outpatient visits for influenza-like illness, %	<10	≥10
7. Virologic characterization	Genetic markers for transmissibility absent	Genetic markers for transmissibility present
8. Animal models—transmission studies	Less efficient or similar to seasonal influenza	More efficient than seasonal influenza
Clinical severity		
1. Upper boundary of case-fatality ratio, %	<1	≥1
2. Upper boundary of case-hospitalization ratio, %	<10	≥10
3. Ratio, deaths: hospitalizations, %	<10	≥10
4. Virologic characterization	Genetic markers for virulence absent	Genetic markers for virulence present
5. Animal models	Less virulent or similar to seasonal influenza	More virulent than seasonal influenza

Table 2. Scaled measures of transmissibility and clinical severity for the refined assessment of pandemic influenza effects

Parameter no. and description	Scale: 1	2	3	4	5	6	7
Transmissibility							
1. Symptomatic attack rate, community, %	≤10	11–15	16–20	21–24	≥25		
2. Symptomatic attack rate, school, %	≤20	21–25	26–30	31–35	≥36		
3. Symptomatic attack rate, workplace, %	≤10	11–15	16–20	21–24	≥25		
4. Household secondary attack rate, symptomatic, %	≤5	6–10	11–15	16–20	≥21		
5. R_0: basic reproductive no.	≤1.1	1.2–1.3	1.4–1.5	1.6–1.7	≥1.8		
6. Peak % outpatient visits for influenza-like illness	1–3	4–6	7–9	10–12	≥13		
Clinical severity							
1. Case-fatality ratio, %	<0.02	0.02–0.05	0.05–0.1	0.1–0.25	0.25–0.5	0.5–1	>1
2. Case-hospitalization ratio, %	<0.5	0.5–0.8	0.8–1.5	1.5–3	3–5	5–7	>7
3. Ratio, deaths: hospitalization, %	≤3	4–6	7–9	10–12	13–15	16–18	>18

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Appendix 2
Worked Examples

Scenarios:

1. Administrative/Office Worker, Novel influenza outbreak,
    a. Risk Phrase: R-2
    b. 20 Contacts/8 hour shift
    c. Exposure Probability: Probable(+) = 20%; 20 / day x 0.20 = 4 contacts
    d. Time: 3-6 contacts and 5-30 min/contact T-3
    e. Exposure Intensity - Office/Cubical Environment >6 ft.; I-2

    RESULT: Control Band B
    Admin: Hand washing, spatial distancing, limiting group gatherings; active immunization program
    Environ: Barriers, room dilution
    PPE: Voluntary N95
    Mitigating factors: Could go to T-1, I-1 giving Control B and A if social distancing and telework options are used.

2. Law Enforcement Patrol in Rural Area (e.g. BP Patrol); Novel influenza outbreak
    a. Risk Phrase: R-2
    b. 10 Contacts/8 hour shift
    c. Exposure probability: Unlikely=0.1%: 10/day x 0.001= 0.01 Contacts
    d. Time: <3 contacts with time 5-30 min T-2
    e. Exposure Intensity: Outside work, >6 ft, mainly walk-by contact with occasional direct contact with individuals not suspected to be infected. I-1

    RESULT: Control Band B
    Admin: Spatial distancing, limiting group or in-vehicle activities; active immunization program
    Environ: Use of open spaces and natural ventilation
    PPE: Voluntary N95, gloves
    Mitigating factors: Could go to T-1, I-1 giving Control B and A if number and duration of contacts could be reduced by changes in staffing or patrol procedures.

3. Law Enforcement Patrol in Urban Area (e.g. FPS Officer); Novel influenza outbreak
    a. Risk Phrase: R-2
    b. 100 Contacts/8 hour shift
    c. Exposure probability: Probable = 5%: 100/day x 0.05= 5 Contacts
    d. Time: 3-6 contacts with time 5-30 min T-3
    e. Exposure Intensity: >6 ft, mainly walk-by contact with occasional direct contact with individuals not suspected to be infected. I-1

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RESULT: Control Band B
Admin: Spatial distancing, avoid unnecessary contact with individuals or their possessions, active immunization program
Environ: Barriers, room dilution
PPE: Voluntary N95, nitrile gloves
Mitigating factors: Possible move to B and A by reducing duration of contacts to T-2, <5 minutes. Eliminate all casual or personal contacts.

4. Law Enforcement/Detention Offices; Novel influenza outbreak
    a. Risk Phrase: R-3
    b. 200 Contacts/8 hour shift
    c. Exposure probability: Probable+ = 10%: 200/day x 0.10= 20 Contacts
    d. Time: >6 contacts with time >30 min T-4
    e. Exposure Intensity: Casual contact with symptomatic persons in ventilated space with occasional direct contact with individuals not suspected to be infected. I-2

RESULT: Control Band B-C
Admin: Spatial distancing, avoid unnecessary contact with individuals or their possessions, active immunization program
Environ: Barriers, room dilution
PPE: Voluntary N95, nitrile gloves
Mitigating factors: Reduction in contact length and directness could reduce to T-3 and I-1, which is Band B.

5. FEMA Disaster Worker performing Survivor Assistance low transmissibility, high clinical severity, H7N9, possibly prodromal shedders
    a. Risk Phrase: R-3
    b. 1 Individual/30 min with 8-hr shift, 10-30 min per customer = 16 different Individuals
    c. Exposure Probability (Possible) = 1% 16/day x 0.01 = <1 infected persons / day
    d. For <3 contacts/day and 5-30 min per Individual, T-2
    e. Exposure Intensity: More than pass-by, less than direct care: I-2

RESULT: Control Band B
Admin: -Basic hygiene training, Provide sick-leave option(if sick, stay home), Encourage vaccination, Early ID and isolation of symptomatic persons, Signage to warn workers, Masking symptomatic persons, Prompt use of anti-viral drugs
Environ: Hand washing / sanitizer stations, Social Distancing, Dilution ventilation, surface disinfection between interviews
PPE: - Surgical/ Procedure masks for symptomatic persons, Gloves, Voluntary N95
Mitigating factors: Individuals reporting for disaster assistance may not have access to hygiene facilities or vaccinations; this part of the population may have higher incidence of infection than

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general national statistics. Hand washing/ sanitizer stations and Surgical/ Procedure masks should be considered to provide Individuals seeking assistance at FEMA centers.

6. Immigration Officers conducting interviews, including Adjudication Officers , Asylum Officers and Refugee Officers, Seasonal influenza
    a. Risk Phrase: R-1
    b. 1 case (1-3 interviewees) / 60 min; 8-hr/ day = 24 customers
    c. Exposure Probability - Possible = 1% 24/day x 0.01 = <1 infected person/day
    d. For <2 contacts per day and 5 min/contact, T-1
    e. Exposure Intensity: More than pass-by, less than direct care: I-2

    RESULT: Control Band A
    Admin: Social distancing, basic hygiene, hand washing, active immunization program
    Environ: maintain good ventilation in building
    PPE: None
    Mitigating factors: None

7. Immigration Officers conducting interviews, including Adjudication Officers , Asylum Officers and Refugee Officers, low transmissibility, high clinical severity, H7N9, possibly prodromal shedders
    a. Risk Phrase: R-3
    b. 1 case (1-3 interviewees) / 60 min; 8-hr/ day = 24 customers
    c. Exposure Probability - Possible = 1% 24/day x 0.01 = <1 infected person/day
    d. For <2 contacts per day and 5 min/contact, T-1
    e. e. Exposure Intensity: More than pass-by, less than direct care: I-2

    RESULT: Control Band A
    Admin: Social distancing, basic hygiene, hand washing, active immunization program
    Environ: maintain good ventilation in building
    PPE: None
    Mitigating factors: None

8. TSA screener, Novel influenza/Low R_0 outbreak.
    a. Risk Phrase: R-2
    b. 1 traveler/2 min; 8 hr/day = 240 travelers
    c. Exposure probability (Possible) = 1%; 240/day x 0.01 = 3 infected persons/day
    d. For 3-6 contacts per day and <5 min/contact, T-2
    e. Exposure intensity, casual contact more than pass-by: I-2

    RESULT: Control Band B
    Admin: Social distancing; lenient absentee policy, spacing workers apart, hand washing; access to medical counseling

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Environ: Directional airflow
PPE: Voluntary N95
Mitigating factors: None

9. 3rd Grade School Teacher, Novel Influenza outbreak, not providing direct care to some sick children
    a. Risk Phrase: R-2
    b. 30 children in class for 6 hours / day
    c. Exposure Probability = Probable(+) = 20%; 30 / day x 0.20 = 6 contacts
    d. For 3-6 contacts and > 30 min/contact T-4
    e. Exposure Intensity - Classroom 3-6 f.t; lunch room >3 ft.; outdoors >6 ft. I-2

    RESULT: Control Band B
    Admin: Hand washing, spatial distancing, limiting group gatherings; active immunization program
    Environ: Barriers, room dilution
    PPE: Voluntary N95
    Mitigating factors: Could go to T-2, I-1 giving Control Band A if ill children are promptly sent home.

10. City Bus Driver, Mild to moderate influenza outbreak
    a. Risk Phrase: R-2
    b. 200 passengers/day; driving 6-hours per day
    c. Exposure Probability (Possible) = 1%. 200/day x 0.01 = 2 infected persons/day
    d. For < 3 contacts with > 30 minutes = T-3
    e. Exposure Intensity: Closer contact than passing-by: I-2

    RESULT: Control Band B
    Admin: Distribute surgical masks to symptomatic customers; provide waterless hand cleaner.
    Environ: Frequent decontamination of touched surfaces.
    PPE: Voluntary N95; surgical masks for droplet & contact; gloves if exchanging money, etc.

11. Customs Passport Control Officer: low transmissibility, high clinical severity, H7N9, possibly prodromal shedders
    a. Risk Phrase: R-3
    b. 1 traveler/2 min with 8-hr shift, <2 min per customer = 240 different customers
    c. Exposure Probability (Possible) = 1% 240/day x 0.01 = 2 infected persons / day
    d. For 2 contacts/day and <5 min per customer, T-1
    e. Exposure Intensity: More than pass-by, less than direct care: I-2

    RESULT: Control Band A
    Admin: Hand washing, worker vaccination encouraged,

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Environmental: Hand washing stations/hand sanitizer stations
PPE: Mitigating factors: vaccination, sick leave policy
Mitigating factors: Airports receiving passengers from highly infected countries/ regions may have higher Probability than 1%, may spend >5 min with some travelers when sick which could make the evaluation T-2 leading to Band B, voluntary use of N95.

12. Child daycare center worker; 8 hour work day. Children can be infants, toddlers (18 mon-3 yrs), pre-school (3-5 yrs); state will have defined student/teacher ratios depending upon age group. Ratios for these age groups can be (in same order) 4/1; 5/1; 10/1. May have multiple teachers in a room e.g. 20 preschoolers with 3 teachers, 14 toddlers with 4 teachers. Worker will have children they are assigned to plus help with other children in the room; possibility of asymptomatic shedders, illness onset shedding. For this scenario: toddlers – five assigned plus 13 additional children assigned to other 3 daycare staff.
    a. Risk Phrase: R-3
    b. Contact time: 8 hours contact time
    c. Exposure probability – Likely = 50%+ Time:
    d. For >6 contacts with time >30 min T-3
    e. Exposure Intensity: (child exhibiting ILI symptoms would be separated and parents contacted to come pick up child.) I-2

RESULT: Control Band C
Admin: Policy to segregate symptomatic children and send them home right away; vaccination of staff.
Environ: Bands A & B; hand sanitizer stations, HEPA filtration
PPE: N95
Mitigating factors: Mask use may be a problem for staff re concern about children's reaction; relative humidity between 40-50% not a conducive to virus survival; increased housekeeping procedures (e.g., disinfection of high contact surfaces, toys, vaccination status of children (requirements of day care center).

13. Physical Techniques Instructor (e.g. FLETC); Novel influenza outbreak
    a. Risk Phrase: R-2
    b. 200 Contacts/8 hour shift
    c. Exposure probability: Unlikely = .1%: 200/day x 0.001=0.2 Contacts
    d. Time: <3 contacts with time >30 min T-3
    e. Exposure Intensity: >6 ft, mainly walk-by contact with occasional direct contact with individuals not suspected to be infected. I-1

RESULT: Control Band B
Admin: Spatial distancing when feasible, avoid unnecessary contact with individuals or their possessions, active immunization program
Environ: Room dilution or utilize outside training areas.

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PPE: Voluntary N95, nitrile gloves
Mitigating factors: Could go to T-2, I-1 giving Control B and A if number of contacts could be reduced by either increasing the contact distance and/or number of close contacts per day.

14. Emergency Medical Technicians, 24-hour shift, severe disease profile.
    a. Risk Phrase: R-3
    b. 6 responses to requests for assistance; 1 fire; 2 vehicle collisions; 1 emergency medical at the hotel; 2 residential call for medical assistance. Contact times for purposes of this scenario: fire – 0; 2 vehicle collisions 30 minutes each, 6 people, 2 transport to hospital (additional contact time); 40 minutes hotel run and transport to emergency room; 2 – 30 minute responses, 1 transport to emergency room for the 2 residential response.
    c. Exposure probability: During flu season with R-3, 0.1% to 50% = 9 potential contacts (excludes co-workers, family members at residences and hotel, hospital staff) – contact is individuals receiving direct assistance from worker.
    d. For >6 contacts with time >30 min T-4
    e. Exposure Intensity: I-2

RESULT: Control Band C (Depends upon initial determination for medical runs)
Admin: Nature of call for assistance; vaccination;; symptoms exhibited by person requiring assistance and history; ventilation system in rescue squad transport vehicle; masking of patient with surgical mask or ventilator assistance device.
Environ: Ambulance vehicle equipment
PPE: Use of gloves; N-95; prepare for I-3 exposure intensity during transport N95 required.
Mitigating factors: Must prepare for exposure intensity potential to I-3 leading to Control Band D.

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SECTION 3

Respiratory Protection Guidance for Pandemic/Infectious Disease Events

Some ICE personnel must wear respirators regularly as part of their expected duties and are trained, fit-tested, and medically cleared to use them under an existing Component respiratory protection program. Pandemic influenza and infectious diseases with similar human-to-human transmission characteristics present new or different airborne hazards to the ICE workforce. During an infectious disease event, ICE personnel that do not wear respirators as a part of their routine duties may potentially be required to wear respiratory protection. Additionally, ICE personnel who are not specifically identified as working within the infection distance of potentially infected people may gain some protection and/ or peace of mind through "voluntary use" of respirators.

As part of ICE Pandemic Workforce Protection Plan development, ICE sub-components at the regional level must perform a risk assessment of their workforce to identify the appropriate control band(s) for each duty position/ task their workforce performs. That band identification along with disease-specific guidance, will allow ICE sub-component regional leadership to identify whether their workforce has a need for respirator use. This guidance is provided as a framework for the development of the ICE pandemic and infectious disease-related respiratory protection program in accordance with OSHA, DHS, and ICE regulations, policies and procedures, and SOPs. The ICE Respiratory Protection/Infectious Disease Control SOPs have been designed to be used as a template that local ICE regional sub-components may adapt in order to be in compliance with the aforementioned regulations and standards, along with having the appropriate written program(s) available for review.

Type of Respirator Use:

All respirator use is governed by risk assessment and hazards. OSHA recognizes two types of respiratory equipment use situations based on risk; mandatory and voluntary.

Mandatory Use: This is the most restrictive and regulated situation and the most common use of respirators. Mandatory use requires compliance with all aspects of 29 CFR 1910.134. It occurs when any of the following conditions exist:

1. A known hazard is present in the workplace and exposure levels exceed an established OSHA level.

2. Risk assessments indicate a hazard is present at levels that have potential to cause injury or illness.

3. A non OSHA-regulated hazard is present in the workplace at levels that have produced serious injury, illness, or death.

4. The employer requires an employee to wear a respirator, regardless of actual hazard level. This includes situations when no significant hazard is present, but the employer chooses to mandate respirator use in an abundance- of- caution approach.

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Mandatory use requires the employer to provide training, medical clearance and respirator fit testing (in the exact make and model of respirator to be used by the employee) for all employees who must wear respirators. Respirator fit testing (appendices A, B) and medical clearance Appendix C) is detailed in 29 CFR 1910.134. Note that medical clearance is required before an employee can be fit tested. Mandatory use also requires that that there is no facial hair between the respirator seal and the face.

Voluntary Use: This is the least- regulated situation, and many of the requirements in 29 CFR 1910.134 do not apply. Fundamentally, voluntary use applies when there is no significant respiratory hazard present. Voluntary is permissible when:

1. There is no applicable OSHA standard that requires respirator use.
2. Risk assessments indicate no hazard is present at levels that would be expected to cause injury or illness.
3. The employer does not require the employee to wear a respirator for their job.
4. The employee voluntarily chooses to wear a respirator, provided by either the employer or by the employee.
5. The employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard.
6. The employee understands that wearing a respiratory may cause distress in individuals with impaired lung function (e.g., asthmatics) and may produce a greater risk than the perceived hazard.

For voluntary use, the employee must be provided with a copy of Appendix D of 29 CFR 1910.134 (attached), and a record made that the employee received the appendix and what model/ type of equipment was provided. Voluntary use still requires a written respiratory protection program UNLESS only filtering face-piece respirators (including N-95 masks, dust masks, surgical masks, etc.) are used.

Note: OSHA states the employer MAY allow voluntary use of respirators if the respirator does not create a hazard. Managers should bear in mind that employee concerns would be considerable for them to voluntarily request wearing a mask; therefore they should conduct a thorough analysis before restricting voluntary use. Such restrictions should be made in as limited scope as possible and should be applied universally throughout a Component to establish an equitable approach.

Authorities and Roles:

Occupational Safety and Health Administration (OSHA). The sole regulatory authority for respiratory protection is OSHA. This is true regardless of the workplace type. The applicable standard is 29 CFR 1910.134, Respiratory Protection. This standard applies to all workplaces including private and public sectors as well as industrial and non-industrial (e.g., medical, office, retail). Respirator use, respirator protection factors, approved devices, training; medical clearance and fit-testing are all specified in this standard and its mandatory appendices.

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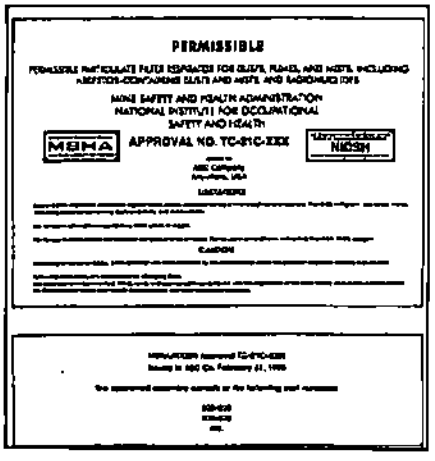
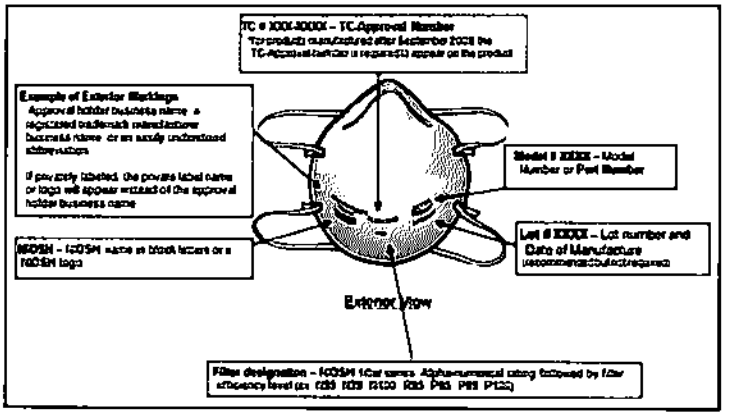
Department of Health and Human Services, National Institute of Occupational Safety and Health (NIOSH). NIOSH, a sub- organization of HHS/Center for Disease Control and Prevention (CDC), is responsible for testing and certifying respiratory devices worn in the workplace. If a respirator is worn to comply with OSHA requirements, it must carry NIOSH certification, demonstrated by the NIOSH symbol and a TC-Number, found on the respirator or the respirator package and directions, as shown in the examples below.





Department of Homeland Security (DHS). The DHS Occupational Safety and Health (OSH) Program, housed in the Office of the Chief Human Capital Officer (OCHCO) develops overarching polices and guidance for use in DHS workplaces. Directive 066-1, Occupational Safety and Health Programs, describes the Department's OSH program and the DHS Safety Manual is the supporting instruction. The DHS Safety Manual addresses specific issues and OSHA requirements. Chapter 12 covers respiratory, including the development of Component-level written respiratory protection plans. The Department OSH office also provides assessment and oversight of Component programs, including the evaluation of respiratory protection programs.

Immigration and Customs Enforcement (ICE) Component-Level Respiratory Protection Program. The ICE OSH Program Requirements Handbook, along with the ICE Respiratory Protection/Infectious Disease Control SOP provides guidance to ensure the local ICE sub-components are in compliance with OSHA, DHS and ICE requirements. ICE sub-components are responsible for establishing and maintaining their own OSH programs, including developing and issuing policies, directives, guidance for managing respiratory protection programs locally.

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OSHA Required Document for Voluntary Respirator Users

Appendix D - 1910.134 (Mandatory)

The employer must provide this document to any employee or volunteer who uses an employer-provided respirator voluntarily or provides his or her own respirator.

Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.

You should do the following:

1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations.

2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.

3. Do not wear your respirator into atmospheres containing contaminants for which your respirator is not designed to protect against. For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke.

4. Keep track of your respirator so that you do not mistakenly use someone else's respirator.

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SECTION 4

PPE/Respiratory Protections Hazard Assessments, Distribution, Storage and Training

Hazard Assessment and PPE/Respirator Selection

The selection of the proper type of respirator(s) is based on the potential workplace hazards and potential for employee exposures associated with work activities, job positions, and or work locations. A hazard evaluation will be performed for each operation, process, or work area where the potential for a variety of workplace hazards are suspected of being present. This includes, but is not limited to identifying/evaluating respiratory hazards that may exist in routine/non-routine operations and or emergency response operations. Employees may request a copy of any hazard assessment performed in the workplace. Any quantitative exposure monitoring results will be provided to employees in a timely manner in accordance with OSHA requirements.

The hazard evaluation shall:

a. Identify and develop a list of all potential hazards that may be encountered in the workplace, broken out by job position, organization, and/or work process.

b. Review work processes and conduct the necessary assessments to determine specifically where potential respiratory exposures hazards exist. This review should include at minimum, surveying the workplace, reviewing work processes and records, along with feedback from managers/supervisors/employees that perform the work tasks being evaluated.

c. Based on the qualitative analysis above, determine the need for either mandatory/voluntary respiratory protection use.

d. Where applicable, conduct quantitative exposure monitoring to determine the actual exposure level found during a work process.

Updating the Hazard Assessment

The Respirator Program Administrator shall revise and update the hazard assessment as needed (i.e., anytime work process changes potentially affect exposure or when new hazards are introduced or encountered). If an employee feels that PPE/respiratory protection is needed during a particular activity, contact their manager/supervisor who will work with the Respirator Program Administrator for possible solutions. The Respirator Program Administrator will evaluate the potential hazard, arranging for technical assistance from their local ICE Field CDSO or HQ ICE OAFM Safety and Health Unit, as required. The manager/supervisor will communicate the results of that assessment to the employee(s). If it is determined that respiratory protection is necessary, elements of this program will be in effect for those tasks. The Respirator Program Administrator will update the hazard assessment and, if necessary, update this respiratory protection program.

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ANNEX E: ICE PANDEMIC/INFECTIOUS DISEASE WORKPLACE CONTROLS

PPE/Respirator Distribution Options

It has been determined that DHS/ICE is required use PPE to meet the operational and pandemic needs of its workforce. PPE is required by some DHS/ICE employees to protect themselves while exposed to workplace hazards perform everyday which supports the DHS/ICE mission. PPE is also used to support and sustain the safety of DHS/ICE employees operating during a pandemic event. ICE has elected to use the DHS Integrated Logistic Support plan guidance in order to develop and maintain pandemic preparedness strategy includes efforts to develop and execute pandemic contingency plans and preparedness actions. In the event of an emergency, as identified by the Center of Disease Control (CDC) and the Office of Health Affairs (OHA), federal employees will be expected to continue operations to sustain agency functions. The DHS Integrated Logistics Support Plan (ILSP) will assist in identifying and describing specific logistics guidance, practices and methodologies to standardize the general process to follow when supporting the operational PPE and pandemic PPE.

- Locally-stored PPE/Respirator: Appropriate PPE, as identified by hazard assessments and EF duties, is stored locally (e.g., in the place of employment or available for timely distribution); designated employees would access PPE stocks when directed to do so.

- Individually-issued PPE/Respirator: Limited amounts of PPE are issued to employees who cannot get reasonable access to locally-stored PPE; these employees are responsible for storing the equipment at an easily -accessible location (e.g., home, workspace).

- Component-level Warehouse Storage: Large supplies of PPE acquired and stored at central warehouses (this is not recommended as the primary method of distribution; however it could serve as an intermediate step in PPE distribution for original receipt of equipment and to store reserve supplies).

- Combination Distribution: The previous options are combined to include initial, centralized storage as well as local and individual distribution.

Planning Requirements

All DHS Component pandemic workforce protection plans will address the following items:

- Assign roles and responsibilities Coordinate with the Component Occupational Safety and Health (OSH) managers to ensure OSHA compliance

- Perform hazard assessments; identify quantity needed for PPE, based on EFs

- Maintain a mechanism to obtain and distribute PPE

- Identify non-PPE protective measures, in coordination with OCHCO Occupational Safety and Health (OSH) that may be used to reduce reliance on PPE, e.g. telework, social distancing, shift work, etc.

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- Identify facilities (to include storage)
- Prepare and validate a timeline for in-field availability of PPE
- Acquire PPE, store, and distribute PPE.
- Ensure procedures are developed enabling personnel access to sufficient PPE to maintain EFs upon declaration of a pandemic.
- Develop and implement medical clearance and fit-test procedures for personnel prior to issuance of respiratory protection, if a hazard assessment warrants fit testing and workforce rules authorize it.
- Supply training, medical clearance, and fit-testing, if required.
- Maintain all OSHA-required records related to PPE use, medical clearance, training, and fit-testing as appropriate for the type of PPE.
- Periodically review and amend, as necessary, the Component plan to include any changes in procedures, tasks, or exposure information.

STORAGE REQUIREMENTS

- All PPE must be stored in conditions per manufacturers' recommendations (i.e., avoid exposure to moisture, excessive heat, or cold).
- Local storage areas and, if used, centralized warehousing, must be readily accessible
- Ensure that National Fire Protection Association standards and OSHA guidelines are followed wherever supplies are warehoused.
- The Component will assign personnel to manage the inventory of each type of PPE stored at each location.
- If employees are issued individual materials, the PPE training program must include information on storage and maintenance of the materials.
- Respirators must be stored in a clean, dry area, and in accordance with the manufacturer's recommendations. Each employee will clean and inspect their own APR in accordance with the provisions of this program prior to storage and will then store their respirator in a plastic bag in their locker, storage area, vehicle, cabinet, desk, or other clean area, as appropriate. Each employee will have his/her name on the bag, and that bag will only be used to store that employee's respirator. Do not store respirators in the open air. Do not hang respirators from their straps when in storage. Replace the storage bag when it becomes torn or can no longer be sealed. Also see Appendix 5 of this SOP for respirator

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storage.

- The Respirator Program Administrator will store a supply of respirators and respirator components in the original manufacturer's packaging (or sealed bag or container if previously used and returned) and in a designated equipment storage room/area that is under the control of the Respirator Program Administrator. The Respirator Program Administrator will apply a system to ensure respirator accountability of the stored inventory and issued respirators.

TRACKING

- Supervisors will be responsible for tracking and reporting information on employee use of PPE.
- OSHA required documentation will be maintained at the issuing office. Component OSH personnel will maintain overall Component documentation.
- Component OSH personnel will track activities to ensure appropriate levels of PPE are used.
- MGMT/OCHCO/OSH and OHA will be responsible for providing PPE use and Departmental oversight.

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Appendix 3

ICE Hazard Assessment/Employee Protection Report

Please use the attached ICE Hazard Assessment/Employee Protection Report for that has been locally developed to assist each ICE regional area of responsibility (AOR) keep track of their hazard assessments and PPE requirements for the employees requiring protection. The reports have been conveniently broken into all the five risk bands discussed previously for your use.

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SECTION 5

Training Requirements

Training recommendations are provided below for Respirator Program Administrators, Supervisors of Respirator Users, Respirator Users, and ICE HQ/Field CDSOs.

Respiratory Protection Program Administrators/ICE HQ/Field CDSOs:

1. ICE Respiratory Protection Course or equivalent.

2. OSHA Course 2225, Respiratory Protection or other with content on respiratory protection program development, implementation, and administration.

Supervisors of Respirator Users:

1. ICE Respiratory Protection Course or equivalent.

2. Briefing by the Respirator Program Administrator/ICE HQ/Field CDSO/Supervisor responsibilities for the HQ/Field respiratory protection program.

3. Respirator Fit Testing training for all the types of respirators under their span of control.

Mandatory Respirator Users:

1. ICE Respiratory Protection Course or equivalent.

2. Supplemental training/briefing by the Respirator Program Administrator/ICE HQ/Field CDSO/ Supervisor on the use of the make, model, and type of respiratory protection equipment issued to the Respirator User.

Voluntary Respirator Users:

1. Training/briefing by the Respirator Program Administrator/ICE HQ/Field CDSO/Supervisor on the use of the make, model, and type of respiratory protection equipment issued to the Respirator User.

2. Provide Appendix D of 29 CFR 1910.134, Respiratory Protection and ensure that the Voluntary User reads and acknowledges the information.

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Appendix D FOR OFFICIAL USE ONLY
Technical Guidance for Personal Protective Equipment (PPE)
Acquisition and Distribution

PURPOSE

To provide guidance for the DHS components on the development of PPE acquisition and distribution plans that protect DHS personnel and those in the care and custody of DHS who are potentially exposed in an anthrax event.

SCOPE

Covered personnel are DHS personnel located within the U.S. borders and territories or traveling overseas that may be required to respond to an anthrax event or enter an anthrax-contaminated area following an anthrax attack.

a. Note: Internationally-embedded DHS employees receive safety and health services under already-established Department of State (e.g., International Cooperative Administrative Support Services) or Department of Defense agreements. Components will ensure safety and health provisions are addressed, in situations where employees require training, equipment, or materials outside the scope of the agreements.

b. Many contractors support the DHS mission by providing mission essential services. Components will include contract provisions to address safety and health requirements for contactors who will be required to continue operations following an anthrax event. Model language will be supplied by the Office of the Chief Procurement Officer for incorporation in contract agreements.

PPE implementation (e.g., hazard assessment, acquisition, storage, fit-testing, training, and distribution) will:

a. Provide the appropriate level of protection based on hazard assessments once PPE is acquired.

b. Provide immediate access to PPE by distributing PPE locally.

c. Place responsibility at the component level for all procurement of PPE, storage, distribution, training, and fit-testing, if needed.

PPE CRITICAL ASSUMPTIONS

a. Sufficient risk and threat justifies PPE (e.g., respirators, disposable clothing, goggles, and gloves) planning for DHS personnel.

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b. Planning will address DHS personnel, including DHS working animals, who may be required to respond to an anthrax event or enter an anthrax-contaminated area.

c. Components will identify covered personnel and contractors in each location.

d. Components will develop estimates of the level of risk based on hazard assessments conducted for each task performed by the covered personnel.

e. Components will select and purchase PPE appropriate for the mission(s) or task(s) performed by the covered personnel.

f. PPE will be purchased and distributed in advance due to the need for immediate availability following an anthrax attack.

g. Components will provide, in advance, any fit-testing or training associated with PPE use.

h. Sufficient supplies of PPE will be available.

i. Components will develop, approve, exercise, and revise PPE distribution plans.

OBJECTIVE

DHS component plans must ensure the provision of PPE to covered personnel.

There are many effective approaches for the distribution and use of PPE, and multiple approaches are expected due to the complexities and variables associated with the geographical dispersion of DHS employees. Components have the option to choose any combination of the options list below.

PPE DISTRIBUTION OPTIONS

a. Locally-stored PPE: Appropriate PPE, as identified by hazard assessments, is stored locally (e.g., in the place of employment); designated employees would access PPE stocks when directed to do so.

b. Individually-issued PPE: Limited amounts of PPE are issued to employees and employees are responsible for storing the equipment at an easily and rapidly accessible location (e.g., home, workspace).

c. Component-level Warehouse Storage: Large supplies of PPE acquired and stored at central warehouses (this is not recommended as the primary method of distribution; however, it could serve as an intermediate step in PPE distribution for original receipt of equipment and to store reserve supplies).

d. Combination Distribution: The previous options are combined to include initial, centralized storage as well as local and individual distribution.

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PLANNING REQUIREMENTS

All DHS component anthrax operations plans will address the following items:

a. Ensure procedures are developed enabling personnel access to PPE within 6 hours of notification of an anthrax event to maintain MEFs.

b. Develop and implement fit-test procedures for personnel prior to issuance of respiratory protection.

c. Supply required fit-testing and training.

d. Identify interim measures, in coordination with OSEP, for any employees who cannot be provided PPE within 6 hours.

e. Perform hazard assessments.

f. Acquire PPE.

g. Store and distribute PPE.

h. Identify facilities (to include storage).

i. Assign roles and responsibilities.

j. Coordinate with the Component Occupational Safety and Health (OSEP) personnel managers to ensure OSHA compliance.

k. Prepare and validate a timeline for in-field availability of PPE.

l. Maintain all OSHA-required records related to PPE use, training, and fit-testing.

m. Amend the component plan to include any changes in procedures, tasks, or exposure information.

STORAGE REQUIREMENTS

a. All PPE must be stored in tempered or room temperature conditions (i.e., avoid excessive heat or cold).

b. Local storage areas and, if used, centralized warehousing, must be accessible on a 24 hours a day, seven days a week.

c. If significant quantities are warehoused, National Fire Protection Association standards must be followed.

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d. The component will assign personnel to manage the inventory of each type of PPE stored at each location.

e. If employees are issued individual materials, the PPE training program must include information on storage and maintenance of the materials.

TRACKING

a. Supervisors will be responsible for coordinating with component OSH personnel managers and their designees to track and report information on employee use of PPE.

b. Component OSH personnel will maintain all OSHA-required documentation of PPE use.

c. Component OSH personnel will track activities to ensure appropriate levels of PPE are used.

d. MGMT/OCAO/OSEP and OHA will be responsible for providing PPE use oversight.

APPLYING THE HIERARCHY OF CONTROLS

When planning pandemic and infectious disease workplace readiness and response, workplace controls are defined as processes, procedures, and equipment that are used to reduce/eliminate health hazards/risks to ICE employees. Typically, workplace controls are derived from risk assessments of their duties, work tasks, and the potential hazards/risks. Workplace controls for health hazards/risks will often differ from standard controls for "ordinary" work hazards because the risk of contracting a pandemic type disease is often increased by activities that normally do not usually pose much risk in the workplace.

Hierarchy of Controls. The Occupational Safety and Health Administration (OSHA) regulations and guidance require the use of a "hierarchy of controls" to reduce or eliminate workplace hazards. In controlling the potential hazards during an infectious disease/pandemic event, this hierarchy approach prioritizes controls based on the concept that the best way to control a hazard is to remove it from the workplace, and not rely on employees to take an action to reduce exposure.

The "Hierarchy of Controls" are as follows:

1. Work Practices and Environmental Controls are designed to reduce/eliminate the duration, frequency, or exposure of a recognized workplace hazard/risk(s).

2. Administrative Controls are designed to reduce the hazards/risks by scheduling work tasks in ways that minimize employee exposure to a recognized workplace hazard/risk.

3. Personal Protective Equipment (PPE) is designed to provide an immediate barrier between the employee and a recognized workplace hazard. PPE is normally used in

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conjunction with Administrative Controls, training, and work practices developed as an effective means in minimizing exposure to infectious diseases and a pandemic event.

During an infectious disease/pandemic event, this hierarchy should be used in concert with OSHA guidance and public health recommendations. As mentioned above, most workplaces within ICE will use a combination of hierarchy control methods. There are advantages and disadvantages to each control measure based on ease of implementation, effectiveness, and cost. For example, hygiene measures and social distancing can be implemented easily and with little expense, but this control method requires employees to modify and maintain their behavior during a stressful situation. On the other hand, installing clear plastic barriers will be more expensive and take longer to implement, but does not require the worker to remember a new procedure and ultimately may be more effective and available for future events.

Applying the Hierarchy Controls in ICE Workplaces. The hierarchy of controls must be included as part of the safety and health risk management planning for pandemic and infectious diseases events. Workplace Practice and Engineering Controls, along with Administrative Control options must be examined for each response phase so that any required items can be can be procured, installed, or implemented in advance. For some ICE facilities/operations and the associated work tasks, PPE has been determined to be the only option. However, before PPE is determined to be the only feasible answer, managers/supervisors should be examined ways to reduce exposures to ICE employees and the workplace and still continue to fulfill their missions. The following examples include controls applicable to ICE workplaces.

Work Practice and Environmental Controls. Work practices and engineering controls are often in the hands of local ICE managers, supervisors with consultations from facilities/safety personnel. New technologies that reduce exposure from unavoidable person-to-person contact can also be included in this category. Examples include:

a. Work Practice - Hygiene and Personal Contacts:
   1) Providing resources that promote personal hygiene. For example, provide tissues, hand soap, and hand sanitizer.
   2) Training employees on risk factors and proper behaviors (e.g., cough etiquette and disinfection of shared equipment).
   3) Developing policies and procedures to minimize contacts between employees and between employees and the public.
   4) Conducting interactions at distances of 6 feet or other disease- specific recommendations. In some locations markings can be placed on the floor to indicated 6 feet.
   5) Using the largest available room when conducting long interviews or one-to-one meetings.
   6) If someone in ICE custody or visiting an ICE workplace is displaying symptoms, give them a "procedure mask" to wear and if possible isolate them. If available, consider using a cell designed for potentially ill detainees.
   7) For pandemic influenza, getting a seasonal influenza vaccine. The vaccines can prevent multiple infections (i.e., a pandemic and seasonal strain) and may reduce the severity of a pandemic strain.

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b. Environmental Control – Building Ventilation:
   1) Increasing the percentage of fresh air brought into the building by the ventilation system. Increasing fresh air dilutes the hazard. Note that **fresh** air must be supplied; simply increasing the flow of air in the space does not provide the same benefits and may increase risk. Ventilation changes should be discussed with facilities personnel.
   2) Evaluating the ventilation in offices; air moves from supply vents toward returns. If possible, re- position ICE employees closer to the supply vent. If ICE employees conduct interviews with the public, make sure the interviewee is closer to the return vent so the clean air flow moves across the breathing zone of the ICE employee and toward the potentially infectious person.
   3) If ICE employee use a personal fan, make sure it is not blowing air from a potentially contaminated source into their face, e.g., from a detainee or symptomatic person on to them. Fans can also produce disturbance and mixing that can spread germs and disrupt air flow supplied by building systems. During an infectious disease outbreak, it may be best to turn off fans.
   4) Use rooms with the best ventilation supply for meetings or interviews.

c. Work Practice - Disinfection:
   1) Providing disinfectants for ICE employees to clean their own work surfaces and shared services (copiers, door handles, break rooms). Disinfectants should be EPA listed and that list is available at: www.epa.gov/oppad001/chemregindex.htm . All disinfectants should be used following product directions. Aerosol or spray products can be flammable, so should never be sprayed around flames, heating elements, or electronic equipment. Many sprays cans also damage electronics. Surface disinfectants should not be used on people. Some are very harsh and can seriously damage the skin, respiratory system or eyes.
   2) Working with ICE facility building managers or GSA (if at a GSA leased facility) to conduct additional or special disinfecting cleaning. Janitorial staff can be asked to wipe down surfaces and doors several times per day. This will require additional funding, but allows a potentially severely reduced ICE workforce to concentrate on their work rather than cleaning.

d. Environmental Control - Physical Barriers:
   1) If the task permits, installing physical barriers, such as acrylic plastic barriers between employees and the public.
   2) Isolate symptomatic visitors or detainees by placing them in a separate, closed room.

Administrative Controls. Many administrative controls are related to human capital and guidance is directed by the Office of Personnel Management (OPM). The DHS Office of the Chief Human Capital Officer (OCHCO) develops DHS policies and has information for employees and supervisors available on their Connect intranet pages:

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Many Component human capital offices have additional, Component-specific information also derived from OPM guidance. Examples include:

- Utilizing policies that encourage ill employees to stay at home without fear of any reprisals.
- Encouraging approval of telework for all employees who can perform their function at home or an alternate location.
- Utilizing policies that allow employees who do not serve a critical function to stay at home, similar in concept to a bad weather day.
- Providing supervisors with guidance on asking a symptomatic employee to either go home, or stay at home.
- Restricting face-to-face meetings to only the most critical meetings.
- Staggering work hours or implementing shift plans to reduce the number of individuals in an office at one time.
- Reducing the number of facilities in use. If the workforce is greatly reduced, the remaining critical workers can work from a single location. The location would be selected on the basis of the ventilation system, workspace design, room size, or parking facilities that allow employees to avoid public transportation (which may be shut down during a serious infectious disease event).
- Discontinuing unessential travel to locations with high illness transmission rates.
- Developing emergency communications plans that will provide employees with timely and accurate information about their workplace and their risks.
- Developing a method for employees to ask questions and express concerns, ensuring they are provided with accurate answers.

Personal Protective Equipment (PPE). While administrative and engineering controls and proper work practices are considered to be more effective in minimizing exposure to diseases, the use of PPE may still be indicated during certain exposures.

- Selecting PPE based on risk assessment and the hazard to the employee;
- Properly fitting and for respirators, periodically refitting;
- Wearing PPE correctly, following directions and understanding the limits of protection offered by various types of PPE;
- Inspecting regularly and maintain and replace, as necessary;
- Properly removed and disposed of to avoid contamination of self, others or work surfaces.
- The types of PPE recommended for infectious disease events will be based on the mode of transmission (droplet, direct contact, insect bite) and the risk of contracting the disease while working.

NOTE: PPE use may be mandatory or voluntary. When a regulation, hazard level, or an employer requires PPE to perform a task, use is mandatory. If there is no regulation and the hazard level is below OSHA levels for PPE use and the employer does not require PPE be worn, use is voluntary. Voluntary use includes both employer and employee-supplied PPE. If PPE is used voluntarily, the employer must determine that the PPE does not introduce a hazard into the workplace.

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Annex G: ACRONYMS AND GLOSSARY

Acronyms

AD	Assistant Director
AOR	Area of Responsibility
CAP	Crisis Action Plan
CAT	Crisis Action Team
CDC	Centers for Disease Control and Prevention
CDSO	Collateral Duty Safety Officer
CMO	Chief Medical Officer
DHS	Department of Homeland Security
EMU	Emergency Management Unit
ESF	Emergency Support Function
EUA	Emergency Use Authorization
HEPA	High-Efficiency Particulate Absorption
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HQ	Headquarters
HSEEP	Homeland Security Exercise and Evaluation Process
HSIN	Homeland Security Information Network
HSPD	Homeland Security Presidential Directive
HVAC	Heating, Ventilation and Air Conditioning
ICE	U.S. Immigration and Customs Enforcement
ICS	Incident Command System
IHSC	ICE Health Service Corps
JIOC	Joint Intelligence Operations Center
MCM	Medical Countermeasure
MGMT	Directorate for Management (DHS)
MEFs	Mission Essential Functions
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NICCL	National Incident Communications Conference Line
NIOSH	National Occupational Safety and Health
NRF	National Response Framework
NOC	National Operations Center
OAFM	Office of Asset and Facility Management
OCAO	Office of the Chief Administrative Officer (DHS)
OCHCO	Office of the Chief Human Capital Officer (DHS)
OGC	Office of General Counsel (DHS)
OHA	Office of Health Affairs (DHS)
OLA	Office of Legislative Affairs (DHS)
OPA	Office of Public Affairs (DHS)
OPLAN	Operations Plan
OPS	Office of Operations Coordination and Planning (DHS)
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
POD	Point of Dispensing

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PPD	Presidential Policy Directive
PPE	Personal Protective Equipment
PWPP	Pandemic Workforce Protection Plan
SFO	Senior Field Official
SOP	Standard Operating Procedure

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GLOSSARY

For the purposes of this Plan, the following definitions shall apply:

Bacteria. Single-celled or noncellular spherical, spiral, or rod-shaped organisms lacking chlorophyll that reproduce by fission; important as pathogens and for biochemical properties.

Catastrophic Incident. Any natural or manmade incident, including terrorism that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions. A Catastrophic Incident could result in sustained nationwide impacts over a prolonged period of time; almost immediately exceeds resources normally available to State, local, tribal, territorial, and private sector authorities in the impacted area; and significantly interrupts governmental operations and emergency services to such an extent that national security could be threatened. These factors drive the urgency for coordinated national planning to ensure accelerated Federal and/or national assistance.

Component. Organization or office that is a member of the Department of Homeland Security (DHS) and under the direction and authorities of the Secretary of DHS. This includes both operational and support components of DHS (Management Directive 252-1).

Containment. Efforts undertaken to limit an outbreak to the affected location(s) and limit spread of the pandemic through aggressive attempts to contain.

Critical Contractors. Contractors who occupy positions and perform functions that are maintained under all circumstances to ensure the safety and security of the Nation and its citizens. The critical nature of these positions is inherent in the position description (e.g., securing the Nation's borders, protecting the Nation's transportation system, etc.). These contractors report for duty regardless of the emergency or operating status.

Critical Information Requirements. Information needed by senior executives to support situational awareness and formulate decisions within the context of expected operations.

Critical Infrastructure. Systems and assets, whether physical or virtual, so vital that the incapacity or destruction of such may have a debilitating impact on the security, economy, public health or safety, environment, or any combination of these matters, across Federal, State, regional, territorial, or local jurisdiction. They include publicly or privately controlled resources essential to the minimal operations of the economy and government.

Critical Infrastructure Partner. Federal, state, local, tribal or territorial government entities, public and private sector owners and operators and representative organizations, regional organizations and coalitions, academic and professional entities, and certain not-for-profit and private volunteer organizations that share in the responsibility for protecting the Nation's Critical Infrastructure.

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DHS Personnel. Full-time DHS employees and temporary and part-time DHS employees, including, but not limited to, summer hires, detailees from other agencies, interns, and fellows.

Emergency Use Authorizations (EUAs). Permit the Food and Drug Administration (FDA) Commissioner to authorize the use of an unapproved medical product or an unapproved use of an approved medical product. The FDA may issue an EUA in a number of scenarios, including when there is a public health emergency, or a significant potential for a public health emergency that affects or has a significant potential to affect, national security and involves a biological agent or agents, or a disease or condition that may be attributable to such agent or agents.

Emerging Infectious Disease. Infection that recently appeared within a population or whose incidence or geographic range is rapidly increasing or threatens to increase in the near future. It can be caused by: 1) previously undetected or unknown infectious agents; known agents that spread to new geographic locations or new populations; 3) previously known agents whose role in specific diseases went unrecognized; and/or 4) re-emergence of agents after the incidence of disease significantly declined, but reappears. This class of diseases is known as re-emerging infectious diseases.

Epidemic. Pronounced clustering of cases of disease within a short period of time; more generally, a disease whose frequency of occurrence is in excess of the expected frequency in the population during a given time interval.

Government Functions. The collective functions of the heads of executive departments and agencies as defined by statute, regulation, presidential direction, or other legal authority, and the functions of the legislative and judicial branches.

Human-to-Human Transmission. Occurs when a person contracts a disease from another person who has the same disease as opposed to contracting the disease directly from animals (birds, swine, insects, etc.) or the environment (soil, water).

Immunity. Process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease.

Infection. Invasion and multiplication of microorganisms in body tissues; an infectious disease.

Interagency. For the purposes of this Plan, the term "interagency" is used to refer to the Federal departments and agencies listed in Homeland Security Presidential Directive-*1* having a substantial role in homeland security.

Mission Essential Functions or MEFs. The essential functions directly related to accomplishing the department or agency's mission as set forth in its statutory or executive

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charter. Generally, MEFs are unique to each department or agency.

Medical Countermeasures (MCM). Use of pharmaceutical (e.g., vaccines, antibiotics, and antitoxins), non-pharmaceutical (e.g., ventilators, and U.S. Department of Health and Human Services (HHS)/FDA-approved devices such as surgical gowns, gloves, masks, and respirators intended for use by healthcare workers), and public health intervention (e.g., contact and transmission interventions, social distancing, and community shielding) methods to prevent and mitigate the effects of diseases. MCM include those drugs, biological products, and devices that meet the definitions of *qualified countermeasure* and *qualified pandemic or epidemic product* found in the *Public Health Service Act, as amended.* See 42 U.S.C. §§ 247d-6a(a)(2)(A), 247d-6b(i)(7).

Operations Plan. Plan that identifies detailed resources, personnel, and asset allocations in order to execute the objectives of the strategic plan and turn strategic priorities into operational execution. It contains a full description of the concept of operations, to include specific roles and responsibilities, tasks, integration, and actions required, with support function annexes, as appropriate.

Outbreak. An epidemic limited to localized increase in the incidence of disease (e.g., in a village, town, or closed institution); a cluster of cases of an infectious disease.

Pandemic. Worldwide epidemic when a new or novel virus, bacteria, or other pathogen emerges in which humans have little or no immunity and can be readily infected.

Pathogen. Agent causing disease or illness to its host, such as an organism or infectious particle capable of producing a disease in another organism.

Point of Dispensing. Specific locations that can be opened for the purpose of dispensing (distributing) medication or giving vaccinations to large populations in a public health emergency.

Preparedness. Range of deliberate, critical tasks and activities necessary to build, sustain, and improve operational capability to prevent, protect against, respond to, and recover from domestic incidents. Preparedness is a continuous process involving efforts at all levels of government and between government and private-sector and Non-Governmental Organizations to identify threats, determine vulnerabilities, and identify required resources.

Protection. Actions or measures taken to cover or shield from exposure, injury, or destruction. Protection safeguards citizens and their freedoms, critical infrastructure, property and the economy from acts of terrorism, natural disasters, or other emergencies.

Public Health Emergency Declaration. Declaration by the Secretary of HHS, upon the determination, after consultation with such public health officials as may be necessary, that (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists

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(Public Health Service Act 319). Following such a declaration, the Secretary may: (1) access the Public Health Emergency Fund (note that Congress has not made any appropriations to the Public Health Emergency Fund); (2) consistent with other authorities, make grants, provide awards for expenses, and enter into contracts, and conduct and support investigations; and (3) extend deadlines and waive sanctions for submission of data and reports.

Reassortant. 1) The mixing of genetic material specifically the exchange of whole RNA strands in viruses. 2) Viruses containing two or more pieces of genetic information from other viruses. Such viruses are produced in mammalian cells infected with more than one virus.

Response. Activities that address the short-term, direct effects of an incident. Response includes immediate actions to save lives, protect property, and meet basic human needs. Response also includes the execution of emergency operations plans and of incident mitigation activities designed to limit the loss of life, personal injury, property damage, and other unfavorable outcomes. As indicated by the situation, response activities include: applying intelligence and other information to lessen the effects or consequences of an incident; increased security operations; continuing investigations into the nature and source of the threat; ongoing public health and agricultural surveillance and testing processes; immunizations, isolation, or quarantine; and specific law enforcement operations aimed at preempting, interdicting, or disrupting illegal activity, and apprehending actual perpetrators and bringing them to justice.

Recovery. Development, coordination, and execution of service- and site-restoration plans; the reconstitution of government operations and services; individual, private- sector, non-governmental, and public assistance programs to promote restoration; long-term care and treatment of affected persons; additional measures for social, political, environmental, and economic restoration; evaluation of the incident to identify lessons learned; post-incident reporting; and development of initiatives to mitigate the effects of future incidents.

Standard Workplace Controls. Three primary types of workplace control measures (Engineering; Administrative; and Personnel Protective Equipment) that may be used to prevent infection and reduce the spread of disease in the workplace during a pandemic. The cumulative impact of utilizing all three control measures provides more protection than the application of any single control measure alone. However, the protection offered by effective engineering and/or administrative control measures is considered to have the greatest impact in minimizing exposure to infectious pathogens.

United States. All States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, any possession of the United States, and any waters within the jurisdiction of the United States.

Vaccine. Biological preparation used to establish or improve immunity to a particular disease by stimulating the production of antibodies.

Virus. Any of a large group of submicroscopic infective agents that are capable of growth and

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multiplication only in living cells, and cause various important diseases in humans, lower animals, or plants.

Workforce: ICE personnel, critical contractors with DHS badges, and working animals.

Workplace Controls: Control strategies and equipment used to reduce or prevent personnel exposure to a hazard. These consist of:

- *Engineering Controls*: measures used to remove a hazard or place a barrier between the worker and the hazard. Engineering controls can be highly effective in protecting workers and will typically be independent of worker actions to provide protection. Examples include structural, mechanical, or chemical controls, such as ventilation, barriers, and disinfection.
- *Administrative Controls*: measures aimed at reducing employee exposure to hazards through social controls or changes to work methods. Examples include procedure changes, training, telework, shift rotation/limitation, and social distancing.
- *Personal Protective Equipment*: equipment and/or clothing worn by an individual to mitigate risk, such as protective clothing, gloves, and respirators.

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ANNEX P: Employee Messaging

Purpose:

This annex is intended to be an internal communications guideline that incorporates employee messaging procedures and communications channel instructions to make sure actionable information is provided to ICE employees in the event of a public health emergency during a pandemic or in the wake of an emerging infectious disease threat. Communications must be consistent, clear and timely. In crisis situations, ensuring employees are informed is necessary for their well-being and helps foster their confidence in the agency and its leadership as it moves forward in recovery.

Guidance regarding providing the general public and media outlets with information is found in the DHS Domestic Communications Strategy document, a copy of which can be obtained by contacting the DHS Public Affairs Incident Communications staff. Due to the sensitive nature of the options in this strategy, it is restricted in distribution to senior Federal communications authorities. The ICE Office of Public Affairs (OPA) has been provided with this strategy and is well-versed in carrying out the tactics contained within.

Background:

In addition to the DHS requirement for a standard operating procedure for situational employee messaging in the event of a public health emergency, ICE is a large agency with several offices that share different aspects of internal communication roles and responsibilities. In the past, those roles and responsibilities have not always been clearly defined. When time is of the essence and lives are at stake, it is imperative that roles and responsibilities are clearly defined and messaging is pre-approved for quick release.

Roles and Responsibilities:

The table below depicts employee messaging roles and responsibilities for each office involved.

Office	Role	Responsibilities
ICE Director's Office	Final Approval	Approves all messages from the ICE Director or Deputy Director to ICE employees Communicates on a daily basis throughout the situation
ICE Crisis Action Team (CAT)	Lead	Organizes immediate crisis communication meetings with appropriate ICE offices

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Office	Role	Responsibilities
ICE OPA Internal Communications	Advisor, Writer/Editor, Distributer	Edits, gains approval and sends broadcast messages via email and can employ other communications channels, such as the ICE Communications Network digital signage and the ICE inSight intranet homepage
ICE EMU	Writer/Editor Distributor	Creates and sends messages through ENS via email, SMS or desktop alert
Other ICE Offices	SME, Providers of Information	Provides information and wording, if necessary, for employee messaging
ICE IHSC	Providers of Information	Provides information to those in ICE custody (See Annex I for details.)

Communications Time and Action Table:
The table below is intended to provide a quick reference in the event of a public health emergency for those in designated communications roles. In the event of a pandemic or in the wake of an emerging infectious disease threat, delivering clear and timely communication will further the containment of the disease and could save lives. Frequent communication from ICE senior leadership, especially the Director or Deputy Director, is of upmost importance during these situations and should be treated as a top priority by all parties responsible for distributing messages to employees.

Timeline	Action	Audience	Checklist/Template
Immediately upon threat confirmation	CAT convenes meeting to confirm messaging actions	Predetermined emergency communication POCs	☐ Confirm POC from each communication group and authority on subject matter expertise ☐ Set communication and reporting expectations ☐ Determine situational details, e.g., time, description of what happened, instructions for employees concerning work location, etc. ☐ Set future meeting cadence expectations for during and after the crisis
Immediately upon threat confirmation	ENS alert describing incident and informing that instructions will follow for those in affected areas	All employees in the affected areas	At approximately (time) _____, a confirmed case(s) of (describe what happened) _____ was reported (describe location) _____. We are currently assessing the situation. Please remain calm and stay alert. Further instructions will be forthcoming. (If immediate actions are

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Timeline	Action	Audience	Checklist/Template
			required of employees, e.g., shelter in place, replace last sentence with those instructions.)
Preferably within first 4 hours, no later than first 8 hours after confirmed threat	Broadcast message from ICE Director acknowledging threat	All ICE employees	At approximately (time) _____, a (brief description of what happened and where) _____ _____. The situation is (under) / (not yet under) control and we are working with (local, state, federal) authorities to (contain this situation, determine how this happened, determine what actions may be needed to prevent this from happening again). The ICE Crisis Action Team (CAT) has been activated. As the CAT continues gathering information, they will share that information with you via the Enterprise Notification System (ENS). Please respond to the ENS announcements as quickly as possible as they may contain instructions that are vital to your well-being. ENS messages will appear on your desktop, in your email and as SMS messages on your government-issued mobile phones. Your health and safety are my highest priority, and I encourage you to remain calm and follow instructions to the best of your ability. For more information about (type of threat) _____, click here (official link) _____. Please direct your questions to _____.
Immediately upon	ENS point of dispensing	POD team members	This is not a drill.

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Timeline	Action	Audience	Checklist/Template
POD activation	(POD) activation alert		Activate the POD in your area of responsibility immediately. The POD must be open within one hour. More details will follow as soon as possible. Respond with the appropriate number below. 1. Acknowledged
Shortly after 1st POD activation alert	ENS POD activation 2nd alert	POD team members	Emergency Activation of POD Staff All POD staff in LOCATION PLACED HERE must respond to their POD immediately. Report to the primary POD location unless the local POD Manager redirects you to an alternate POD site. This is not a drill. Respond with the appropriate number below. 1. Acknowledged and Responding to POD immediately 2. Acknowledged, but will have a delayed response to the POD 3. Acknowledged, but will be unable to respond to the POD
Immediately upon achieving POD readiness	ENS POD activation 3rd alert	All personnel in the area designated by S-1 or OHA CMO as infected by the bio-threat	This is an alert due to a public health emergency from a biological threat. All ICE personnel shall report to ADDRESS PLACED HERE immediately to receive medication. Respond with appropriate number below.

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Timeline	Action	Audience	Checklist/Template
			1. Acknowledged and en route
Every 24 hours until threat is resolved or whenever new, significant information is available	Broadcast message from ICE Director	All ICE employees	At approximately (time) _____, a (brief description of what we know now – if nothing new, then say that and explain why) _____ _____. Please continue to follow (reiterate OHC or OMB workplace instructions – telework, shelter in place, AOF) _____ until further notice.
Immediately upon threat resolution	ENS alert indicating threat resolution	All employees in the affected areas	The threat has now been resolved. Thank you for your cooperation. No further action is required.
Within 12 hours once threat is resolved	Broadcast message from ICE Director acknowledging threat	All ICE employees	At approximately (time) _____, the _____ (threat/situation) was resolved. (Give appropriate details.) _____ _____. I am proud of the quick and professional manner in which you responded to this threat. It is a testament to the advance planning and execution abilities of our employees, especially those with the responsibility of ensuring ICE's important mission is carried out without disruption regardless of circumstances. Thank you for all you do to keep our nation safe. Your tireless dedication does not go unnoticed.

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ANNEX R: REPORTING

This is a DHS Annex. The purpose of inserting it into the ICE PWPP is for quick reference concerning Department concerns regarding reporting.

The guidance below was provided by DHS Office of Policy.

PURPOSE
This annex provides reporting instructions on workplace controls, PPE, and MCM operations for all DHS Components and personnel covered under the PWPP.

REFERENCES

- DHS Pandemic Workforce Protection Plan (PWPP), 08 November 2013.
- Standard Operating Procedures for providing Anthrax Medical Countermeasures from Points of Dispensing Staffed by Non-Medical Personnel, DHS OHA, 20 June 2014.
- Immediate Pandemic Influenza Distribution Plan, 17 January 2014.

BACKGROUND
On November 8, 2013, acting Secretary Beers signed the PWPP. The PWPP included placeholder language for required content regarding MCM, Workplace Controls, and PPE requests and usage information that had yet to be developed when the PWPP was approved.

The DHS National Capital Region Consolidated Pandemic Workforce Protection Plan for Select DHS Support Components (NCR PWP Plan) was developed in 2014 based on the guidance established in the PWPP, and it includes detailed coordination and reporting instructions developed specifically for the Components participating in that plan.

This annex applies the concepts and processes developed for the entire Department via the PWPP.

CONCEPT OF OPERATION

Reporting Instructions:
Steady-state reporting will follow established MCM, PPE, and operations reporting processes and the timelines associated with each group such as the Pandemic Working Group, MCM Working Group, Continuity Working Group, Safety Council, as well as any applicable coordination body developed in the future. OHA/Component MCM MOUs provide the required guidance applicable to MCM reporting.

During steady-state, PPE inventory management and consumption will be reported through the Department's Asset Management System, Sunflower or Consolidated Asset Portfolio & Sustainability Information System (CAPSIS) monthly. For more detailed information, reference the Management Directorate Standard Operating Procedure (SOP) document.

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Crisis reporting will be unique to the type of report:

- The Enterprise Notification System may be the primary mode for crisis information conveyance. However, other modes are acceptable.
- MCM dispensing reports will be emailed by Component MCM program managers for the PODs serving facilities covered in this plan to the DHS/OHA MCM Program Manager and/or OHA NOC desk, depending on OHA guidance.
- During emerging infectious disease with pandemic potential or pandemic events, PPE inventory management and consumption will be reported through the use of the Department's Asset Management System, Sunflower or Consolidated Asset Portfolio & Sustainability Information System (CAPSIS) weekly. For more detailed information, reference the Management Directorate Standard Operating Procedure (SOP) document.
- Each change in phase during an emerging infectious disease with pandemic potential or pandemic event will elicit further guidance regarding what information must be provided in that phase.
- Consolidated reports developed by OHA and MGMT will be posted to the HSIN Pandemic collaboration page for inclusion in National-level reports.

Storage Reporting Instructions:
Component[1] sites that have medical oversight may be approved by OHA for medical storage and may request MCM for pre-positioning. DHS Components will be responsible for submitting Quarterly Inventory Reports to OHA observing established MCM Working Group procedures. These quarterly reports feature a range of data fields that OHA uses to manage this program. These fields include, for instance, key Component MCM personnel; the type of storage provided, storage temperature, and security accessibility information; number of PODs, dates when exercised; type and quantity of MCM and associated LOT numbers with expiration dates.

MCM/POD Reporting: During the period of MCM/POD activations, Component MCM program managers will provide daily, or as appropriate, status reporting, using the following link hosted on the DHS OHA Connect Site, which features a range of data fields gathered by OHA to manage this program in the event POD operations commence. The fields include: identification of Component/reporting employee/employee's contact data; address/ location/ time/date of POD activation; number and type medication dispensed if more than one medication provided; number persons receiving MCM vs number of persons POD intends to serve; any request for MCM resupply by type / quantity; and, if requested, a summary of any reports of serious, suspected adverse effects of administered /dispensed MCM containing no personally identifiable information (e.g. name or SSN).
http://dhsconnect.dhs.gov/org/comp/oha/whpomd/Pages/MedicalCounterMeasures.aspx.

[1] Per DHS Delegation 5001 and DHS ASHA/CMO Delegation 5002, USCG will align to this Annex through its specific policy to provide for the protection of its workforce.

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- The completed report will be submitted via email to the OHA Desk Officer (noc.oha@hq.dhs.gov) or calling 202-282-(b)(6); (b)(7)(C) located in the NOC and the DHS/OHA MCM Program Manager (MCMWorkingGroup@hq.dhs.gov).
- Further MCM/POD reporting guidance regarding recipients, timing and frequency will be provided in future updates and may be modified as required during an incident.

Workplace Controls/PPE: Reporting of Component workplace controls, including but not limited to PPE, will be conducted consistent with guidance provided by MGMT. During an emerging infectious disease or pandemic event, Component PPE Coordinators and safety officers will provide Situation Reports (SITREPs) to the MGMT Emergency Operations Center. Both MCM and Workplace Controls/PPE reporting will be posted to the HSIN Pandemic Page for situational awareness. Both MCM and Workplace Controls and PPE reporting will be posted to the HSIN Pandemic Page for further use.

Reporting Diagram: The reporting box in the diagram below depicts the pandemic reporting structure of PPE/WC and MCM/POD distribution and dispensing during emerging infectious disease with pandemic potential or pandemic event.

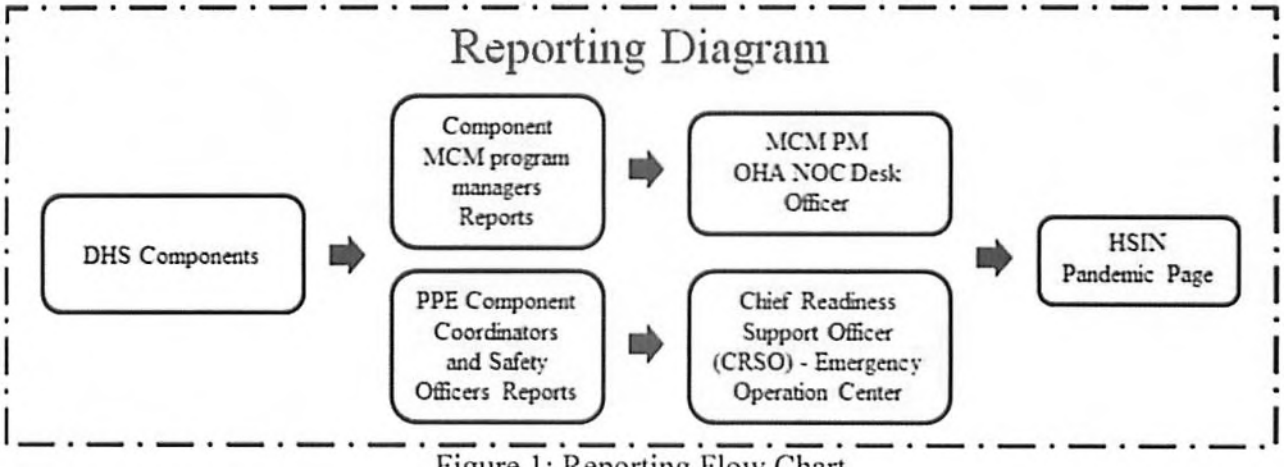

Figure 1: Reporting Flow Chart

Homeland Security Information Network Instructions (HSIN):
HSIN is the national mechanism used by all DHS Components to share information. DHS personnel responsible for pandemic preparedness and response are required via the PWPP to maintain and receive training on HSIN.

New HSIN Users:
New users require nomination and acceptance into one or more HSIN Communities of Interest (COIs). Access can be acquired by sending an email to HSIN.Outreach@hq.dhs.gov including; full name, email address, physical address, phone number, employer information, supervisor, supervisor's contact information, and COI access requests. The application will be reviewed by the sponsoring organization of the requested COI.

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After HSIN access has been verified and the user is nominated and invited to join HSIN, they will be asked to complete their registration and the identity proofing process. Finally, the account information will be reviewed by a validator who will confirm access to HSIN and the requested COIs. The user will be notified via email when their account is approved.

Current HSIN Users:
Current HSIN user requesting access to additional COIs can visit the Site Directory located in the HSIN Toolbox found in the upper right-hand corner of any HSIN screen. The Site Directory lists all active COIs on HSIN including their requirements for access as well as a Request Access link. This is the easiest way for current HSIN users to request access to other COIs.

For assistance with accounts or HSIN training, please contact the HSIN Help Desk at (866) 430-0162 or HSIN.HelpDesk@hq.dhs.gov.

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ANNEX T: Component Planning Checklist

This U.S. Immigration and Customs Enforcement (ICE) Pandemic Workforce Protection Plan (PWPP) *Annex T: Component Planning Checklist* will provide the confirmation that ICE has planned and prepared for a public health emergency due to an influenza pandemic or another significant viral outbreak.

PURPOSE

This annex provides the checklist with corresponding plan location reference and potential notes associated with each requirement.

Table 1: Component Planning Checklist

Requirement	Location of Requirement	Notes
Component plans should prepare the component to respond to: RFIs that involve providing real-time medical and health information to DHS leaders; RFAs that generate technical assistance to operations.	3.b.2), 3.b.2).h) – i), 3.c.2).g) – h), 3.c.5).b), 3.c.6), 3.c.8).b), 3.c.8).f), 3.c.8).f), 5.b.10), and Annexes P and R	ICE uses a CAT structure during a significant incident. Processing RFIs is a common practice for CATs.
Component plans should have a mechanism to integrate lessons learned from previous exercises/training, responses, and recommendations from OIG reports.	3.b.3).d), 3.c.2).m), 3.c.3).e), and 5.b.6)	
Component plans should include strategies and templates for: Scheduled/Situational Employee Messaging; Increased hygiene measures; Social Distancing measures; Expanded Telework Options; Disposition of people in DHS Custody; and MCM/PPE distribution	3.b.2).b), 3.b.2).i), 3.c.4).b), 3.c.5).b), 3.c.8).c)	
Component plans should include steps to develop, consolidate, establish frequency, and manage pandemic reporting requirements based on formats and guidance established in Annex R, Reporting	3.b.2), and Annexes E, P and R	ICE uses a CAT structure during a significant incident. Processing RFIs is a common practice for CATs.

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Component plans should include review of continuity plans' EFs and associated business processes, as appropriate and in coordination with the OPS Continuity Division	1.b.2) and 3.c.1).f)	The Continuity plan is a separate plan, but also addresses how to manage continuity during a pandemic. The business process analysis is conducted for continuity planning.
Component plans should address formal procedures for redeployment, demobilization of assets, and integration of lessons learned	3.b.3)	
Component plans are developed with readiness planning risk (based on an R2 influenza virus pandemic) for the workforce	1.f.6).a), 3.b.1).d), 3.b.2).k), and Annex E	
Component plans should prepare estimates of daily PPE needs and submit them to MGMT initially and every 2 years unless directed otherwise	Annex E	
Component plans should include strategies to integrate pandemic/emerging infectious disease into risk communications per DHS guidance - to include continuity readiness and coordination, as appropriate.	3.b.2) and Annex P	
Component plans should include Business Continuity, training programs, and staffing plans to accommodate for absenteeism	1.a, 2, 3.a.4), 3.b.1).a), 3.b.1).b)	See also the ICE Continuity Plan
Component plans should provide specific guidance for working animals, if applicable and service animals, if appropriate or when present	N/A	N/A
Component plans should enable internal operations centers and crisis action teams to integrate biological incidents (as covered by this Plan) into internal SOPs (to include structure to support long duration events)	1.b.2) and 3.b.2)	ICE uses a CAT structure during a significant incident. Processing RFIs is a common practice for CATs. See also the ICE continuity Plan.
Component plans adequately address all instructions in regards to continuity capabilities	1.b.2)	See ICE Continuity Plan ad ICE Crisis Action Plan.

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Component plans describe internal process to receive technical guidance from MGMT regarding: Conducting risk assessments; Establishing and maintaining proper respiratory protection programs, including medical clearance, training, and fit-testing personnel	1.f.6), 3.b.e), 3.c.4), 3.c.5).c) – e), and Annex E	
Component plans identify appropriate POD plans that are in place, which describe POD locations, POD staffing, and POD training	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax Operations Plan (OPLAN)
Component plans identify approved and implemented plans to receive and dispense antivirals at Component sites or PODs in accordance with the PEIDWPP and with POD training materials provided by OHA	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN
Component plans assign and identify training for POD team member roles.	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN
Component plans indicate POD plan exercise schedules for each Component POD location at least annually	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN
Component plans establish and implement the means to track which employees have received MCM	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN
Component plans provide security procedures, physical address, POC, cell phone number, and secondary POC to receive MCM shipment.	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), 4.a.3).a), and Annex D	See the ICE Anthrax OPLAN
Component plans identify sites that have medical oversight approved by OHA for medical storage and that are issued antivirals for prepositioning. Component plans identify responsibility for providing OHA with quarterly inventory reporting	First part N/A, and Annex D	ICE does not store antivirals at this time.
Component plans identify authorized Component personnel who will have 24/7 access to secured MCM in Component caches.	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN

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Component plans detail how tracking inventory of Component-held MCM caches will be maintained using DHS systems and who will be the point of contact to work closely with the MCM Work Group Program Managers at OHA	1.b.2), 1.f.e), 3.c.2).k), 3.c.3), and Annex D	See the ICE Anthrax OPLAN
Component plans assign roles and responsibilities to staff for PPE.	1.f.6), 3.b.2).k), 3.c.4), 3.c.5), 3.c.7).f), and Annex E	
Component plans describe coordination the component Occupational Safety and Health (OSH) manager will take to ensure OSHA compliance.	Annex E	
Component plans use PEIDP guidance to describe how to perform risk assessments.	Annex E	
Component plans identify types and quantities of PPE needed, based on EFs.	Annex E	
Component plans use mandatory DHS PPE Strategic Sourcing Contracts.	Annex E	
Component plans describe how the component will develop, implement, and maintain a mechanism to obtain and distribute any additional PPE items not currently included as part of the mandatory DHS PPE Strategic Contracts.	Annex E	
Component plans present a prepared and validated timeline for in-field availability of PPE.	Annex E	
Component plans follow guidance from the DHS PPE ILSP for acquiring, storing, and distributing PPE.	Annex E	
Component plans include procedures designed to enable personnel access to sufficient PPE to maintain EFs when PEIDP is activated	Annex E	
Component plans apply full requirements of 29 CFR 1910.134 Respiratory Protection, departmental respiratory protection program, and component respiratory protection programs for mandatory and voluntary respiratory use.	Annex E	
Component plans describe, with respect to DHS personnel, how the component will maintain all OSHA-required records related to PPE use, medical clearance, training, and fit-testing as appropriate for the type of PPE.	Annex E	

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Component plans include a mechanism to make component plans and risk assessments available to MGMT for review and amendment, as appropriate, to address changes in hazard level, procedures, tasks, or exposure information.	**Annex E**	

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Office of the Director

U.S. Department of Homeland Security
500 12th Street, SW
Washington, D.C. 20536

U.S. Immigration and Customs Enforcement

MEMORANDUM FOR: Daniel H. Ragsdale
Deputy Director

FROM: (b)(6); (b)(7)(C)
Acting Executive Associate Director
Management and Administration

SUBJECT: Authorization to Evacuate

This memorandum seeks approval to authorize the evacuation of U.S. Immigration and Customs Enforcement (ICE) employees and his/her dependents impacted by an emergency for the purpose of ensuring their safety for a period of time not to exceed 180 days.

This authorization is effective on August 1, 2015, however, valid, allowable expenses incurred prior to this date related to an official evacuation of employees and their dependents from an area impacted by an emergency may be retroactively approved by an ICE Executive Associate Director/Assistant Director or designee consistent with established authorities.

The Deputy Assistant Director of the National Emergency Management Division or designee will obtain approval from the Deputy Director to invoke this Authorization to Evacuate.

Authorization to Evacuate

1. I hereby grant the authority, effective August 1, 2015, to authorize the departure of ICE employees and dependents (evacuees) from the areas impacted by an emergency where there is a threat to personnel and their dependents safety. This authorized departure is approved for a period not to exceed 180 days. The authority for this evacuation order and associated payments is found at 5 C.F.R. §§ 550. 401-408. Additional guidance is contained in the ICE Policy on Emergency and Special Evacuation Allowances and the supporting procedures.

2. I hereby authorize ICE Executive Associate Directors/Assistant Directors or designee consistent with established authorities, effective August 1, 2015, to provide to evacuees advance payments, evacuation payments and special allowances including reimbursement for subsistence expenses, travel costs, and per diem for a period not to exceed 180 days.

3. I hereby authorize ICE managers to designate safe haven locations for all evacuees.

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4. I hereby inform evacuees that they should not return to their permanent duty stations until ICE authorizes their return.

5. ICE employees in travel status or on leave from their duty stations as of August 1, 2015, must contact their supervisor for instructions as to whether to return to their permanent duty stations or proceed to a safe haven location.

6. All employees recently assigned to a new permanent duty station and who are in transit status must contact their supervisor for instructions as to whether to proceed to the duty station, report to an alternative duty station, or proceed to a safe haven location. The decision to proceed will be made on a case-by-case basis by the employee's respective chain of command.

7. For purposes of this evacuation order, the following definitions apply:

   a. Dependent: A relative of the employee residing with the employee and dependent on the employee for support.

   b. Safe Haven: A designated area to which an employee or dependent will be or has been evacuated.

Daniel H. Ragsdale
Deputy Director
U.S. Immigration and Customs Enforcement

Date

FOR DISTRIBUTION TO ALL ICE PROGRAM HEADS

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Clinical Infectious Diseases Advance Access published August 10, 2016

Clinical Infectious Diseases

IDSA GUIDELINE

Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis

Payam Nahid,[1] Susan E. Dorman,[2] Narges Alipanah,[1] Pennan M. Barry,[3] Jan L. Brozek,[4] Adithya Cattamanchi,[1] Lelia H. Chaisson,[1] Richard E. Chaisson,[2] Charles L. Daley,[5] Malgosia Grzemska,[6] Julie M. Higashi,[7] Christine S. Ho,[8] Philip C. Hopewell,[1] Salmaan A. Keshavjee,[9] Christian Lienhardt,[6] Richard Menzies,[10] Cynthia Merrifield,[1] Masahiro Narita,[12] Rick O'Brien,[13] Charles A. Peloquin,[14] Ann Raftery,[1] Jussi Saukkonen,[15] H. Simon Schaaf,[16] Giovanni Sotgiu,[17] Jeffrey R. Starke,[18] Giovanni Battista Migliori,[11] and Andrew Vernon[8]

[1]University of California, San Francisco; [2]Johns Hopkins University, Baltimore, Maryland; [3]California Department of Public Health, Richmond; [4]McMaster University, Hamilton, Ontario, Canada; [5]National Jewish Health, Denver, Colorado; [6]World Health Organization, Geneva, Switzerland; [7]Tuberculosis Control Section, San Francisco Department of Public Health, California; [8]Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia; [9]Harvard Medical School, Boston, Massachusetts; [10]McGill University, Montreal, Quebec, Canada; [11]WHO Collaborating Centre for TB and Lung Diseases, Fondazione S. Maugeri Care and Research Institute, Tradate, Italy; [12]Tuberculosis Control Program, Seattle and King County Public Health, and University of Washington, Seattle; [13]Ethics Advisory Group, International Union Against TB and Lung Disease, Paris, France; [14]University of Florida, Gainesville; [15]Boston University, Massachusetts; [16]Department of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa; [17]University of Sassari, Italy; and [18]Baylor College of Medicine, Houston, Texas

The American Thoracic Society, Centers for Disease Control and Prevention, and Infectious Diseases Society of America jointly sponsored the development of this guideline for the treatment of drug-susceptible tuberculosis, which is also endorsed by the European Respiratory Society and the US National Tuberculosis Controllers Association. Representatives from the American Academy of Pediatrics, the Canadian Thoracic Society, the International Union Against Tuberculosis and Lung Disease, and the World Health Organization also participated in the development of the guideline. This guideline provides recommendations on the clinical and public health management of tuberculosis in children and adults in settings in which mycobacterial cultures, molecular and phenotypic drug susceptibility tests, and radiographic studies, among other diagnostic tools, are available on a routine basis. For all recommendations, literature reviews were performed, followed by discussion by an expert committee according to the Grading of Recommendations, Assessment, Development and Evaluation methodology. Given the public health implications of prompt diagnosis and effective management of tuberculosis, empiric multidrug treatment is initiated in almost all situations in which active tuberculosis is suspected. Additional characteristics such as presence of comorbidities, severity of disease, and response to treatment influence management decisions. Specific recommendations on the use of case management strategies (including directly observed therapy), regimen and dosing selection in adults and children (daily vs intermittent), treatment of tuberculosis in the presence of HIV infection (duration of tuberculosis treatment and timing of initiation of antiretroviral therapy), as well as treatment of extrapulmonary disease (central nervous system, pericardial among other sites) are provided. The development of more potent and better-tolerated drug regimens, optimization of drug exposure for the component drugs, optimal management of tuberculosis in special populations, identification of accurate biomarkers of treatment effect, and the assessment of new strategies for implementing regimens in the field remain key priority areas for research. See the full-text online version of the document for detailed discussion of the management of tuberculosis and recommendations for practice.

Keywords. *Mycobacterium tuberculosis*; HIV infections; antitubercular agents; case management; public health.

Received 4 June 2016; accepted 6 June 2016.

These guidelines were endorsed by the European Respiratory Society (ERS) and the US National Tuberculosis Controllers Association (NTCA). It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The sponsoring and endorsing societies consider adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.

Correspondence: P. Nahid, University of California, San Francisco, San Francisco General Hospital, Pulmonary and Critical Care Medicine, 1001 Potrero Ave, 5K1, San Francisco, CA 94110 (pnahid@ucsf.edu).

Clinical Infectious Diseases®

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DOI: 10.1093/cid/ciw376

EXECUTIVE SUMMARY

The American Thoracic Society (ATS), Centers for Disease Control and Prevention (CDC), and Infectious Diseases Society of America (IDSA) jointly sponsored the development of this guideline on the treatment of drug-susceptible tuberculosis, which is also endorsed by the European Respiratory Society (ERS) and the US National Tuberculosis Controllers Association (NTCA). This guideline provides recommendations on the clinical and public health management of tuberculosis in children and adults in settings in which mycobacterial cultures, molecular

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Table 1. Interpretation of "Strong" and "Conditional" Grading of Recommendations Assessment, Development, and Evaluation-Based Recommendations

Implications for:	Strong Recommendation	Conditional Recommendation
Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
Policy	The recommendation can be adopted as policy in most situations.	Policymaking will require substantial debate and involvement of various stakeholders.

Source: Grading of Recommendations Assessment, Development and Evaluation Working Group [1, 2].

and phenotypic drug susceptibility tests, and radiographic studies, among other diagnostic tools, are available on a routine basis. Nine PICO (population, intervention, comparators, outcomes) questions and associated recommendations, developed based on the evidence that was appraised using GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology [1, 2], are summarized below. A carefully selected panel of experts, screened for conflicts of interest, including specialists in pulmonary medicine, infectious diseases, pharmacokinetics, pediatrics, primary care, public health, and systematic review methodology were assembled and used GRADE methods to assess the certainty in the evidence (also known as the quality of evidence) and strength of the recommendations (see Supplementary Appendix A: Methods and Table 1). This executive summary is a condensed version of the panel's recommendations. Additional detailed discussion of the management of pulmonary and extrapulmonary tuberculosis is available in the full-text version of this guideline.

OBJECTIVES OF ANTITUBERCULOSIS THERAPY

Treatment of tuberculosis is focused on both curing the individual patient and minimizing the transmission of *Mycobacterium tuberculosis* to other persons, thus, successful treatment of tuberculosis has benefits both for the individual patient and the community in which the patient resides.

The objectives of tuberculosis therapy are (1) to rapidly reduce the number of actively growing bacilli in the patient, thereby decreasing severity of the disease, preventing death and halting transmission of *M. tuberculosis*; (2) to eradicate populations of persisting bacilli in order to achieve durable cure (prevent relapse) after completion of therapy; and (3) to prevent acquisition of drug resistance during therapy.

The decision to initiate combination chemotherapy for tuberculosis is based on clinical, radiographic, laboratory, patient, and public health factors (Figure 1). In addition, clinical judgment and the index of suspicion for tuberculosis are critical in making a decision to initiate treatment. For example, in patients (children and adults) who, based on these considerations, have a high likelihood of having tuberculosis or are seriously ill with a disorder suspicious for tuberculosis, empiric treatment with a 4-drug regimen (Tables 2 and 3) should be initiated promptly even before the results of acid-fast bacilli (AFB) smear microscopy, molecular tests, and mycobacterial culture are known.

Sixty-five years of investigation, including many clinical trials, have consistently supported the necessity of treating with multiple drugs to achieve these treatment objectives, minimize drug toxicity, and maximize the likelihood of treatment completion [3, 4]. The success of drug treatment, however, depends upon many factors, and numerous studies have found an increased risk of relapse among patients with signs of more extensive disease (ie, cavitation or more extensive disease on chest radiograph) [5–9], and/or slower response to treatment (ie, delayed culture conversion at 2–3 months) [4, 6, 10, 11].

ORGANIZATION AND SUPERVISION OF TREATMENT

Because of the public health implications of prompt diagnosis and effective treatment of tuberculosis, most low-incidence countries designate a government public health agency as legal authority for controlling tuberculosis [12, 13]. The optimal organization of tuberculosis treatment often requires the coordination of public and private sectors [14–16]. In most settings, a patient is assigned a public health case manager who assesses needs and barriers that may interfere with treatment adherence [17]. With active input from the patient and healthcare providers, the case manager, together with the patient, develops an individualized "case management plan" with interventions to address the identified needs and barriers [18–20] (see PICO Question 1 and Supplementary Appendix B, Evidence Profiles 1–3). The least restrictive public health interventions that are effective are used to achieve adherence, thereby balancing the rights of the patient and public safety. Given that tuberculosis treatment requires multiple drugs be given for several months, it is crucial that the patient be involved in a meaningful way in making decisions concerning treatment supervision and overall care. International standards have been developed that also emphasize the importance of using patient-centered approaches to the management of tuberculosis [14–16].

Key considerations when developing a case management plan include (1) improving "treatment literacy" by educating the

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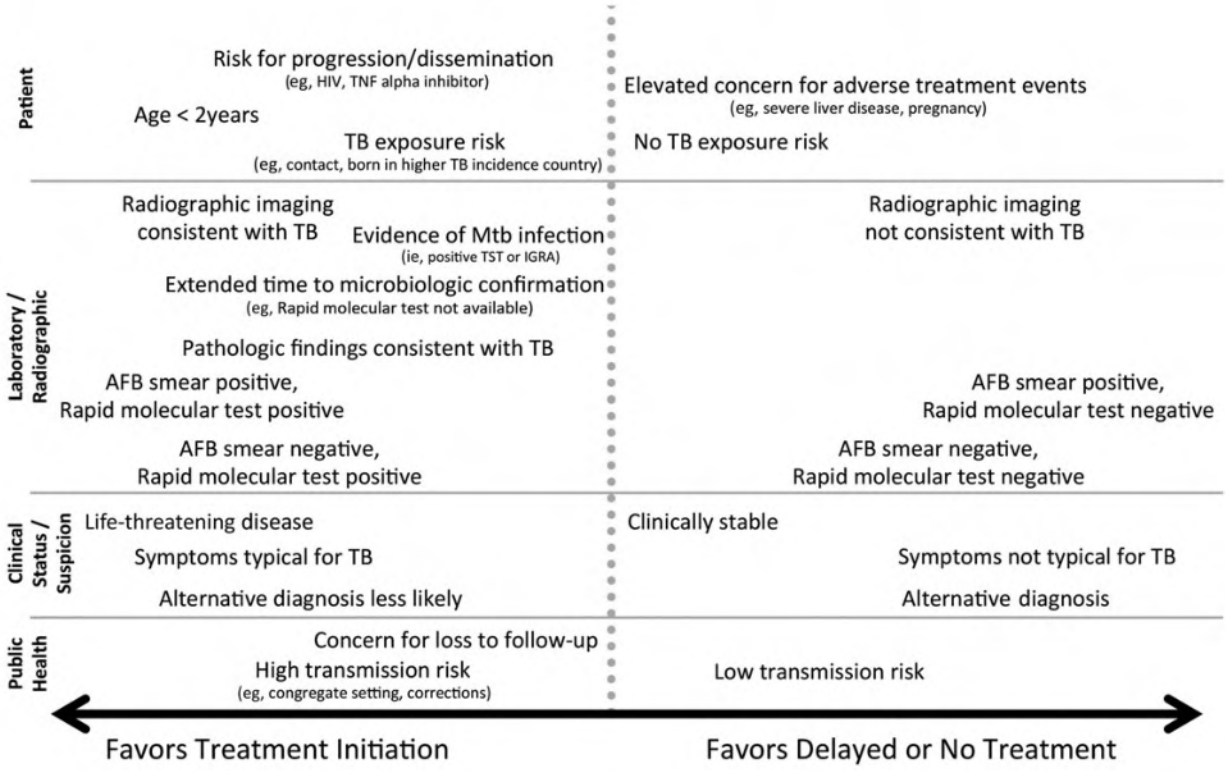

Figure 1. Factors to be considered in deciding to initiate treatment empirically for active tuberculosis (TB) (prior to microbiologic confirmation). Abbreviations: AFB, acid-fast bacilli; HIV, human immunodeficiency virus; IGRA, interferon-γ release assay; Mtb, *Mycobacterium tuberculosis*; TNF, tumor necrosis factor; TST, tuberculin skin test.

patient about tuberculosis and its treatment, including possible adverse effects [21, 22]; (2) discussing expected outcomes of treatment, specifically the ability to cure the patient of the disease; (3) reviewing methods of adherence support and plans for assessing response to therapy; and (4) discussing infectiousness and infection control measures using terminology that is appropriate to the culture, language, age, and reading level of the patient [23]. For non-English-speaking patients, the use of medical interpreter services is preferred over using family or friends as interpreters [24]. Relevant information should be reinforced at each visit. Other components of the case management plan include, but are not limited to, setting up patient reminders and systems to follow-up missed appointments [23, 25–29], use of incentives and enablers [30, 31], field and home visits [32], and integration and coordination of tuberculosis care with the patient's primary and specialty care (including mental health services, if appropriate and requested by the patient) (Table 4).

PICO Question 1: Does adding case management interventions to curative therapy improve outcomes compared to curative therapy alone among patients with tuberculosis? (Case management is defined as patient education/counseling, field/home visits, integration/coordination of care with specialists and medical home, patient reminders, and incentives/enablers).

Recommendation 1: We suggest using case management interventions during treatment of patients with tuberculosis *(conditional recommendation; very low certainty in the evidence).*

Given the critical importance of chemotherapy, both to the patient and to the public, approaches to ensuring adherence to the treatment regimen are a major focus of the overall management plan. To maximize completion of therapy, management strategies should utilize a broad range of approaches (see "Patient-Centered Care and Case Management" in the full-text version of the guideline). Among these, directly observed therapy (DOT), the practice of observing the patient swallow their antituberculosis medications, has been widely used as the standard of practice in many tuberculosis programs, and deserves special emphasis (see PICO Question 2 and Supplementary Appendix B, Evidence Profile 4). The systematic review conducted to obtain evidence in support of this practice guideline did not find any significant differences between self-administered therapy (SAT) and DOT when assessing several outcomes of interest, including mortality, treatment completion, and relapse. However, DOT was significantly associated with improved treatment success (the sum of patients cured and patients completing treatment) and with increased sputum smear conversion during treatment, as compared to SAT. Because DOT is a multifaceted public health intervention that is not amenable to the conventional clinical trial approaches to assessing benefits, and because participation in DOT can be advantageous for early recognition of adverse drug reactions and treatment irregularities, for allowing providers to establish

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Table 2. Drug Regimens for Microbiologically Confirmed Pulmonary Tuberculosis Caused by Drug-Susceptible Organisms

	Intensive Phase		Continuation Phase				
Regimen	Drug[a]	Interval and Dose[b] (Minimum Duration)	Drugs	Interval and Dose[b,c] (Minimum Duration)	Range of Total Doses	Comments[c,d]	Regimen Effectiveness
1	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk)	182–130	This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis.	Greater
2	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	110–94	Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve.	
3	INH RIF PZA EMB	3 times weekly for 24 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	78	Use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance.	
4	INH RIF PZA EMB	7 d/wk for 14 doses then twice weekly for 12 doses[e]	INH RIF	Twice weekly for 36 doses (18 wk)	62	Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	Lesser

Abbreviations: DOT, directly observed therapy; EMB, ethambutol; HIV, human immunodeficiency virus; INH, isoniazid; PZA, pyrazinamide; RIF, rifampin.

[a] Other combinations may be appropriate in certain circumstances; additional details are provided in the section "Recommended Treatment Regimens."

[b] When DOT is used, drugs may be given 5 days per week and the necessary number of doses adjusted accordingly. Although there are no studies that compare 5 with 7 daily doses, extensive experience indicates this would be an effective practice. DOT should be used when drugs are administered <7 days per week.

[c] Based on expert opinion, patients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy should receive a 7-month (31-week) continuation phase.

[d] Pyridoxine (vitamin B6), 25–50 mg/day, is given with INH to all persons at risk of neuropathy (eg, pregnant women; breastfeeding infants; persons with HIV; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or patients with advanced age). For patients with peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/day.

[e] See [426]. Alternatively, some US tuberculosis control programs have administered intensive-phase regimens 5 days per week for 15 doses (3 weeks), then twice weekly for 12 doses.

rapport with the patient and for addressing treatment complications expeditiously, DOT remains the standard of practice in the majority of tuberculosis programs in the United States [33–35] and Europe [15] (Table 5). To be consistent with the principles of patient-centered care noted previously, decisions regarding the use of DOT must be made in concert with the patient [14–16]. For example, DOT can be provided in the office, clinic, or in the "field" (patient's home, place of employment, school, or any other site that is mutually agreeable) by appropriately trained personnel [32].

PICO Question 2: Does self-administered therapy (SAT) have similar outcomes compared to directly observed therapy (DOT) in patients with various forms of tuberculosis?

Recommendation 2: We suggest using DOT rather than SAT for routine treatment of patients with all forms of tuberculosis *(conditional recommendation; low certainty in the evidence).*

RECOMMENDED TREATMENT REGIMENS

The preferred regimen for treating adults with tuberculosis caused by organisms that are not known or suspected to be drug resistant is a regimen consisting of an intensive phase of 2 months of isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol (EMB) followed by a continuation phase of 4 months of INH and RIF (see Tables 2, 3, 10, 11, and Supplementary Appendix C) [3, 36, 37]. The intensive phase of treatment consists of 4 drugs (INH, RIF, PZA, EMB) because of the current proportion of new tuberculosis cases worldwide caused by organisms that are resistant to INH [38–41]; however, if therapy is being initiated after drug susceptibility test results are known and the patient's isolate is susceptible to both INH and RIF, EMB is not necessary, and the intensive phase can consist of INH, RIF, and PZA only. EMB can be discontinued as soon as the results of drug susceptibility studies demonstrate that the isolate is susceptible to INH and RIF. Pyridoxine (vitamin B6) is given with INH to all persons at risk of neuropathy (eg, pregnant women; breastfeeding infants; persons infected with human immunodeficiency virus [HIV]; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or those who are of advanced age) [42, 43].

With respect to administration schedule, the preferred frequency is once daily for both the intensive and continuation phases (see PICO Questions 3 and 4 and Supplementary Appendix B, Evidence Profiles 5–11). Although administration of antituberculosis drugs using DOT 5 days a week has been reported in a large number of studies, it has not been compared with 7-day administration in a clinical trial. Nonetheless, on the basis of substantial clinical experience, experts believe that 5-days-a-week drug administration by DOT is an acceptable alternative to 7-days-a-week administration, and either approach

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Table 3. Doses[a] of Antituberculosis Drugs for Adults and Children[b]

Drug	Preparation	Population	Daily	Once-Weekly	Twice-Weekly	Thrice-Weekly
First-line drugs						
Isoniazid	Tablets (50 mg, 100 mg, 300 mg); elixir (50 mg/5 mL); aqueous solution (100 mg/mL) for intravenous or intramuscular injection. Note: Pyridoxine (vitamin B6), 25–50 mg/day, is given with INH to all persons at risk of neuropathy (eg, pregnant women; breastfeeding infants; persons with HIV; patients with diabetes, alcoholism, malnutrition, or chronic renal failure; or patients with advanced age). For patients with peripheral neuropathy, experts recommend increasing pyridoxine dose to 100 mg/d.	Adults	5 mg/kg (typically 300 mg)	15 mg/kg (typically 900 mg)	15 mg/kg (typically 900 mg)	15 mg/kg (typically 900 mg)
		Children	10–15 mg/kg	. . .	20–30 mg/kg	. . .[b]
Rifampin	Capsule (150 mg, 300 mg). Powder may be suspended for oral administration. Aqueous solution for intravenous injection.	Adults[c]	10 mg/kg (typically 600 mg)	. . .	10 mg/kg (typically 600 mg)	10 mg/kg (typically 600 mg)
		Children	10–20 mg/kg	. . .	10–20 mg/kg	. . .[b]
Rifabutin	Capsule (150 mg)	Adults[d]	5 mg/kg (typically 300 mg)	. . .	Not recommended	Not recommended
		Children	Appropriate dosing for children is unknown. Estimated at 5 mg/kg.			
Rifapentine	Tablet (150 mg film coated)	Adults		10–20 mg/kg[e]	. . .	. . .
		Children	Active tuberculosis: for children ≥12 y of age, same dosing as for adults, administered once weekly. Rifapentine is not FDA-approved for treatment of active tuberculosis in children <12 y of age.			
Pyrazinamide	Tablet (500 mg scored)	Adults	See Table 10	. . .	See Table 10	See Table 10
		Children	35 (30–40) mg/kg	. . .	50 mg/kg	. . .[b]
Ethambutol	Tablet (100 mg; 400 mg)	Adults	See Table 11	. . .	See Table 11	See Table 11
		Children[f]	20 (15–25) mg/kg	. . .	50 mg/kg	. . .[b]
Second-line drugs						
Cycloserine	Capsule (250 mg)	Adults[g]	10–15 mg/kg total (usually 250–500 mg once or twice daily)	There are inadequate data to support intermittent administration.		
		Children	15–20 mg/kg total (divided 1–2 times daily)			
Ethionamide	Tablet (250 mg)	Adults[h]	15–20 mg/kg total (usually 250–500 mg once or twice daily)	There are inadequate data to support intermittent administration.		
		Children	15–20 mg/kg total (divided 1–2 times daily)			
Streptomycin	Aqueous solution (1 g vials) for IM or IV administration.	Adults	15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.			
		Children	15–20 mg/kg [427]	. . .	25–30 mg/kg[i]	. . .
Amikacin/ kanamycin	Aqueous solution (500 mg and 1 g vials) for IM or IV administration.	Adults	15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function, including older patients, may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.			
		Children	15–20 mg/kg [427]	. . .	25–30 mg/kg[i]	. . .
Capreomycin	Aqueous solution (1 g vials) for IM or IV administration.	Adults	15 mg/kg daily. Some clinicians prefer 25 mg/kg 3 times weekly. Patients with decreased renal function, including older patients, may require the 15 mg/kg dose to be given only 3 times weekly to allow for drug clearance.			
		Children	15–20 mg/kg [427]	. . .	25–30 mg/kg[i]	. . .
Para-amino salicylic acid	Granules (4 g packets) can be mixed in and ingested with soft food (granules should not be chewed). Tablets (500 mg) are still available in some countries, but not in the United States. A solution for IV administration is available in Europe.	Adults	8–12 g total (usually 4000 mg 2–3 times daily)	There are inadequate data to support intermittent administration.		
		Children	200–300 mg/kg total (usually divided 100 mg/kg given 2 to 3 times daily)			
Levofloxacin	Tablets (250 mg, 500 mg, 750 mg); aqueous solution (500 mg vials) for IV injection.	Adults	500–1000 mg daily	There are inadequate data to support intermittent administration.		
		Children	The optimal dose is not known, but clinical data suggest 15–20 mg/kg [427]			

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Table 3 continued.

Drug	Preparation	Population	Daily	Once-Weekly	Twice-Weekly	Thrice-Weekly
Moxifloxacin	Tablets (400 mg); aqueous solution (400 mg/250 mL) for IV injection	Adults	400 mg daily	There are inadequate data to support intermittent administration.[j]		
		Children	The optimal dose is not known. Some experts use 10 mg/kg daily dosing, though lack of formulations makes such titration challenging. Aiming for serum concentrations of 3–5 μL/mL 2 h postdose is proposed by experts as a reasonable target.			

Abbreviations: FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; IM, intramuscular; INH, isoniazid; IV, intravenous.

[a] Dosing based on actual weight is acceptable in patients who are not obese. For obese patients (>20% above ideal body weight [IBW]), dosing based on IBW may be preferred for initial doses. Some clinicians prefer a modified IBW (IBW + [0.40 × (actual weight − IBW)]) as is done for initial aminoglycoside doses. Because tuberculosis drug dosing for obese patients has not been established, therapeutic drug monitoring may be considered for such patients.

[b] For purposes of this document, adult dosing begins at age 15 years or at a weight of >40 kg in younger children. The optimal doses for thrice-weekly therapy in children and adolescents have not been established. Some experts use in adolescents the same doses as recommended for adults, and for younger children the same doses as recommended for twice-weekly therapy.

[c] Higher doses of rifampin, currently as high as 35 mg/kg, are being studied in clinical trials.

[d] Rifabutin dose may need to be adjusted when there is concomitant use of protease inhibitors or nonnucleoside reverse transcriptase inhibitors.

[e] TBTC Study 22 used rifapentine (RPT) dosage of 10 mg/kg in the continuation phase of treatment for active disease [9]. However, RIFAQUIN and PREVENT TB safely used higher dosages of RPT, administered once weekly [164, 210]. Daily doses of 1200 mg RPT are being studied in clinical trials for active tuberculosis disease.

[f] As an approach to avoiding ethambutol (EMB) ocular toxicity, some clinicians use a 3-drug regimen (INH, rifampin, and pyrazinamide) in the initial 2 months of treatment for children who are HIV-uninfected, have no prior tuberculosis treatment history, are living in an area of low prevalence of drug-resistant tuberculosis, and have no exposure to an individual from an area of high prevalence of drug-resistant tuberculosis. However, because the prevalence of and risk for drug-resistant tuberculosis can be difficult to ascertain, the American Academy of Pediatrics and most experts include EMB as part of the intensive-phase regimen for children with tuberculosis.

[g] Clinicians experienced with using cycloserine suggest starting with 250 mg once daily and gradually increasing as tolerated. Serum concentrations often are useful in determining the appropriate dose for a given patient. Few patients tolerate 500 mg twice daily.

[h] Ethionamide can be given at bedtime or with a main meal in an attempt to reduce nausea. Clinicians experienced with using ethionamide suggest starting with 250 mg once daily and gradually increasing as tolerated. Serum concentrations may be useful in determining the appropriate dose for a given patient. Few patients tolerate 500 mg twice daily.

[i] Modified from adult intermittent dose of 25 mg/kg, and accounting for larger total body water content and faster clearance of injectable drugs in most children. Dosing can be guided by serum concentrations.

[j] RIFAQUIN trial studied a 6-month regimen. Daily isoniazid was replaced by daily moxifloxacin 400 mg for the first 2 months, followed by once-weekly doses of moxifloxacin 400 mg and RPT 1200 mg for the remaining 4 months. Two hundred twelve patients were studied (each dose of RPT was preceded by a meal of 2 hard-boiled eggs and bread). This regimen was shown to be noninferior to a standard daily administered 6-month regimen [164].

may be considered as meeting the definition of "daily" dosing. There are alternative regimens that are variations of the preferred regimen, which may be acceptable in certain clinical and/or public health situations (see "Other Regimens" and "Treatment in Special Situations" in the full-text version of the guideline).

PICO Question 3: Does intermittent dosing in the intensive phase have similar outcomes compared to daily dosing in the intensive phase for treatment of drug-susceptible pulmonary tuberculosis?

Recommendation 3a: We recommend the use of daily rather than intermittent dosing in the intensive phase of therapy for drug-susceptible pulmonary tuberculosis *(strong recommendation; moderate certainty in the evidence)*.

Recommendation 3b: Use of thrice-weekly therapy in the intensive phase (with or without an initial 2 weeks of daily therapy) may be considered in patients who are not HIV infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) *(conditional recommendation; low certainty in the evidence)*.

Recommendation 3c: In situations where daily or thrice-weekly DOT therapy is difficult to achieve, use of twice-weekly therapy after an initial 2 weeks of daily therapy may be considered for patients who are not HIV-infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) *(conditional recommendation; very low certainty in the evidence)*. Note: If doses are missed in a regimen using twice-weekly dosing, then therapy is equivalent to once weekly, which is inferior (see PICO Question 4).

Table 4. Possible Components of a Multifaceted, Patient-Centered Treatment Strategy

Enablers	Incentives
Interventions to assist the patient in completing therapy [130]	Interventions to motivate the patient, tailored to individual patient wishes and needs and, thus, meaningful to the patient [130]
Transportation vouchers [30]	Food stamps or snacks and meals [30]
Convenient clinic hours and locations [30]	Restaurant and grocery store coupons [30]
Clinic personnel who speak the languages of the populations served [428]	Assistance in finding or provision of housing [429]
Reminder systems and follow-up of missed appointments [28]	Clothing or other personal products [30]
Social service assistance (referrals for substance abuse treatment and counseling, housing, and other services) [429]	Books [428]
Outreach workers (bilingual/bicultural as needed; can provide many services related to maintaining patient adherence, including provision of directly observed therapy, follow-up on missed appointments, monthly monitoring, transportation, sputum collection, social service assistance, and educational reinforcement) [428]	Stipends [30]
Integration of care for tuberculosis with care for other conditions [428]	Patient contract [30]

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Table 5. Examples of Priority Situations for the Use of Directly Observed Therapy

Patients With the Following Conditions/Circumstances [17, 130, 137, 139, 430, 431]:
• Positive sputum smears
• Delayed culture conversion (sputum obtained at/after completion of intensive-phase therapy is culture-positive)
• Treatment failure
• Relapse
• Drug resistance
• Homelessness
• Current or prior substance abuse
• Use of intermittent dosing
• HIV infection
• Previous nonadherence to therapy
• Children and adolescents
• Mental, emotional or physical disability (ie, cognitive deficits such as dementia; neurological deficits; medically fragile patients; or patients with blindness or severe loss of vision)
• Resident at correctional or long-term care facility
• Previous treatment for active or latent tuberculosis

Abbreviation: HIV, human immunodeficiency virus.

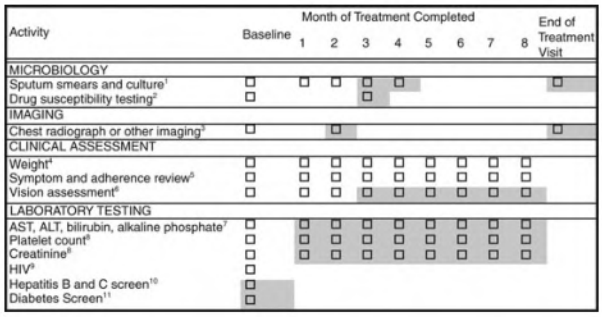

Figure 2. Baseline and follow-up evaluations for patients treated with first-line tuberculosis medications. Shading around boxes indicates activities that are optional or contingent on other information. [1]Obtain sputa for smear and culture at baseline, then monthly until 2 consecutive specimens are negative. Collecting sputa more often early in treatment for assessment of treatment response and at end of treatment is optional. At least one baseline specimen should be tested using a rapid molecular test. [2]Drug susceptibility for isoniazid, rifampin, ethambutol (EMB), and pyrazinamide should be obtained. Repeat drug susceptibility testing if patient remains culture positive after completing 3 months of treatment. Molecular resistance testing should be performed for patients with risk for drug resistance. [3]Obtain chest radiograph at baseline for all patients, and also at month 2 if baseline cultures are negative. End-of-treatment chest radiograph is optional. Other imaging for monitoring of extrapulmonary disease. [4]Monitor weight monthly to assess response to treatment; adjust medication dose if needed. [5]Assess adherence and monitor improvement in tuberculosis symptoms (eg, cough, fever, fatigue, night sweats) as well as development of medication adverse effects (eg, jaundice, dark urine, nausea, vomiting, abdominal pain, fever, rash, anorexia, malaise, neuropathy, arthralgias). [6]Patients on EMB: baseline visual acuity (Snellen test) and color discrimination tests, followed by monthly inquiry about visual disturbance and monthly color discrimination tests. [7]Liver function tests only at baseline unless there were abnormalities at baseline, symptoms consistent with hepatotoxicity develop, or for patients who chronically consume alcohol, take other potentially hepatotoxic medications, or have viral hepatitis or history of liver disease, human immunodeficiency virus (HIV) infection, or prior drug-induced liver injury. [8]Baseline for all patients. Further monitoring if there are baseline abnormalities or as clinically indicated. [9]HIV testing in all patients. CD4 lymphocyte count and HIV RNA load if positive. [10]Patients with hepatitis B or C risk factor (eg, injection drug use, birth in Asia or Africa, or HIV infection) should have screening tests for these viruses. [11]Fasting glucose or hemoglobin A1c for patients with risk factors for diabetes according to the American Diabetes Association including: age >45 years, body mass index >25 kg/m^2, first-degree relative with diabetes, and race/ethnicity of African American, Asian, Hispanic, American Indian/Alaska Native, or Hawaiian Native/Pacific Islander. Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase.

Recommended baseline and follow-up evaluations for patients suspected of having tuberculosis and treated with first-line medications are summarized in Figure 2. During treatment, a sputum specimen for AFB smear and culture are obtained at monthly intervals until 2 consecutive specimens are negative on culture. Duration of the continuation phase regimen hinges on the microbiological status at the end of the intensive phase of treatment; thus, obtaining sputum specimens at the time of completion of 2 months of treatment is critical if sputum culture conversion to negative has not already been documented. The culture result of a sputum specimen obtained at the completion of the intensive phase of treatment (2 months) has been shown to correlate with the likelihood of relapse after completion of treatment for pulmonary tuberculosis, albeit with low sensitivity [9, 44–46]. Cavitation on the initial chest radiograph has also been shown to be a risk factor for relapse [9, 47]. In patients treated for 6 months, having both cavitation and a positive culture at completion of 2 months of therapy has been associated with rates of relapse of approximately 20% compared with 2% among patients with neither factor [9, 45].

In view of this evidence, for patients who have cavitation on the initial chest radiograph and who have positive cultures at completion of 2 months of therapy, expert opinion is to extend the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy). Additional factors to be considered in deciding to prolong treatment in patients with either cavitation or a positive culture at 2 months (but not both) might include being >10% below ideal body weight; being an active smoker; having diabetes, HIV infection, or any other immunosuppressing condition; or having extensive disease on chest radiograph [46, 48–52].

Interruptions in therapy are common in the treatment of tuberculosis. When interruptions occur, the person responsible for supervision must decide whether to restart a complete course of treatment or simply to continue as intended originally. In general, the earlier the break in therapy and the longer its duration, the more serious the effect and the greater the need to restart treatment from the beginning (Table 6). Continuous treatment is more important in the intensive phase of therapy when the bacillary population is highest and the chance of developing drug resistance greatest. During the continuation phase, the number of bacilli is much smaller and the goal of therapy is to kill the persisting organisms. The duration of the interruption and the bacteriologic status of the patient prior to and after the

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Table 6. Management of Treatment Interruptions[a]

Time Point of Interruption	Details of Interruption	Approach
During intensive phase	Lapse is <14 d in duration	Continue treatment to complete planned total number of doses (as long as all doses are completed within 3 mo)
	Lapse is ≥14 d in duration	Restart treatment from the beginning
During continuation phase	Received ≥80% of doses and sputum was AFB smear negative on initial testing	Further therapy may not be necessary
	Received ≥80% of doses and sputum was AFB smear positive on initial testing	Continue therapy until all doses are completed
	Received <80% of doses and accumulative lapse is <3 mo in duration	Continue therapy until all doses are completed (full course), unless consecutive lapse is >2 mo If treatment cannot be completed within recommended time frame for regimen, restart therapy from the beginning (ie, restart intensive phase, to be followed by continuation phase)[b]
	Received <80% of doses and lapse is ≥3 mo in duration	Restart therapy from the beginning, new intensive and continuation phases (ie, restart intensive phase, to be followed by continuation phase)

Abbreviation: AFB, acid-fast bacilli.

[a] According to expert opinion, patients who are lost to follow-up (on treatment) and brought back to therapy, with interim treatment interruption, should have sputum resent for AFB smear, culture, and drug susceptibility testing.

[b] The recommended time frame for regimen, in tuberculosis control programs in the United States and in several European countries, is to administer all of the specified number of doses for the intensive phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months.

interruption are also important considerations (see "Interruptions in Therapy" in the full-text version of the guideline).

PICO Question 4: Does intermittent dosing in the continuation phase have similar outcomes compared to daily dosing in the continuation phase in patients with drug-susceptible pulmonary tuberculosis patients?

Recommendation 4a: We recommend the use of daily or thrice-weekly dosing in the continuation phase of therapy for drug-susceptible pulmonary tuberculosis *(strong recommendation; moderate certainty in the evidence)*.
Recommendation 4b: If intermittent therapy is to be administered in the continuation phase, then we suggest use of thrice-weekly instead of twice-weekly therapy *(conditional recommendation; low certainty in the evidence)*. This recommendation allows for the possibility of some doses being missed; with twice-weekly therapy, if doses are missed then therapy is equivalent to once weekly, which is inferior.
Recommendation 4c: We recommend against use of once-weekly therapy with INH 900 mg and rifapentine 600 mg in the continuation phase *(strong recommendation; high certainty in the evidence)*. In uncommon situations where more than once-weekly DOT is difficult to achieve, once-weekly continuation phase therapy with INH 900 mg plus rifapentine 600 mg may be considered for use only in HIV-uninfected persons without cavitation on chest radiography.

PRACTICAL ASPECTS OF TREATMENT

Guidance on the practical aspects of tuberculosis treatment, drug–drug interactions, therapeutic drug monitoring (TDM), and management of adverse effects are available in the full-text version of this guideline. In brief, mild adverse effects usually can be managed with treatment directed at controlling the symptoms; severe effects usually require the offending drug(s) to be discontinued, and may require expert consultation on management. If a drug is permanently discontinued, then a replacement drug, typically from a different drug class, is included in the regimen. Patients with severe tuberculosis often require the initiation of an alternate regimen during the time the offending drug(s) are held. In general, for complicated diagnostic or management situations, consultation with local and state health departments is advised. In the United States, the Centers for Disease Control and Prevention's Division of Tuberculosis Elimination funds tuberculosis regional training and medical consultation centers (http://www.cdc.gov/tb/education/rtmc/), which provide medical consultation to programs and health providers on management of tuberculosis. In Europe, the World Health Organization (WHO)/ERS Tuberculosis Consilium (https://www.tbconsilium.org) provides similar consultation services regarding the diagnosis and treatment of tuberculosis.

Gastrointestinal reactions are common, especially early in therapy [53]. The optimum approach to management of epigastric distress or nausea with tuberculosis drugs is not clear. To minimize symptoms, patients receiving SAT may take the medications at bedtime. Gastrointestinal intolerance not associated with hepatotoxicity can be treated with antacids, which have less impact on absorption or peak concentration of first-line drugs than administration with food [54]. Any combination of otherwise unexplained nausea, vomiting, and abdominal pain is evaluated with a physical examination and liver function tests, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, and alkaline phosphatase to assess for possible hepatotoxicity [55]. Drug-induced hepatitis is the most frequent serious adverse reaction to the first-line drugs. INH, RIF, and PZA can cause drug-induced liver injury (DILI), which is suspected when the ALT level is ≥3 times the upper limit of normal in the presence of hepatitis symptoms, or ≥5 the upper limit of normal in the absence of symptoms. In either situation, hepatotoxic drugs are stopped immediately and the patient is evaluated carefully. Other causes of abnormal liver function tests must be excluded before diagnosing drug-induced hepatotoxicity (Table 7). An official American Thoracic Society statement on the hepatotoxicity of antituberculosis

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Table 7. Other Causes of Abnormal Liver Function Tests That Should Be Excluded

Viral hepatitis (hepatitis A, B, and C in all patients; Epstein-Barr virus, cytomegalovirus, and herpes simplex in immunosuppressed patients)
Biliary tract disease
Alcohol
Other hepatotoxic drugs (eg, acetaminophen, acetaminophen-containing multiagent preparations, lipid-lowering agents, other drugs)
Select herbal and dietary supplements

Source: American Thoracic Society [56].

therapy (http://www.thoracic.org/statements/resources/mtpi/hepatotoxicity-of-antituberculosis-therapy.pdf) provides additional details on the management of tuberculosis in the setting of drug-induced liver injury, as well as suggestions on drug rechallenge [56]; however, the optimal approach to reintroducing tuberculosis treatment after hepatotoxicity is still not known [57, 58].

TREATMENT IN SPECIAL SITUATIONS

Detailed recommendations on the management of tuberculosis in special situations (HIV infection, extrapulmonary tuberculosis, culture-negative pulmonary tuberculosis, advanced age, children, tuberculosis during pregnancy and breastfeeding, renal disease, and hepatic disease, among others) are available in the full-text version of this guideline. Five PICO questions with summary recommendations pertinent to the management of tuberculosis in HIV patients, steroid use in pericardial or meningeal tuberculosis, and culture-negative tuberculosis are summarized below.

HIV Infection

Treatment of tuberculosis in patients with HIV infection has several important differences compared with treatment of patients who do not have HIV infection. The need for antiretroviral therapy (ART), the potential for drug–drug interactions, especially between the rifamycins and antiretroviral agents (Table 8), paradoxical reactions that may be interpreted as clinical worsening, and the potential for developing resistance to rifamycins when using intermittent tuberculosis therapy are some of these differences. Detailed information on these topics is provided in the full-text version of this practice guideline. In regard to duration of treatment for drug-susceptible pulmonary tuberculosis in the presence of HIV infection, our updated systematic review of randomized trials and cohort studies comparing various durations of tuberculosis therapy (6 months vs 8 months or longer), most of which were conducted prior to the era of highly active ART, showed that the risk of recurrence is lower when the continuation phase of treatment is extended. However, it is important to note that the majority of these studies were reports on nonrandomized cohorts, most were completed prior to the era of routine antiretroviral use, many tested intermittent regimens and few distinguished between reinfection and relapse (see "HIV Infection" in the full-text version of the guideline). As discussed below, based on data that show significant reductions in mortality and AIDS-defining illnesses, patients with HIV infection and tuberculosis should receive ART in conjunction with daily antituberculosis medications. For HIV-infected patients receiving ART, we suggest using the standard 6-month daily regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF for the treatment of drug-susceptible pulmonary tuberculosis. In the uncommon situation in which an HIV-infected patient does not receive ART during tuberculosis treatment, we suggest extending the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy) for treatment of drug-susceptible pulmonary tuberculosis (see PICO Question 5 and Supplementary Appendix B, Evidence Profile 12). As is noted for drug-susceptible pulmonary tuberculosis in patients without HIV coinfection, the continuation phase is extended in specific situations that are known to increase risk for relapse, as well as for selected extrapulmonary sites of disease, namely tuberculous meningitis, and bone, joint, and spinal tuberculosis (see "Identification and Management of Patients at Increased Risk of Relapse" and "Extrapulmonary Tuberculosis" in the full-text version of the guideline).

PICO Question 5: Does extending treatment beyond 6 months improve outcomes compared to the standard 6-month treatment regimen among pulmonary tuberculosis patients coinfected with HIV?

Recommendation 5a: For HIV-infected patients receiving ART, we suggest using the standard 6-month daily regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF for the treatment of drug-susceptible pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence)*.

Recommendation 5b: In uncommon situations in which HIV-infected patients do NOT receive ART during tuberculosis treatment, we suggest extending the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy) for treatment of drug-susceptible pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence)*.

Use of intermittent tuberculosis treatment regimens in HIV-infected patients has been associated with high rates of relapse and the emergence of drug resistance [9, 59]. In a trial of rifabutin (RFB)–based antituberculosis therapy in combination with antiretroviral drugs, patients treated with twice-weekly RFB had a relapse rate of 5.3%, but 8 of 9 patients with relapse had acquired rifamycin resistance [60]. Relapse and resistance were associated with low CD4 lymphocyte counts, as all recurrences occurred in patients with baseline CD4 lymphocyte counts <100 cells/μL. In the pharmacokinetic substudy of the trial, lower plasma concentrations of RFB and INH were identified as key risk factors for acquiring rifamycin resistance [61]. More recently, the use of a thrice-weekly RIF-based regimen during the intensive and continuation phases of treatment was associated with a higher rate of relapse and emergence of

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Table 8. Clinically Significant Drug–Drug Interactions Involving the Rifamycins[a]

Drug Class	Drugs Whose Concentrations Are Substantially Decreased by Rifamycins	Comments
Antiretroviral agents	HIV-1 protease inhibitors (lopinavir/ritonavir, darunavir/ritonavir, atazanavir, atazanavir/ritonavir)	RFB preferred with protease inhibitors. For ritonavir-boosted regimens, give RFB 150 mg daily. Double-dose lopinavir/ritonavir can be used with RIF but toxicity increased. Do not use RIF with other protease inhibitors.
	NNRTIs Nevirapine Efavirenz Rilpivirine Complera (fixed-dose combination tablet containing emtricitabine, rilpivirine, TDF) Etravirine	RIF decreases exposure to all NNRTIs. If nevirapine is used with RIF, lead-in nevirapine dose of 200 mg daily should be omitted and 400 mg daily nevirapine dosage given. With RIF, many experts advise that efavirenz be given at standard dosage of 600 mg daily, although FDA recommends increasing efavirenz to 800 mg daily in persons >60 kg. In young children double-dose lopinavir/ritonavir given with RIF results in inadequate concentrations – super-boosted Lopinavir/ritonavir is advised (if available) by some experts. Rilpivirine and etravirine should not be given with RIF. RFB can be used with nevirapine and etravirine at usual dosing. Efavirenz and RFB use requires dose increase of RFB to 600 mg daily, as such RIF is preferred. Rilpivirine should not be given with RFB.
	INSTIs Raltegravir Dolutegravir Elvitegravir (coformulated with cobicistat, tenofovir and emtricitabine as Stribild) Genvoya (fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)	Increase dose of raltegravir to 800 mg twice daily with RIF, although clinical trial data show similar efficacy using 400 mg twice daily. Dolutegravir dose should be increased to 50 mg every 12 h with RIF. Do not use RIF with elvitegravir. RFB can be used with all INSTIs.
	CCR5 inhibitors Maraviroc	RIF should not be used with maraviroc. RFB can be used with maraviroc.
Anti-infectives	Macrolide antibiotics (azithromycin, clarithromycin, erythromycin)	Azithromycin has no significant interaction with rifamycins. Coadministration of clarithromycin and RFB results in significant bidirectional interactions that can increase RFB to toxic levels increasing the risk of uveitis. Erythromycin is a CYP3A4 substrate and clearance may increase in setting of rifamycin use.
	Doxycycline	May require use of a drug other than doxycycline.
	Azole antifungal agents (ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, isavuconazole)	Itraconazole, ketoconazole, and voriconazole concentrations may be subtherapeutic with any of the rifamycins. Fluconazole can be used with rifamycins, but the dose of fluconazole may have to be increased.
	Atovaquone	Consider alternate form of *Pneumocystis jirovecii* treatment or prophylaxis.
	Chloramphenicol	Consider an alternative antibiotic.
	Mefloquine	Consider alternate form of malaria prophylaxis.
Hormone therapy	Ethinylestradiol, norethindrone	Women of reproductive potential on oral contraceptives should be advised to add a barrier method of contraception when on a rifamycin.
	Tamoxifen	May require alternate therapy or use of a non-rifamycin-containing regimen.
	Levothyroxine	Monitoring of serum TSH recommended; may require increased dose of levothyroxine.
Narcotics	Methadone	RIF and RPT use may require methadone dose increase. RFB infrequently causes methadone withdrawal.
Anticoagulants	Warfarin	Monitor prothrombin time; may require 2- to 3-fold warfarin dose increase.
Immunosuppressive agents	Cyclosporine, tacrolimus	RFB may allow concomitant use of cyclosporine and a rifamycin; monitoring of cyclosporine and tacrolimus serum concentrations may assist with dosing.
	Corticosteroids	Monitor clinically; may require 2- to 3-fold increase in corticosteroid dose.
Anticonvulsants	Phenytoin, lamotrigine	TDM recommended; may require anticonvulsant dose increase.
Cardiovascular agents	Verapamil, nifedipine, diltiazem (a similar interaction is also predicted for felodipine and nisoldipine)	Clinical monitoring recommended; may require change to an alternate cardiovascular agent.
	Propranolol, metoprolol	Clinical monitoring recommended; may require dose increase or change to an alternate cardiovascular drug.
	Enalapril, losartan	Monitor clinically; may require a dose increase or use of an alternate cardiovascular drug.
	Digoxin (among patients with renal insufficiency), digitoxin	TDM recommended; may require digoxin or digitoxin dose increase.
	Quinidine	TDM recommended; may require quinidine dose increase.
	Mexiletine, tocainide, propafenone	Clinical monitoring recommended; may require change to an alternate cardiovascular drug.
Theophylline	Theophylline	TDM recommended; may require theophylline dose increase.
Sulfonylurea hypoglycemics	Tolbutamide, chlorpropamide, glyburide, glimepiride, repaglinide	Monitor blood glucose; may require dose increase or change to an alternate hypoglycemic drug.
Hypolipidemics	Simvastatin, fluvastatin	Monitor hypolipidemic effect; may require use of an alternate antihyperlipidemic drug.

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Table 8 continued.

Drug Class	Drugs Whose Concentrations Are Substantially Decreased by Rifamycins	Comments
Psychotropic drugs	Nortriptyline	TDM recommended; may require dose increase or change to alternate psychotropic drug.
	Haloperidol, quetiapine	Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.
	Benzodiazepines (eg, diazepam, triazolam), zolpidem, buspirone)	Monitor clinically; may require a dose increase or use of an alternate psychotropic drug.

Abbreviations: CCR5, C chemokine receptor type 5; CYP, cytochrome P450; FDA, US Food and Drug Administration; HIV, human immunodeficiency virus; INSTI, integrase strand transfer inhibitor; NNRTI, nonnucleoside reverse transcriptase inhibitor; RFB, rifabutin; RIF, rifampin; RPT, rifapentine; TDF, tenofovir disoproxil fumarate; TDM, therapeutic drug monitoring; TSH, thyroid-stimulating hormone.

[a] See the following useful websites for updated information regarding drug interactions: AIDSinfo, Centers for Disease Control and Prevention, University of California San Francisco, University of Liverpool, Indiana University, and University of Maryland.

rifamycin resistance in HIV-infected individuals not receiving antiretrovirals compared with HIV-infected patients also receiving antiretrovirals or HIV-uninfected patients [62]. Based in part on systematic reviews conducted to obtain evidence in support of this guideline, our expert opinion is that treatment of HIV-related tuberculosis be given daily in both the intensive and continuation phases to avoid recurrent disease and the emergence of rifamycin resistance (see "Recommended Treatment Regimens" in the full-text version of the guideline).

Mortality among patients with HIV and tuberculosis is high, principally due to complications of immunosuppression and occurrence of other HIV-related opportunistic diseases. Cotrimoxazole (trimethoprim-sulfamethoxazole) prophylaxis has been shown to reduce morbidity and mortality in HIV-infected patients with newly diagnosed tuberculosis [63–65]. Whereas cotrimoxazole is recommended by WHO for all HIV-infected people with active tuberculosis disease regardless of the CD4 cell count [66], in high-income countries, co-trimoxazole is primarily used in HIV-infected patients with CD4 counts <200 cells/μL [67]. The use of ART during tuberculosis treatment in persons with HIV infection also reduces mortality rates significantly and decreases the risk of developing AIDS-related conditions. We performed a systematic review and meta-analysis to address the concurrent initiation of ART with tuberculosis treatment. On the basis of high certainty in the evidence that the benefits outweigh the harms, we recommend that patients with tuberculosis and HIV infection receive ART during antituberculosis treatment. ART should ideally be started within 2 weeks for those patients with a CD4 count <50 cells/μL and by 8–12 weeks for those with a CD4 count ≥50 cells/μL (see PICO Question 6 and Supplementary Appendix B, Evidence Profile 13). An exception is HIV-infected patients with tuberculous meningitis, in whom ART is not initiated in the first 8 weeks of antituberculosis therapy (see full-text version of the guideline). The concurrent administration of antiretrovirals and rifamycins is a major therapeutic challenge, and additional details on the coadministration of these medications, including the use of RFB, are available in the full-text version of this guideline.

PICO Question 6: Does initiation of ART during tuberculosis treatment compared to at the end of tuberculosis treatment improve outcomes among tuberculosis patients coinfected with HIV?

Recommendation 6: We recommend initiating ART during tuberculosis treatment. ART should ideally be initiated within the first 2 weeks of tuberculosis treatment for patients with CD4 counts <50 cells/μL and by 8–12 weeks of tuberculosis treatment initiation for patients with CD4 counts ≥50 cells/μL *(strong recommendation; high certainty in the evidence)*. Note: an exception is patients with HIV infection and tuberculous meningitis (see Immune Reconstitution Inflammatory Syndrome).

Patients with HIV infection and tuberculosis are at increased risk of developing paradoxical worsening of symptoms, signs, or clinical manifestations of tuberculosis after beginning antituberculosis and antiretroviral treatments. These reactions presumably develop as a consequence of reconstitution of immune responsiveness brought about by ART, and are designated as the immune reconstitution inflammatory syndrome (IRIS). Tuberculosis IRIS has been noted to be more common in participants with earlier ART initiation and $CD4^+$ cell counts <50 cells/μL [68]. Signs of IRIS may include high fevers, worsening respiratory symptoms, increase in size and inflammation of involved lymph nodes, new lymphadenopathy, expanding central nervous system lesions, worsening of pulmonary parenchymal infiltrations, new or increasing pleural effusions, and development of intra-abdominal or retroperitoneal abscesses [69]. Such findings are attributed to IRIS only after excluding other possible causes, especially tuberculosis treatment failure from drug-resistant tuberculosis or another opportunistic disease, such as non-Hodgkin lymphoma or infection.

Management of IRIS is symptomatic. Based on expert opinion, for most patients with mild IRIS, tuberculosis and antiretroviral therapies can be continued with the addition of anti-inflammatory agents such as ibuprofen. For patients with worsening pleural effusions or abscesses, drainage may be necessary. For more severe cases of IRIS, treatment with corticosteroids is effective. In a placebo-controlled trial of prednisone for patients with moderate IRIS, prednisone 1.25 mg/kg/day significantly reduced the need for hospitalization or surgical

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procedures [70]. For patients who develop IRIS, prednisone may be given at a dose of 1.25 mg/kg/day (50–80 mg/day) for 2–4 weeks, with tapering over a period of 6–12 weeks or longer.

Tuberculous Pericarditis

Based on small studies that have shown mortality and morbidity benefits [71–73], corticosteroids have previously been universally recommended in combination with a standard 6-month regimen (Table 2) for treating tuberculosis pericarditis; however, a recent placebo-controlled randomized clinical trial with 1400 participants did not find a difference in the combined primary endpoint of the trial, which included mortality, cardiac tamponade, or constrictive pericarditis, between patients treated with adjunctive corticosteroids vs placebo [74]. A subgroup analysis, however, did suggest a benefit in preventing constrictive pericarditis. Similarly, a systematic review conducted to obtain evidence in support of this guideline did not find a statistically significant benefit in terms of mortality or constrictive pericarditis from the use of corticosteroids [71–75]. Therefore, we suggest that adjunctive corticosteroids should not be used routinely in the treatment of patients with pericardial tuberculosis (see PICO Question 7 and Supplementary Appendix B, Evidence Profile 14). However, selective use of corticosteroids in patients who are at the highest risk for inflammatory complications might be appropriate. Such patients might include those with large pericardial effusions, those with high levels of inflammatory cells or markers in pericardial fluid, or those with early signs of constriction [76].

PICO Question 7: Does the use of adjuvant corticosteroids in tuberculous pericarditis provide mortality and morbidity benefits?

Recommendation 7: We suggest initial adjunctive corticosteroid therapy not be routinely used in patients with tuberculous pericarditis *(conditional recommendation; very low certainty in the evidence).*

Tuberculous Meningitis

Chemotherapy for tuberculous meningitis is initiated with INH, RIF, PZA, and EMB in an initial 2-month phase. After 2 months of 4-drug therapy, for meningitis known or presumed to be caused by susceptible strains, PZA and EMB may be discontinued, and INH and RIF continued for an additional 7–10 months, although the optimal duration of chemotherapy is not defined. Based on expert opinion, repeated lumbar punctures should be considered to monitor changes in cerebrospinal fluid cell count, glucose, and protein, especially early in the course of therapy. In children with tuberculous meningitis, the American Academy of Pediatrics (AAP) lists an initial 4-drug regimen composed of INH, RIF, PZA, and ethionamide, if possible, or an aminoglycoside, followed by 7–10 months of INH and RIF as the preferred regimen [77]. There are no data from controlled trials to guide the selection of EMB vs an injectable or ethionamide as the fourth drug for tuberculosis meningitis [78]. Most societies and experts recommend the use of either an injectable or EMB. For adults, based on expert opinion, our guideline committee prefers using EMB as the fourth drug in the regimen for tuberculous meningitis.

The role of adjunctive corticosteroid therapy in the treatment of tuberculous meningitis has been reported by numerous studies [79–91], and our updated systematic review found a mortality benefit from the use of adjuvant corticosteroids. Therefore, we recommend adjunctive corticosteroid therapy with dexamethasone or prednisolone tapered over 6–8 weeks for patients with tuberculous meningitis (see PICO Question 8 and Supplementary Appendix B, Evidence Profile 15).

PICO Question 8: Does the use of adjuvant corticosteroids in tuberculous meningitis provide mortality and morbidity benefits?

Recommendation 8: We recommend initial adjunctive corticosteroid therapy with dexamethasone or prednisolone tapered over 6–8 weeks for patients with tuberculous meningitis *(strong recommendation; moderate certainty in the evidence).*

Culture-Negative Pulmonary Tuberculosis in Adults

Failure to isolate *M. tuberculosis* from appropriately collected sputum specimens in persons who, because of clinical or radiographic findings, are suspected of having pulmonary tuberculosis does not exclude a diagnosis of active tuberculosis. Some causes of failure to isolate organisms include low bacillary populations, inadequate sputum specimens, temporal variations in the number of expelled bacilli, overgrowth of cultures with other microorganisms, and errors in specimen processing [92]. Alternative diagnoses must be considered and appropriate diagnostic studies undertaken in patients who appear to have culture-negative tuberculosis. At a minimum, patients suspected of having pulmonary tuberculosis have 2 sputum specimens (using sputum induction with hypertonic saline if necessary) for AFB smears and cultures for mycobacteria or for rapid molecular testing for *M. tuberculosis* as part of the diagnostic evaluation. Other diagnostic procedures, such as bronchoscopy with bronchoalveolar lavage and biopsy, are considered before making a presumptive diagnosis of culture-negative tuberculosis.

Patients who, on the basis of careful clinical and radiographic evaluation, are thought to have pulmonary tuberculosis should have treatment initiated with INH, RIF, PZA, and EMB even when the initial sputum smears are negative. If *M. tuberculosis* is isolated in culture or a rapid molecular test is positive, treatment for active disease is continued for a full, standard 6-month course (Table 2), if appropriate based on drug susceptibility test results. Patients who have negative cultures but who still are presumed to have pulmonary tuberculosis should have thorough clinical and radiographic follow-up after 2–3 months of therapy [93]. If there is clinical or radiographic improvement and no other etiology is identified, treatment should be continued.

The optimum treatment regimens and duration for smear-negative, culture-negative tuberculosis have not been convincingly established. We performed a systematic review that evaluated treatment regimens of varying durations in adult patients with

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culture-negative, paucibacillary tuberculosis, and we suggest that a 4-month treatment regimen is adequate for smear-negative, culture-negative pulmonary tuberculosis (see PICO Question 9 and Supplementary Appendix B, Evidence Profile 16). Operationally, treatment is initiated with an intensive phase of INH, RIF, PZA, and EMB daily and continued even when the initial bacteriologic studies are negative. If all cultures on adequate samples are negative (defining culture-negative tuberculosis) and there is clinical or radiographic response after 2 months of intensive phase therapy, the continuation phase with INH and RIF can be shortened to 2 months. Alternatively, if there is concern about the adequacy of workup or the accuracy of the microbiologic evaluations, a standard 6-month regimen remains preferred (see Table 2 and "Culture-Negative Pulmonary Tuberculosis" in the full-text version of the guideline) [14, 15].

PICO Question 9: Does a shorter duration of treatment have similar outcomes compared to the standard 6-month treatment duration among HIV-uninfected patients with paucibacillary tuberculosis (ie, smear negative, culture negative)?

Recommendation 9: We suggest that a 4-month treatment regimen is adequate for treatment of HIV-uninfected adult patients with AFB smear- and culture-negative pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence).*

CONCLUSIONS

Treatment of tuberculosis is focused on both curing the individual patient and minimizing the transmission of *M. tuberculosis* to other persons, thus, successful treatment of tuberculosis has benefits both for the individual patient and the community in which the patient resides. A 4-drug regimen of INH, RIF, PZA, and EMB remains the preferred initial treatment for drug-susceptible pulmonary tuberculosis. Treatment is initiated promptly even before AFB smear microscopy, molecular tests, and mycobacterial culture results are known in patients with high likelihood of having tuberculosis or those seriously ill with a disorder suspicious for tuberculosis. Initiation of treatment should not be delayed because of negative AFB smears for patients in whom tuberculosis is suspected and who have a life-threatening condition. There are variations of the preferred regimen that are appropriate in certain public health situations or in special clinical situations. Additional detailed and extensively referenced information on treatment of tuberculosis in special situations (patients with renal disease or hepatic disease, those of advanced age, etc), the use of case management strategies (including DOT), regimen and dosing selection in adults and children (daily vs intermittent), the role of TDM, treatment of tuberculosis in the presence of HIV infection (duration of tuberculosis treatment and timing of initiation of ART), treatment of tuberculosis in children, treatment of tuberculosis during pregnancy, and treatment of extrapulmonary tuberculosis, as well as key research priorities, are provided in the full-text version of this practice guideline.

BACKGROUND

The ATS, the CDC, and the IDSA have jointly developed this guideline for the treatment of drug-susceptible tuberculosis. This document provides guidance on the clinical and public health management of tuberculosis in low-incidence countries.

The current document differs from its predecessor, published in 2003 [94], in 3 important areas. First, the process by which the recommendations were developed was substantially modified. For the first time, the Guideline Writing Committee based its recommendations on the certainty in the evidence (also known as the quality of evidence) assessed according to the GRADE methodology (see Supplementary Appendix A: Methods), which incorporates patient values and costs as well as judgments about trade-offs between benefits and harms [1, 2]. A carefully selected panel of experts, screened for conflicts of interest, including specialists in pulmonary medicine, infectious diseases, pharmacokinetics, pediatrics, primary care, public health, and systematic review methodology were assembled to assess the evidence supporting each recommendation. The GRADE method was used to assess the certainty in the evidence and to rate the strength of the recommendations. Second, the ERS has become an endorser of the statement, along with the US NTCA. Representatives from the AAP, the Canadian Thoracic Society, the International Union Against Tuberculosis and Lung Disease, and the WHO also participated in the development of this guideline. Together, these committee members served to provide broader input, thereby expanding the applicability of the guidance beyond North America to include Europe and other low-incidence settings. Last, practice guidelines for the treatment of drug-resistant tuberculosis (including INH monoresistance) are no longer included in this statement and are now covered in a separate practice guideline under development by the ATS, CDC, ERS, and IDSA.

Whereas significant changes have been made, the current document also retains many of the basic principles of tuberculosis care described in the 2003 version. As before, a fundamental aspect of tuberculosis care, regardless of the treatment selected, is ensuring patient adherence to the drug regimen and successful completion of therapy. The responsibility for successful treatment of tuberculosis is placed primarily on the provider or program initiating therapy rather than on the patient. It is well established that appropriate treatment of tuberculosis rapidly renders the patient noninfectious, prevents drug resistance, minimizes the risk of disability or death from tuberculosis, and nearly eliminates the possibility of relapse [95]. Provider responsibility is a central concept in treating patients with tuberculosis, no matter what the source of their care.

The recommendations in this statement are not applicable under all epidemiological circumstances or across all levels of resources that are available to tuberculosis control programs worldwide. It should be emphasized that these guidelines are intended for areas in which mycobacterial cultures, molecular and

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phenotypic drug susceptibility tests, and radiographic facilities are available on a routine basis—typically low-incidence (<100 tuberculosis cases per million population), well-resourced countries, where in some settings tuberculosis epidemiology is at or nearing preelimination levels (<10 cases per million) [96, 97]. The WHO has developed tuberculosis practice guidelines (currently under revision) specifically for high-incidence, resource-limited areas of the world [98].

OBJECTIVES OF ANTITUBERCULOSIS THERAPY

Treatment of tuberculosis is focused on both curing the individual patient and minimizing the transmission of *Mycobacterium tuberculosis* to other persons; successful treatment of tuberculosis has benefits both for the individual patient and the community in which the patient resides.

The objectives of tuberculosis therapy are:

1. To reduce the bacillary population rapidly thereby decreasing severity of the disease, preventing death and halting transmission of *M. tuberculosis*;
2. To eradicate persisting bacilli in order to achieve durable cure (prevent relapse) after completion of therapy; and
3. To prevent acquisition of drug resistance during therapy.

Sixty-five years of investigation, including many clinical trials, have consistently supported the requirement for treatment with multiple drugs to achieve these objectives, minimize drug toxicity, and maximize the likelihood of treatment completion [3, 4]. The most effective agents to curtail rapid multiplication of tuberculous bacilli are INH and the fluoroquinolones. Persisting bacilli appear to curtail their metabolic activity; drugs known to be effective against such persisters include the rifamycins and PZA, the latter with activity believed limited to special microenvironments of relatively increased acidity [99].

Objective 1: Rapid killing of multiplying bacilli ("bactericidal effect"): Rapid reduction in the number of replicating bacilli reduces mortality risk [100, 101], and appears to diminish infectiousness, but even optimal therapy on average requires 4–5 weeks to render sputum cultures negative [102–105]. Studies of early bactericidal activity (EBA) measure the rate of decline in bacillary numbers in sputum during the initial 1–2 weeks of treatment; EBA studies have been used in the initial evaluation of virtually every new tuberculosis drug since 1980 [106, 107]. However, the relationship of a drug or regimen's EBA to its ability to achieve durable cure is still uncertain [108]. For example, INH has a remarkable EBA but acts only slowly on persisting bacilli; RIF at the dose currently used (10 mg/kg) has moderate EBA but potent activity against persisters; and PZA has almost no measurable EBA, but acts potently to assist in achieving durable cure [99, 109].

Objective 2: Achievement of relapse-free cure ("sterilizing effect"): Demonstration of relapse-free cure requires lengthy clinical trials. Among the few drugs effective in preventing relapse, the most prominent have been the rifamycins. Rapid and reliable measurement of the sterilizing effect of antituberculous agents remains elusive. In vitro models are not entirely predictive [110, 111]. The most commonly used animal model is the murine model, which has reliably reproduced the results of standard short-course chemotherapy [112]; however, the murine model has been criticized because mice do not develop cavities and caseous necrosis, pathologic hallmarks of human tuberculosis [113]. Other animal models have been proposed, but none fully replicates the human response to *M. tuberculosis* [114]. Recent evidence suggests that extracellular bacilli in necrotic material within cavities may be the major challenge to prevention of relapse after therapy. Studies using sensitive analytic tools such as positron emission tomography–computed tomography scanning and matrix-assisted laser desorption/ionization mass spectrometry imaging in experimental animals and in patients undergoing pulmonary resection have provided evidence of the marked differences in the ability of key drugs (RIF, PZA, levofloxacin, moxifloxacin) to penetrate into pulmonary tissue, into the cellular granuloma, and into caseous material within cavities [115–119]. However, the pathologic sites from which relapses arise remain unclear.

Objective 3: Protection against acquisition of drug resistance (through use of multidrug therapy): The basic biology underlying the acquisition of drug resistance is well understood, though the details involving some individual agents are still uncertain. As a rule, genetic mutations conferring substantial resistance to individual antituberculous agents occur at constant low rates. For example, rifamycins act primarily by inhibiting the action of bacterial RNA polymerase in the translation of DNA to RNA, by binding to and obstructing access to a subunit of the bacterial RNA polymerase. Mutations in a relatively limited (81 base pairs [bp]) genomic segment encoding for this subunit lead to obstruction of rifamycin binding to the polymerase β subunit (*rpoB*); more than half a dozen amino acid substitutions conferring RIF resistance have been well described. In the case of PZA, resistance is most often conferred by mutations in the *pncA* gene, which encodes for an amidase that is required to convert PZA, a prodrug, into its active form, pyrazinoic acid. The *pncA* mutations occur throughout the 350-bp gene, with no notable preference for specific mutations yet described. INH is also a prodrug requiring activation by a bacterial catalase-peroxidase enzyme (encoded by *katG*), coupling with NADH, and binding to an acyl carrier protein reductase (encoded by *inhA*); the process inhibits the synthesis of mycolic acid needed for the mycobacterial cell wall. Resistance to INH arises through multiple mechanisms, including loss of the *katG*-encoded catalase peroxidase activity, and overexpression or alterations in the *inhA*-encoded reductase [120].

The frequency of mutation engendering resistance to specific agents was estimated some 40 years ago; the highest proportion of resistant mutants expected in an unselected bacterial population were 3.5×10^{-6} for INH and 3.1×10^{-8} for RIF [4, 121].

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Because these mutations generally occur independently, the likelihood of simultaneous resistance mutations to both INH and RIF is in the range of 11×10^{-14}. Thus, in patients with very high bacillary burdens, the occurrence of mutations conferring resistance to a single drug is likely, to 2 drugs is possible, but to 3 drugs is highly unlikely [10]. Acquisition of drug resistance might occur more readily if there is irregular or sporadic drug taking, inadequate drug absorption, inadequate drug dosing, or ill-informed use of single drug treatment (either by error, or because tuberculosis has not been recognized or considered). If resistance to a specific drug occurs, then the resistant clone will possess an advantage relative to susceptible strains when confronted with that drug, and will have no advantage (or possibly a modest disadvantage, if the mutation confers some biologic "cost") if the drug is not used. In the situation of the standard 3-drug regimen (INH, RIF, PZA), 3 circumstances must likely be present for resistance to RIF to emerge: (1) some mutant bacilli resistant to RIF must be present or appear; (2) the bacilli must be exposed to RIF to favor multiplication of the resistant bacteria; and (3) INH and PZA must not be present in sufficient concentration to offset the survival advantage enjoyed by the RIF-resistant clones; this could occur because they are not employed at all (ie, single drug therapy), or because some combination of circumstances affects the other drugs (eg, a nonacidic compartment is involved thereby disadvantaging PZA, and INH happens to be rapidly metabolized [so-called rapid acetylation due to genetic polymorphisms affecting *N*-acetyl transferase], so that INH is not present in adequate concentration) [59].

Multiple Factors Influence the Outcome of Tuberculosis Treatment

Multiple interrelated factors have been associated with the outcome of tuberculosis therapy. These include:

- Patient factors, such as age, comorbid conditions, immunologic competence, nutritional status, alcohol abuse;
- Radiographic features, such as extent of disease, presence and size of cavities;
- Microbiologic factors, such as baseline colony count, culture positivity at 2 or 3 months;
- Genetic factors, including individual genetic features of drug absorption and metabolism, individual vulnerability to toxicities, immunologic characteristics;
- Programmatic factors, including adherence support interventions (enhancers, enablers, monitoring, supervision/DOT), dosing frequency;
- Pharmacokinetic factors, such as absorption, metabolism, protein binding, drug clearance, total drug quantities administered;
- Bacillary factors, such as drug tolerance, strain susceptibilities to drugs in the regimen; and
- Regimen factors, such as number of active drugs, bactericidal and sterilizing potency, synergy or antagonism, and duration of therapy in relation to drugs employed.

The success of therapy depends upon many diverse elements, only some of which are presently predictable, identifiable, or modifiable. Numerous studies have found an increased risk of relapse among patients with signs of more extensive disease (ie, cavitation or more extensive disease on chest radiograph) [5–9], and/or slower response to treatment (ie, culture status at 2 or 3 months) [4, 6, 10, 11]. Better understanding of the causal pathways through which these elements exert their effect, and greater ability to identify and quantify each of these, should lead to increased therapeutic success, and will inform efforts to develop shorter, less toxic, and better-tolerated treatment regimens in the future [122].

ORGANIZATION AND SUPERVISION OF TREATMENT

PICO Question 1: Does adding case management interventions to curative therapy improve outcomes compared to curative therapy alone among patients with tuberculosis?
(Case management is defined as patient education/counseling, field/home visits, integration/coordination of care with specialists and medical home, patient reminders, incentives/enablers).

Recommendation 1: We suggest using case management interventions during treatment of patients with tuberculosis *(conditional recommendation; low certainty in the evidence).*

PICO Question 2: Does self-administered therapy (SAT) have similar outcomes compared to directly observed therapy (DOT) in patients with various forms of tuberculosis?

Recommendation 2: We suggest using DOT rather than SAT for routine treatment of patients with all forms of tuberculosis *(conditional recommendation; low certainty in the evidence).*

Role of Health Department

Due to the public health implications of prompt diagnosis and effective treatment of tuberculosis, most low-incidence countries designate a government public health agency as having legal authority for controlling tuberculosis [12, 13]. To effectively carry out this charge, the public health agency conducts ongoing epidemiologic surveillance of tuberculosis, ensures access to quality-assured microbiological laboratory services, maintains an uninterrupted supply of antituberculosis medications, and monitors and reports treatment outcomes [13]. The public health agency may also have the authority to apply legal measures in situations of nonadherence as a last resort where other interventions have been pursued without effect. In some jurisdictions diagnostic and treatment services are provided directly by the public health agency, whereas in others, these services are provided by the private sector or by a combination of public and private providers.

Patient-Centered Care and Case Management

Patient-centered care respects an individual's right to participate actively as an informed partner in decisions and activities related to tuberculosis diagnosis and treatment [123, 124]. The Institute of Medicine defines patient-centered care as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values

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guide all clinical decisions" [125]. Given that tuberculosis treatment requires multiple drugs be given for several months, it is crucial that the patient be involved in a meaningful way in making decisions concerning treatment supervision and overall care. International standards have been developed that also support using patient-centered approaches to the management of tuberculosis [14–16].

The optimal organization of tuberculosis treatment often requires the coordination not only of primary and specialty clinical care services, but also community-based organizations and agencies in the public and private sectors [14–16]. The inherent complexities of the healthcare delivery system combined with the diversity of characteristics of patients are best addressed by providing individualized patient-centered case management [13]. In most settings, a patient is assigned a case manager who assesses needs and barriers that may interfere with treatment adherence [17]. With active input from the patient and healthcare providers, the case manager, together with the patient, develops an individualized case management plan with interventions to address the identified needs and barriers [18–20]. The plan is reviewed periodically and revised as needed with the patient and medical team to evaluate the clinical response to therapy, monitor potential drug toxicities, and address any challenges identified with adherence. The spectrum of interventions for achieving adherence may range from routine monthly monitoring to legal confinement [126, 127], with confinement being used only as a last resort. The least restrictive public health interventions that are effective are used to achieve adherence.

Key considerations when developing a case management plan include (1) improving "treatment literacy" by educating the patient about tuberculosis and its treatment, including possible adverse effects [21, 22]; (2) discussing expected outcomes of treatment, specifically the ability to cure the patient of the disease; (3) reviewing methods of supervision and assessing response to therapy; and (4) discussing infectiousness and infection control measures using terminology that is appropriate to the culture, language, age, and reading level of the patient [23]. For non-English-speaking patients, the use of medical interpreter services is preferred over using family or friends as interpreters [24]. Relevant information should be reinforced at each visit. Other components of the patient-centered case management plan include, but are not limited to, setting up patient reminders and systems to follow-up missed appointments [23, 28, 29], use of incentives and enablers [25–27, 30, 31], field and home visits [32], integration and coordination of tuberculosis care with the patient's primary and specialty care, and legal interventions when indicated (Table 4). Overall, the quality of evidence is variable in the few studies examining the impact of case management interventions on outcomes such as treatment success; however, these studies suggest that for the most part, patient-centered case management interventions are helpful with little evidence of harm to patients [128] (see Supplementary Appendix B, Evidence Profiles 1–3). For these reasons, we suggest using case management interventions during treatment of patients with tuberculosis (Recommendation 1: *conditional recommendation; very low certainty in the evidence*).

Approaches to Ensuring Adherence and Treatment Success

Given the critical importance of chemotherapy, both to the patient and to the public, approaches to ensuring adherence to the treatment regimen are a major focus of the overall management plan. To maximize completion of therapy, management strategies should utilize a broad range of approaches. Among these, DOT, the practice of observing the patient swallow her or his antituberculosis medications, has been widely used and deserves special emphasis. To be consistent with the principles of patient-centered care, decisions regarding the use of DOT must be made in concert with the patient [14–16]. For example, DOT can be provided in the office, clinic, or in the "field" (patient's home, place of employment, school, or any other site that is mutually agreeable) by appropriately trained personnel [32]. DOT enables early identification of adverse drug reactions, clinical worsening of tuberculosis, and nonadherence [33]. Moreover, frequent contact with the patient allows providers to facilitate linkage to other medical care and services.

However, the implementation of DOT may not be readily feasible when resources are limited [129]. In such circumstances, patients who are more likely to present a transmission risk to others or are more likely to have difficulty with adherence are prioritized for DOT [17]. In addition, experts advise that DOT must be used with regimens that use intermittent drug administration because of the potential serious consequences of missed doses. Careful attention is needed to ensure that ingestion of the medication is, in fact, observed, as the use of DOT does not guarantee ingestion of all doses of every medication [130]. Patients may miss appointments, may not actually swallow the tablets or capsules, or may deliberately regurgitate the medications. Consequently, the use of DOT does not mitigate the continued need for monitoring for signs of treatment failure. DOT is also advised for all patients residing in institutional settings such as hospitals, nursing homes, opiate replacement clinics, or correctional facilities. In special populations such as individuals with treatment failure, recurrence, or at risk for disseminated tuberculosis (eg, HIV coinfected), experts recommend against the use of SAT given the risks involved in developing drug resistance (Table 5). In recent years, DOT has expanded to other modalities such as web-based video and mobile phones, which have been well received by both patients and health department staff [131–133]. Special attention to maintaining patient privacy is needed when web-based and wireless modalities are used for monitoring.

Systematic reviews of studies conducted in countries with high, medium, and low burdens of tuberculosis have not shown improvement in cure or treatment completion in

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patients receiving their antituberculosis treatment by DOT compared with SAT [134–136]. The systematic review conducted to obtain evidence in support of this practice guideline also did not find any significant differences between SAT and DOT when assessing several outcomes of interest, including mortality, treatment completion, and relapse (see Supplementary Appendix B, Evidence Profile 4). However, DOT was significantly associated with improved treatment success (the sum of patients cured and patients completing treatment) and with increased sputum smear conversion during treatment, as compared to SAT. Because DOT is a multifaceted public health intervention that is not amenable to the conventional clinical trials approaches to assessing benefits, and because participation in DOT can be advantageous for early recognition of adverse drug reactions and treatment irregularities, for allowing providers to establish rapport with the patient and for addressing treatment complications expeditiously, DOT remains the standard of practice in the majority of tuberculosis programs in the United States [33–35] and Europe [15]. Population-based studies (representing a low quality of evidence) have suggested that tuberculosis treatment by DOT in comparison to SAT is associated with a reduction in the acquisition and transmission of drug-resistant *M. tuberculosis* (Texas), increased treatment success in HIV-infected patients receiving RFB-containing regimens, shorter duration for completion of treatment (New York City), higher treatment completion rates in incarcerated patients transitioning to the community (Chicago), and a reduction in mortality and loss to follow-up (Brazil) [34, 137–140]. Consequently, we suggest using DOT rather than SAT for routine treatment of patients for all forms of tuberculosis (Recommendation 2: *conditional recommendation; low certainty in the evidence*).

Transfers Between Jurisdictions

Patients being treated for tuberculosis who move from one jurisdiction to another before completion of therapy are more likely to be lost to follow-up than patients who do not move [141]. In the United States, health departments track patients via interjurisdictional referrals, and can use other patient tracking mechanisms (eg, TBNet at http://www.migrantclinician.org/services/network/tbnet.html) for patients who travel internationally) [142–144].

Legal Interventions to Protect Public Health

In extreme circumstances, nonadherent patients may be subject to legal intervention in the form of court-ordered medical examination, DOT, completion of therapy, or civil or criminal detention for completion of tuberculosis treatment when less restrictive measures have been tried and shown to fail [126, 127, 145]. These situations involve special circumstances such as drug resistance, evidence of treatment failure or relapse, and continued concern for transmission in the community, thereby justifying the temporary restriction of individual rights to protect the public's health and safety. Public health laws exist in most jurisdictions that allow these legal interventions, at least for patients who remain infectious, but they should be pursued as a plan of last resort. In the United States, health departments have the sole authority to initiate legal action, and generally the interventions produce good outcomes with treatment completion rates >95% [126, 127]. Outside the United States, legal authority to enforce tuberculosis adherence may originate in other government agencies outside the health department [146].

RECOMMENDED TREATMENT REGIMENS

PICO Question 3: Does intermittent dosing in the intensive phase have similar outcomes compared to daily dosing in the intensive phase for treatment of drug-susceptible pulmonary tuberculosis?

Recommendation 3a: We recommend the use of daily rather than intermittent dosing in the intensive phase of therapy for drug-susceptible pulmonary tuberculosis *(strong recommendation; moderate certainty in the evidence)*.

Recommendation 3b: Use of thrice-weekly therapy in the intensive phase (with or without an initial 2 weeks of daily therapy) may be considered in patients who are not HIV-infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) *(conditional recommendation; low certainty in the evidence)*.

Recommendation 3c: In situations where daily or thrice-weekly DOT therapy is difficult to achieve, use of twice-weekly therapy after an initial 2 weeks of daily therapy may be considered for patients who are not HIV-infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) *(conditional recommendation; very low certainty in the evidence)*. Note: If doses are missed in a regimen using twice-weekly dosing then therapy is equivalent to once weekly, which is inferior (see PICO Question 4).

PICO Question 4: Does intermittent dosing in the continuation phase have similar outcomes compared to daily dosing in the continuation phase in patients with drug-susceptible pulmonary tuberculosis patients?

Recommendation 4a: We recommend the use of daily or thrice-weekly dosing in the continuation phase of therapy for drug-susceptible pulmonary tuberculosis *(strong recommendation; moderate certainty in the evidence)*.

Recommendation 4b: If intermittent therapy is to be administered in the continuation phase, then we suggest use of thrice-weekly instead of twice-weekly therapy *(conditional recommendation; low certainty in the evidence)*. This recommendation allows for the possibility of some doses being missed; with twice-weekly therapy, if doses are missed then therapy is equivalent to once weekly, which is inferior.

Recommendation 4c: We recommend against use of once-weekly therapy with INH 900 mg and rifapentine (RPT) 600 mg in the continuation phase *(strong recommendation; high certainty in the evidence)*. In uncommon situations where more than once-weekly DOT is difficult to achieve, once-weekly continuation phase therapy with INH 900 mg plus RPT 600 mg may be considered for use only in HIV-uninfected persons without cavitation on chest radiography.

Deciding to Initiate Treatment

Empiric treatment with a 4-drug regimen is initiated promptly in patients (children and adults) with high likelihood of having tuberculosis or those seriously ill with a disorder suspicious for tuberculosis, even before AFB smear microscopy, molecular tests, and mycobacterial culture results are known. Initiation of treatment is not delayed because of negative AFB smears for patients in whom tuberculosis is suspected and who have

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a life-threatening condition. The decision to initiate combination chemotherapy for tuberculosis is based on multiple factors including clinical, radiographic, laboratory, patient, and public health factors (Figure 1). Clinical judgment and index of suspicion also play a critical role in deciding to initiate treatment. In addition to smear microscopy and mycobacterial culture, CDC recommends the use of a rapid molecular test on at least one specimen from each patient with signs and symptoms of pulmonary tuberculosis for whom a diagnosis of tuberculosis is being considered but has not been established, and for whom the test result would alter case management or tuberculosis control activities [147]. Use of molecular tests directly on clinical samples has been shown to shorten time to diagnosis, and some tests have the additional ability to provide information on drug susceptibility [147, 148].

In the presence of a clinical syndrome compatible with tuberculosis, a positive AFB smear provides strong inferential evidence for the diagnosis of tuberculosis. If the diagnosis is confirmed by isolation of *M. tuberculosis* or a positive rapid molecular test, or is strongly inferred from clinical or radiographic improvement consistent with a response to tuberculosis treatment, the regimen is continued to complete a standard course of therapy. In patients with a positive AFB smear, but a negative rapid molecular test (including an assessment for polymerase chain reaction inhibitors, reported to be present in 2%–5% of respiratory specimens tested by nucleic acid amplification tests [149, 150]), it is unlikely that the positive smear is due to *M. tuberculosis*, particularly when molecular testing of a second smear-positive specimen is also negative [147]. If empiric treatment is started, cultures throughout are negative, and there is no response to treatment, yet the interferon-γ release assay (IGRA) or purified protein derivative (PPD)–tuberculin skin test (TST) is positive, consideration is given to treatment of latent tuberculosis infection using the following options: (1) stop treatment if RIF and PZA were included in the initial empiric 4-drug therapy, administered for at least 2 months [151]; (2) continue treatment with RIF, with or without INH, for a total of 4 months; (3) give 12 weekly doses of INH/RPT by DOT [152]; or (4) continue treatment with INH for a total of 9 months [83, 153, 154]. In patients in whom there is a low suspicion for active tuberculosis (not initially treated), if cultures remain negative, the IGRA or PPD-TST is positive (≥5 mm), and the abnormal chest radiograph is unchanged after 2 months (ATS/CDC class 4), treatment for latent tuberculosis infection is indicated [155]. If not previously treated, these patients are at increased risk for development of active tuberculosis with case rates 2.5–19 times higher than those of persons infected by *M. tuberculosis* with normal chest radiographs [156–159]. These patients are high-priority candidates for treatment of latent tuberculosis infection.

If clinical suspicion for active tuberculosis is low, the options are to begin treatment with combination chemotherapy or to defer treatment until additional data have been obtained to clarify the situation (usually within 2 months). An advantage of the early use of combination chemotherapy is that once active disease is excluded by negative cultures and lack of clinical or radiographic response to treatment, the patient will have completed 2 months of combination treatment that can be applied to the total duration of treatment for latent tuberculosis infection. Even when the suspicion for active tuberculosis is low, treatment for latent tuberculosis infection with a single drug is *not* initiated until active tuberculosis has been excluded, usually by negative cultures.

In general, for complicated diagnostic or management situations, consultation with local and state health departments is advised. In the United States, the CDC's Division of Tuberculosis Elimination funds tuberculosis regional training and medical consultation centers (http://www.cdc.gov/tb/education/rtmc/), which provide medical consultation to programs and health providers on management of tuberculosis. In Europe, the WHO and ERS Tuberculosis Consilium (https://www.tbconsilium.org) provides similar consultation services regarding the diagnosis and treatment of tuberculosis.

Regimens

The preferred regimen and other choices are listed in Table 2. Patient factors should be considered when selecting administration schedule (intermittency), and in some instances regimen composition. Feasibility of DOT is sometimes an additional consideration when selecting frequency of administration. Regimens for adults and children are identical except in uncommon circumstances where it may be acceptable to omit EMB from the initial treatment regimen for young children (see "Children"). For all regimens, patients are treated until they have received the specified total number of doses for the treatment regimen (ie, not solely based on duration of treatment).

Preferred Regimen

The preferred regimen for treating adults with tuberculosis caused by organisms that are not known or suspected to be drug resistant is a regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF [3, 36, 37]. To reduce the risk of relapse, the continuation phase of treatment is extended for an additional 3 months for patients who had cavitation on the initial (or follow-up) chest radiograph and, in addition, are culture positive at the time of completion of the intensive phase of treatment.

The intensive phase of treatment consists of 4 drugs (INH, RIF, PZA, EMB) because of the current proportion of new tuberculosis cases worldwide caused by organisms that are resistant to INH [38–41]; however, if therapy is being initiated after drug susceptibility test results are known and the patient's isolate is susceptible to both INH and RIF, EMB is not necessary, and the intensive phase can consist of INH, RIF, and PZA only. EMB can be discontinued as soon as the results of drug

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susceptibility studies demonstrate that the isolate is susceptible to INH and RIF.

With respect to administration schedule, the preferred frequency is once daily for both the intensive and continuation phases. Based on systematic reviews conducted to obtain evidence in support of this guideline (see Supplementary Appendix B, Evidence Profiles 5–10), we recommend the use of daily rather than intermittent dosing in the intensive phase of therapy for drug-susceptible pulmonary tuberculosis (Recommendation 3a: *strong recommendation; moderate certainty in the evidence*). For the continuation phase, based on systematic reviews conducted to obtain evidence in support of this guideline (see Supplementary Appendix B, Evidence Profiles 5–10), we recommend use of daily or thrice-weekly dosing for the continuation phase of therapy (Recommendation 4a: *strong recommendation; moderate certainty in the evidence*). Although administration of antituberculosis drugs using DOT 5 days a week has been reported in a large number of studies, it has not been compared with 7-day administration in a clinical trial. Nonetheless, on the basis of substantial clinical experience, experts believe that 5-days-a-week drug administration by DOT is an acceptable alternative to 7-days-a-week administration, and either approach may be considered as meeting the definition of "daily" dosing. Patient-centered care, case management, and DOT are discussed in the "Organization and Supervision of Treatment" section of this guideline.

Other Regimens

There are alternative regimens that are variations of the preferred regimen. As described below, alternative regimens may be acceptable in certain clinical and/or public health situations (see "Treatment in Special Situations"). An administration frequency of less than daily in the intensive phase of treatment is generally not preferred.

Thrice-Weekly Dosing Throughout

In HIV-uninfected patients with noncavitary disease caused by drug-susceptible organisms, thrice-weekly (ie, 3 times per week) dosing throughout both intensive and continuation phases of treatment by DOT may be considered when daily treatment is not feasible or poorly tolerated. Thrice-weekly dosing has been associated with higher rates of treatment failure, relapse, and acquired drug resistance in high-quality systematic reviews [36, 160]. The risks for these poor outcomes of treatment were higher in HIV-infected patients (especially if not treated with antiretrovirals), and patients with cavitary disease or baseline drug resistance. Based on evidence supporting the recommendations obtained through systematic reviews (see Supplementary Appendix B, Evidence Profiles 5,6,8–10), use of thrice-weekly therapy in the intensive phase (with or without an initial 2 weeks of daily therapy) may be considered in patients who are not HIV-infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) (Recommendation 3b: *conditional recommendation; low certainty in the evidence*).

Twice-Weekly Dosing Throughout or Twice-Weekly Dosing After 2–3 Weeks of Daily Dosing

Twice-weekly dosing (ie, 2 times per week) either throughout treatment or after an initial period of 2–3 weeks of daily therapy is not generally recommended because of a lack of high-quality evidence to support its use, and because in twice-weekly therapy, if doses are missed then therapy is equivalent to once weekly, which is inferior (see "Once-Weekly Continuation Phase," below). However, some tuberculosis programs have reported longstanding programmatic treatment success with an initial daily regimen followed by twice-weekly therapy [161], and this regimen remains in use by some public health programs in the United States. In situations where daily or thrice-weekly DOT therapy is difficult to achieve, use of twice-weekly therapy after an initial 2 weeks of daily therapy may be considered for patients who are not HIV infected and are also at low risk of relapse (pulmonary tuberculosis caused by drug-susceptible organisms, that at the start of treatment is noncavitary and/or smear negative) (Recommendation 3c: *conditional recommendation; very low certainty in the evidence*) (see Supplementary Appendix B, Evidence Profile 7).

Twice-Weekly Continuation Phase

Twice weekly treatment in the continuation phase has been studied in clinical trials [36], and is used by US tuberculosis control programs. Based on our systematic review, if intermittent therapy during the continuation phase is considered, then we suggest use of thrice-weekly instead of twice-weekly therapy. (Recommendation 4b: *conditional recommendation; low certainty in the evidence*) (see Supplementary Appendix B, Evidence Profiles 5–8). As noted above for twice-weekly regimens, an advantage of a thrice-weekly regimen is that it allows for the possibility of some doses being missed; with twice-weekly therapy, if doses are missed then therapy is equivalent to once weekly, which is inferior (see "Once-Weekly Continuation Phase," below).

Once-Weekly Continuation Phase

In clinical trials, once-weekly treatment with INH plus RPT 600 mg was less active than standard RIF-based treatment [9, 162]. In the Tuberculosis Trials Consortium (TBTC) Study 22, characteristics independently associated with increased risk of failure or relapse were sputum culture positivity at the end of intensive phase, cavitation on chest radiograph, being underweight, bilateral pulmonary involvement, and being a non-Hispanic white person [9]. Furthermore, relapse with rifamycin-monoresistant tuberculosis occurred among HIV-infected tuberculosis patients treated with the once-weekly INH/RPT continuation phase regimen [59]. In uncommon situations where more than once-weekly DOT is difficult to achieve, once-weekly continuation phase therapy with INH 900 mg plus RPT 600 mg

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may be considered for use only in HIV-uninfected persons without cavitation on chest radiography. Otherwise, we recommend against use of once-weekly therapy with INH 900 mg plus RPT 600 mg (Recommendation 4c: *strong recommendation; high certainty in the evidence*) (see Supplementary Appendix B, Evidence Profile 11).

Alternative Regimen Composition

In some cases, either because of intolerance to first-line drugs or the presence of monoresistance, an alternative regimen may be required. If PZA cannot be included in the initial regimen, or the isolate is determined to be resistant to PZA (an unusual circumstance, except for *M. bovis* and *M. bovis* var BCG), experts recommend a regimen consisting of INH, RIF, and EMB for the initial 2 months followed by INH and RIF for 7 months given either daily or thrice weekly.

Fluoroquinolones (Moxifloxacin and Levofloxacin)

In scenarios in which EMB or INH cannot be used, the role of moxifloxacin or levofloxacin has not been established through clinical trials. Experts on occasion use moxifloxacin or levofloxacin in place of EMB during intensive phase in adults in whom EMB cannot be used, or in place of INH throughout treatment in adults in whom INH cannot be used (see Supplementary Appendix C: Drugs in Current Use for details on adverse effects of fluoroquinolones, including QT prolongation).

There is no evidence that moxifloxacin or levofloxacin can be used in place of a rifamycin or PZA while maintaining a 6-month treatment duration. If a rifamycin cannot be included in the initial regimen due to resistance or intolerance, then a regimen based on the principles described for treating drug-resistant tuberculosis is used. In situations in which several of the first-line agents cannot be used because of intolerance, regimens based on the principles described for treating drug-resistant tuberculosis are used.

Importantly, all alternative regimens using fluoroquinolones in place of EMB or INH are 6 months or longer in duration. There is definitive clinical trial evidence that 4-month daily regimens that substitute moxifloxacin or gatifloxacin for EMB, or moxifloxacin for INH, are significantly less effective than the preferred, standard daily 6-month treatment for drug-susceptible pulmonary tuberculosis [5, 163, 164]. Therefore we recommend against the routine use of 4-month fluoroquinolone-containing regimens for treatment of drug-susceptible pulmonary tuberculosis.

A single randomized trial showed that a regimen of daily moxifloxacin/RIF/PZA/EMB for 2 months followed by once-weekly 1200 mg RPT + 400 mg moxifloxacin for 4 continuation phase months had relapse rates similar to the standard 6-month regimen given daily [164]. Use of this regimen (including a daily moxifloxacin-containing intensive phase) may be considered. It is important to note that each dose of RPT was preceded by a meal of 2 boiled eggs and slices of bread, provided to increase the absorption of RPT. If this regimen is used, it is ideally implemented within the context of program-based operational research with suitable monitoring [165]. Of note, there is no evidence that a once-weekly continuation phase comprised of 1200 mg RPT + 400 mg moxifloxacin after 2 months of intensive phase INH/RIF/PZA/EMB (ie, without moxifloxacin in place of EMB in the intensive phase), would achieve similar outcomes.

Baseline and Follow-up Evaluations

Recommended baseline and follow-up evaluations for patients suspected of having tuberculosis and treated with first-line medications are summarized in Figure 2. At baseline, patients in whom pulmonary tuberculosis is suspected have 3 appropriate sputum specimens collected for microscopic examination and mycobacterial culture, and at least one specimen is tested with a rapid molecular test. When the lung is the site of disease, 3 sputum specimens are obtained 8–24 hours apart [166, 167]. In patients who are not producing sputum spontaneously, induction of sputum using aerosolized hypertonic saline or bronchoscopy (performed under appropriate infection-control procedures) may be necessary to obtain specimens. Susceptibility testing for INH, RIF, EMB, and PZA is performed on an initial positive culture, regardless of the source. A rapid molecular test for drug resistance is performed in patients at risk for drug-resistant tuberculosis, and when resources permit, may be performed in all patients [15, 168]. Second-line drug susceptibility testing should be done only in reference laboratories and is limited to specimens from patients who have had prior therapy, have been in contact with a patient with known multidrug or extensively drug-resistant tuberculosis, have suspected or demonstrated resistance to RIF and/or other first-line drugs, are unable to tolerate RIF, or who have positive cultures after >3 months of treatment [15, 168].

During treatment of patients with pulmonary tuberculosis, at a minimum, a sputum specimen for AFB smear and culture are obtained at monthly intervals until 2 consecutive specimens are negative on culture. Duration of the continuation phase regimen hinges on the microbiological status at the end of the intensive phase of treatment, thus, obtaining sputum specimens at the time of completion of 2 months of treatment is critical if sputum culture conversion to negative has not already been documented. For patients who had positive AFB smears at the time of diagnosis, follow-up smears may be obtained at more frequent intervals (for example, every 2 weeks until 2 consecutive specimens are negative) to provide an early assessment of the response to treatment, especially for patients in situations with high risk of transmission. On occasion, AFB-positive sputa are culture-negative; this occurs most frequently among patients with far-advanced cavitary tuberculosis after the first few months of treatment. It is thought that AFB smear positive (but culture-negative) sputa contain organisms that are dead and that their presence is not a sign of treatment failure, even when noted later in treatment. Dead organisms also can cause

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a positive result on molecular tests; routine performance of molecular tests on follow-up sputum samples, after an initial positive test, is not useful.

Drug susceptibility tests are repeated on *M. tuberculosis* isolated in culture from sputum obtained after a patient has been on treatment for ≥3 months. As described in the "Treatment Failure" section, patients who have *M. tuberculosis* isolated in culture from sputum obtained after 4 months of treatment are considered as having failed treatment and managed accordingly.

For patients with positive cultures at diagnosis, a repeat chest radiograph at completion of 2 months of treatment may be useful but is not essential. Tuberculosis programs often conduct a chest radiograph at completion of therapy as it provides a baseline against which subsequent examinations can be compared, but, as with the 2-month examination, it is not essential. When the initial sputum cultures are negative, a presumptive diagnosis can be made if radiographic improvement is noted, generally by the time 2–3 months of treatment have been completed [93]. Thus, based on expert opinion, in patients with negative initial cultures, a chest radiograph is recommended after 2–3 months of treatment and at the completion of treatment to document response to therapy. Generally, systematic follow-up after completion of therapy is not necessary.

In addition to the microbiological and imaging examinations discussed here, other appropriate assessments and laboratory tests are summarized in Figure 2. For patients with extrapulmonary tuberculosis, the frequency and kinds of evaluations will depend on the sites involved and the ease with which specimens can be obtained. Monitoring assessments for patients treated with second-line drugs are listed by drug in Supplementary Appendix C: Drugs in Current Use.

Identification and Management of Patients at Increased Risk of Relapse

The culture result of a sputum specimen obtained at the completion of the intensive phase of treatment (2 months) has been shown to correlate with the likelihood of relapse after completion of treatment for pulmonary tuberculosis, albeit with low sensitivity [9, 44–46]. Cavitation on the initial chest radiograph has also been shown to be a risk factor for relapse [9, 47]. In patients treated for 6 months, having both cavitation and a positive culture at completion of 2 months of therapy has been associated with rates of relapse of approximately 20% compared with 2% among patients with neither factor [9, 45].

The most effective means of decreasing the likelihood of relapse for patients at risk has not yet been determined by clinical trials; however, indirect evidence from a controlled clinical trial and an observational study among patients with pulmonary tuberculosis in Hong Kong showed that prolonging treatment decreased the rate of relapse [47, 169]. It has also been reported that for patients at high risk of relapse, prolongation of the once-weekly INH/RPT continuation phase from 4 to 7 months resulted in a decreased rate of relapse [170].

In view of this evidence, for patients who have cavitation on the initial chest radiograph and who have positive cultures at completion of 2 months of therapy, expert opinion is to extend the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy).

Because patients who had either cavitation on the initial chest radiograph or a positive culture at 2 months had an increased rate of relapse [9, 45], patients with one or the other of these risk factors are followed more closely and consideration given to extending treatment duration if there are suggestions of a poor response. Additional factors to be considered in deciding to prolong treatment in patients with either cavitation or a positive culture at 2 months (but not both) might include being >10% below ideal body weight; being a smoker; having diabetes, HIV infection, or other immunosuppressing condition; or having extensive disease on chest radiograph [46, 48–52].

Interruptions in Therapy

Interruptions in therapy are common in the treatment of tuberculosis. When interruptions occur, the person responsible for supervision must decide whether to restart a complete course of treatment or simply to continue as intended originally. In general, the earlier the break in therapy and the longer its duration, the more serious the effect and the greater the need to restart treatment from the beginning. Continuous treatment is more important in the intensive phase of therapy when the bacillary population is highest and the chance of developing drug resistance greatest. During the continuation phase, the number of bacilli is much smaller and the goal of therapy is to kill the persisting organisms. The duration of the interruption and the bacteriologic status of the patient prior to and after the interruption are also important considerations.

There is no evidence upon which to base detailed recommendations for managing interruptions in treatment, and no recommendations will cover all of the situations that may arise. The approach summarized in Table 6 (modified from the New York City Bureau of Tuberculosis Control [171]) is presented as an example.

When interruptions are due to an interim loss of follow-up, at the time the patient is returned to treatment, additional sputum are obtained for repeat culture and drug susceptibility testing. If the cultures are still positive, the treatment regimen is restarted. If sputum cultures are negative, the patient could be treated as having culture-negative tuberculosis and given an additional 4 months of INH and RIF chemotherapy, as long as the original specimen was drug susceptible and the original intensive phase regimen included INH, RIF, and PZA. Regardless of the timing and duration of the interruption, DOT is used subsequently. If the patient was already being managed with DOT, additional measures will be necessary to ensure completion of therapy. Consultation with an expert is advised to assist in managing treatment interruptions.

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Definition of Completion of Therapy

The determination of whether or not treatment has been completed is based on the total number of doses taken—not solely on the duration of therapy (Table 2). Tuberculosis control program practice in the United States and in several European countries is to administer all of the specified number of doses for the intensive phase within 3 months and those for the 4-month continuation phase within 6 months, so that the 6-month regimen is completed within 9 months. If these targets are not met, the patient must be considered to have interrupted therapy and be managed as described above (Table 6).

PRACTICAL ASPECTS OF TREATMENT

Drug Administration

In general, tuberculosis drugs are administered together, at one dosing so as to achieve maximal peak serum concentrations and to facilitate DOT. Bioavailability of all of the drugs (except for RPT) is greatest when taken on an empty stomach. The exception is RPT, for which bioavailability increases by up to 86% with high-fat meals [172]. If medications need to be combined with food or liquid for dosing, keep in mind that INH absorption decreases when combined with glucose or lactose; crushed INH tablets in foods containing low glucose, such as sugar-free pudding, are stable. However, crushed tablets mixed with food should not be stored for later use [173]. The commercially prepared INH elixir uses sorbitol as the vehicle; sorbitol may also cause diarrhea, thereby limiting its use.

Parenteral drug administration is indicated for severely ill patients who cannot take oral therapy, and may be useful for the uncommon patient with suspected or documented malabsorption. Of the first-line drugs, parenteral preparations of INH and RIF, as well as most fluoroquinolones, are available.

Fixed-Dose Combination Preparations

Clinical trials and a recent systematic review have concluded that overall, there is no significant difference between fixed-dose combinations (FDCs) and single-drug combinations for key outcomes, including sputum smear or culture conversion, failure, relapse, death, serious adverse events, or adverse events that lead to discontinuation of therapy [174–178]. The patient-specific advantages to using FDC drugs include ease of administration and the potential for reducing medication errors. The key program and clinician-specific advantage of FDC formulations is the simplification of drug supply management (procurement, storage, and distribution) and simpler prescription writing. If FDCs are used, clinicians should be aware that FDC and non-FDC products have similar commercial names with different drug compositions, including Rifadin (RIF only), Rifamate (INH and RIF), and Rifater (INH, RIF, and PZA) (see Supplementary Appendix C).

Management of Common Adverse Effects

Mild adverse effects usually can be managed with treatment directed at controlling the symptoms; severe effects usually require the offending drug(s) to be discontinued. If a drug is permanently discontinued, then a replacement drug, typically from a different drug class, is included in the regimen. Patients with severe tuberculosis often require the initiation of an alternate regimen during the time the offending drug(s) are held. Management of serious adverse effects often requires expert consultation. The suggested practices listed below for handling common adverse effects during treatment (ordered from most to least common) are based on expert opinion.

Gastrointestinal Upset; Nausea, Vomiting, Poor Appetite, Abdominal Pain

Gastrointestinal reactions are common, especially early in therapy [53]. The optimum approach to management of epigastric distress or nausea with tuberculosis drugs is not clear. To minimize symptoms, patients receiving SAT may take the medications at bedtime. Gastrointestinal intolerance not associated with hepatotoxicity can be treated with antacids, which have less impact on absorption or peak concentration of first-line drugs than administration with food [54]. Some experts report success with proton pump inhibitors for reducing gastrointestinal upset. Any combination of otherwise unexplained nausea, vomiting, and abdominal pain is evaluated with a physical examination and liver function tests, including ALT, AST, bilirubin, and alkaline phosphatase to assess for possible hepatotoxicity [55]. Alternatively, a light snack (low-fat food) such as a cracker might suffice for some patients. Either option is preferable to splitting a dose or changing to a second-line drug. It is important to note that divalent cations (calcium, iron, zinc) as occur in some antacids and nutritional supplements are not coadministered with fluoroquinolones because they decrease absorption of the drug, possibly leading to treatment failure [179].

Rash

All antituberculosis drugs can cause a rash, the severity of which determines management [180]. If the rash is mainly itchy without mucous membrane involvement or systemic signs such as fever, treatment is symptomatic with antihistamines, and all antituberculosis medications can be continued. A petechial rash is more concerning and suggests thrombocytopenia from a rifamycin (ie, RIF, RFB, RPT) hypersensitivity [181]. If the platelet count is low, the rifamycin is permanently stopped and the platelet count closely monitored until definite improvement is noted. Drugs are also stopped if the patient has a generalized erythematous rash. Fever and/or mucous membrane involvement suggests Stevens-Johnson syndrome, toxic epidermal necrosis, or drug reaction with eosinophilia and systemic symptoms syndrome or drug hypersensitivity syndrome. Hypersensitive reactions to multiple antituberculosis drugs have been noted, particularly in persons with HIV infection [180].

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Some experts manage severe systemic reactions in the inpatient setting, using an interval of several days between drug rechallenges, closely monitoring markers of hypersensitivity (such as rash, fever, transaminitis, eosinophilia, pruritus, etc). If any of these markers develop, then the drug is stopped and identified as the offender, eliminating it from the regimen. Systemic corticosteroids may be used to treat severe systemic reactions. Using steroids to treat systemic reactions, even in the setting of severe tuberculosis, has not worsened outcomes [182].

When the rash has substantially improved, medications can be restarted individually at intervals of 2–3 days. RIF is restarted first (the most potent drug), followed by INH, then EMB or PZA. If the rash recurs, the last drug added is stopped. If the first 3 drugs have been restarted without a rash, the fourth drug is not restarted unless the rash was mild and that drug essential. Research evaluating drug provocation tests or drug desensitization strategies is needed [180].

Drug Fever

Drug fever is essentially a diagnosis of exclusion. Other causes of fever such as tuberculosis (fever may persist 2 months or longer into treatment) [183, 184]; paradoxical reaction, especially in HIV-infected patients (See "HIV Infection") [185–187]; and superinfection must be excluded. Patients with drug fever generally feel well despite body temperatures ≥39°C. Drug fever does not follow a specific pattern and eosinophilia need not be present. Stopping drugs usually resolves the fever within 24 hours. Once afebrile, the patient should restart drugs individually every 2–3 days, similar to the approach to drug rechallenge for rash.

Hepatotoxicity

Drug-induced hepatitis is the most frequent serious adverse reaction to the first-line drugs (see "Hepatic Disease" and Supplementary Appendix C). INH, RIF, and PZA can cause drug-induced liver injury, which is suspected when the ALT level is ≥3 times the upper limit of normal in the presence of hepatitis symptoms, or ≥5 times the upper limit of normal in the absence of symptoms [56]. If the ALT level is <5 times the upper limit of normal, toxicity can be considered mild, an ALT level 5–10 times normal defines moderate toxicity, and an ALT level >10 times normal (ie, >500 IU) is severe.

An asymptomatic increase in ALT concentration occurs in nearly 20% of patients treated with the standard 4-drug regimen [188, 189]. In the absence of symptoms, therapy should not be altered because of modest asymptomatic elevations of ALT, but the frequency of clinical and laboratory monitoring should be increased. In most patients, asymptomatic ALT elevations resolve spontaneously. However, if ALT levels are ≥5 times the upper limit of normal (with or without symptoms) or ≥3 times normal in the presence of symptoms, hepatotoxic drugs are stopped immediately and the patient is evaluated carefully. Similarly, a significant increase in bilirubin and/or alkaline phosphatase is cause for a prompt evaluation; disproportionate increases in bilirubin and alkaline phosphatase (as compared to increases in serum ALT) may be seen with RIF hepatotoxicity [56].

Other causes of abnormal liver tests must be excluded before diagnosing drug-induced hepatitis (Table 7). If ALT levels are consistent with hepatotoxicity, all hepatotoxic drugs must be stopped and serum ALT and prothrombin time or international normalized ratio (INR) levels followed until levels return to baseline. Consult a liver specialist if the patient's clinical or laboratory status continues to worsen.

Once the ALT concentration returns to <2 times the upper limit of normal, antituberculosis medications are restarted individually (see [56] for additional details). In patients with elevated baseline ALT from preexisting liver disease, drugs are restarted when the ALT returns to near-baseline levels. The optimal approach to reintroducing tuberculosis treatment after hepatotoxicity is not known [57, 58]; however, most tuberculosis programs use sequential reintroduction of drugs. Because RIF is much less likely to cause hepatotoxicity than INH or PZA, it is restarted first. If there is no increase in ALT after approximately 1 week, INH may be restarted. PZA can be started 1 week after INH if ALT does not increase. If symptoms recur or ALT increases, the last drug added should be stopped. If RIF and INH are tolerated and hepatitis was severe, PZA can be assumed to be responsible and is discontinued. In this last circumstance, depending on the number of doses of PZA taken, severity of disease, and bacteriological status, the total duration of therapy might be extended to 9 months.

Optic Neuritis

EMB-related visual impairment during treatment of active tuberculosis has been estimated to occur in 22.5 per 1000 persons (2.25%) receiving EMB at standard doses [190] (see Supplementary Appendix C). The onset of optic neuritis is usually >1 month after treatment initiation but can occur within days [191, 192]. The opinion of experts is that baseline visual acuity (Snellen test) and color discrimination tests followed by monthly color discrimination tests are performed during EMB use. To avoid permanent deficits, EMB is promptly discontinued if visual abnormalities are found. If vision does not improve with cessation of EMB, experts recommend stopping INH as well, as it is also a rare cause of optic neuritis [193].

Drug–Drug Interactions

Interactions Affecting Antituberculosis Drugs

Drug–drug interactions can change the concentrations of the drugs involved. Relatively few interactions substantially change antituberculosis drug concentrations; much more often, the antituberculosis drugs cause clinically relevant changes in the concentrations of other drugs. The exceptions to this general rule are RFB and the fluoroquinolones.

- Inhibitors of CYP3A increase the serum concentrations of RFB and one of its metabolites (25-O-desacetyl-rifabutin),

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sometimes producing toxicities. For example, administering ritonavir, a very potent CYP3A inhibitor, with the standard daily dose of RFB (300 mg) increases the serum concentrations of RFB (4-fold) and 25-O-desacetyl-rifabutin (35-fold) [194] and is associated with increased rates of leukopenia, arthralgias, skin discoloration, and anterior uveitis [195, 196]. Conversely, administering RFB with a CYP3A inducer such as efavirenz or phenytoin may decrease RFB concentrations [197], and this may lead to clinical failures and the selection of rifamycin-resistant *M. tuberculosis*. Recommendations for RFB dose adjustments are available at AIDSinfo, and at the CDC website (http://www.cdc.gov/tb/publications/guidelines/tb_hiv_drugs/default.htm). Because interactions are complex and given the rapid emergence of new data on antiretroviral therapy (ART), the management of HIV-related tuberculosis cases should involve a physician with experience in this field.

- Absorption of the fluoroquinolones is markedly decreased by ingestion of medications containing divalent cations (calcium, iron, zinc) including antacids [198, 199]; supplements or vitamins containing calcium, iron, or zinc [200]; sucralfate [201]; and the chewable tablet formulation of didanosine [202]. These drug interactions can be avoided by ingesting medications containing divalent cations at least 2 hours apart from fluoroquinolones [203]. In addition, moxifloxacin serum concentrations are decreased by 25%–30% in the presence of RIF due to the induction of phase II metabolic enzymes (sulfation and glucuronidation) [204]. RPT and RFB also may decrease moxifloxacin serum concentrations, though the clinical significance of these drug–drug interactions in individual patients is uncertain.

Antituberculosis Drugs Affecting Other Drugs

Drug Interactions Due to Rifamycins

Most of the clinically relevant drug–drug interactions involving the antituberculosis drugs are due to the effect of the rifamycins (RIF, RFB, and RPT) on the metabolism of other drugs [205]. All of the rifamycins are inducers of a variety of metabolic pathways, particularly those involving the various isozymes of the cytochrome P450 (CYP) system [206]. By inducing the activity of metabolic enzymes, rifamycins decrease the serum concentrations of many drugs, sometimes to subtherapeutic levels [207]. RIF is the most potent enzyme inducer and RFB the least, while RPT's potency depends on its frequency of administration [208, 209]. Daily RPT is at least as potent as daily RIF, while once-weekly RPT (as used in combination with INH for latent tuberculosis infection [210]) has limited effects on other drugs.

The well-described, clinically relevant, drug–drug interactions involving the rifamycins are presented in Table 8 [206, 211]; however, many possible interactions involving the rifamycins have not been fully investigated and additional clinically relevant interactions undoubtedly will be described. Therefore, it is important to check all concomitant medications for possible, as well as confirmed, drug–drug interactions with rifamycins.

Rifamycin inductive effects typically take approximately 1–2 weeks to reach steady state after the rifamycin is started, and inductive effects typically resolve over approximately 2 weeks after the rifamycin is discontinued [209]. If the dose of a medication is increased to compensate for the effect of a rifamycin, it is critical to reduce the dose within 2 weeks after the rifamycin is discontinued and its inductive effect resolves.

RFB can be used in place of RIF if there is an unacceptable drug–drug interaction between RIF and another drug such as cyclosporine [212, 213] and most of the HIV-1 protease inhibitors [208, 214, 215]. All the rifamycins may cause unacceptable decreases in the serum concentrations of certain drugs such as itraconazole [216–218].

Drug Interactions Due to INH

INH is a relatively potent inhibitor of several CYP isozymes [219, 220] and increases concentrations of some drugs to the point of toxicity such as the anticonvulsants phenytoin [221, 222] and carbamazepine [223, 224]. INH also increases concentrations of benzodiazepines metabolized by oxidation, such as diazepam [225] and triazolam, but not those metabolized by conjugation, such as oxazepam [226]. Of note, the inductive effect of RIF on CYP isozymes outweighs the inhibitory effect of INH, so that the overall effect of combined therapy with RIF and INH is a decrease in the concentrations of drugs such as phenytoin [227] and diazepam [225].

INH may increase toxicity of other drugs—acetaminophen [228], valproate [229], serotonergic antidepressants [230], warfarin [231], and theophylline [232]—but these potential interactions have not been well studied. A possible interaction between INH and disulfiram was initially described [233]; however, a retrospective study found that disulfiram was safe when added to intermittent, directly observed INH-containing tuberculosis treatment [234].

Drug Interactions Due to the Fluoroquinolones

Ciprofloxacin [235] inhibits the metabolism of theophylline and can cause clinical theophylline toxicity [236]; however, levofloxacin [237], gatifloxacin [238], and moxifloxacin [239] do not affect theophylline metabolism.

Useful Websites Regarding Drug Interactions

Useful websites regarding drug interactions (tuberculosis/HIV and other) are available through the following hyperlinks: AIDSinfo, Centers for Disease Control and Prevention, University of California San Francisco, University of Liverpool, Indiana University, and University of Maryland.

Therapeutic Drug Monitoring

TDM generally consists of measurements of drug concentrations in serum specimens typically collected at 2 and 6 hours after a dose of the drug, or drugs, in question. Other sampling times may be used for selected situations. Blood samples are centrifuged; the serum is harvested and frozen, and then

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shipped frozen to a reference laboratory. Quality-assured laboratories in the United States and in Europe offer assays for some or all of the antituberculosis drugs [240, 241]. There are no prospective randomized trials that clearly define the role of TDM for antituberculosis drugs. As such, opinions vary regarding the utility of TDM. Experts generally use TDM as a specialized tool, providing insight into the adequacy of drug dosing [242]. For example, serum concentrations of tuberculosis drugs among children and HIV-infected patients with tuberculosis are frequently lower than those in healthy volunteers, at the same (mg/kg body weight) dose [243–246]. In some reports, lower concentrations did not have an impact on treatment response or cure [247–249]. Other reports have found an association between low drug exposure and failure, relapse, and acquired rifamycin resistance [250–252]. TDM cannot predict who will be cured, fail, or relapse; however, it does allow for timely, informed decisions regarding the need for dose adjustment when necessary. Experts suggest that TDM may be particularly helpful in situations in which drug malabsorption, drug underdosing, or clinically important drug–drug interactions are suspected (Table 9). Examples of situations in which TDM may be useful include (1) patients with delayed sputum conversion or treatment failure not explained by nonadherence or drug resistance; (2) patients with medical conditions (eg, reduced renal function) that are suspected of leading to subtherapeutic or toxic drug concentrations; and (3) patients undergoing treatment for drug-resistant tuberculosis.

Table 9. Conditions or Situations in Which Therapeutic Drug Monitoring May Be Helpful

Poor response to tuberculosis treatment despite adherence and fully drug-susceptible *Mycobacterium tuberculosis* strain
Severe gastrointestinal abnormalities: severe gastroparesis, short bowel syndrome, chronic diarrhea with malabsorption
Drug–drug interactions
Impaired renal clearance: renal insufficiency, peritoneal dialysis, critically ill patients on continuous renal replacement
HIV infection
Diabetes mellitus
Treatment using second-line drugs

Abbreviation: HIV, human immunodeficiency virus.

TREATMENT IN SPECIAL SITUATIONS

HIV Infection

PICO Question 5: Does extending treatment beyond 6 months improve outcomes compared to the standard 6-month treatment regimen among pulmonary tuberculosis patients coinfected with HIV?

Recommendation 5a: For HIV-infected patients receiving ART, we suggest using the standard 6-month daily regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF for the treatment of drug-susceptible pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence).*

Recommendation 5b: In uncommon situations in which HIV-infected patients do NOT receive ART during tuberculosis treatment, we suggest extending the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy) for treatment of drug-susceptible pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence).*

PICO Question 6: Does initiation of ART during tuberculosis treatment compared to at the end of tuberculosis treatment improve outcomes among tuberculosis patients coinfected with HIV?

Recommendation 6: We recommend initiating ART during tuberculosis treatment. Antiretroviral therapy should ideally be initiated within the first 2 weeks of tuberculosis treatment for patients with CD4 counts <50 cells/μL and by 8–12 weeks of tuberculosis treatment initiation for patients with CD4 counts ≥50 cells/μL *(strong recommendation; high certainty in the evidence).* Note: an exception is patients with HIV infection and tuberculous meningitis (see Immune Reconstitution Inflammatory Syndrome).

Both the CDC and WHO recommend routine HIV testing and counseling to all patients with presumptive and diagnosed tuberculosis [253, 254]. Treatment of tuberculosis in patients with HIV infection has several important differences compared with treatment of patients who do not have HIV infection. These differences include the need for ART, the potential for drug–drug interactions, especially between the rifamycins and antiretroviral agents, paradoxical reactions that may be interpreted as clinical worsening, and the potential for developing resistance to rifamycins when using intermittent tuberculosis therapy. Because of the strong epidemiological association between HIV and tuberculosis infections and the clinical considerations discussed below, all individuals diagnosed with tuberculosis are tested for HIV infection.

Clinical Trials of Treatment for Tuberculosis in HIV-Infected Patients

There have been a number of prospective studies, including 4 randomized controlled trials, of 6-month regimens for the treatment of pulmonary tuberculosis in patients with HIV infection for which recurrence data were reported [59, 247, 248, 255–257]. All reported a good early clinical response to tuberculosis therapy. The time required for sputum culture conversion from positive to negative and tuberculosis treatment failure rates were similar to these indices of treatment efficacy in patients without HIV infection. Recurrence of tuberculosis after treatment completion may be due to relapse or reinfection. Relapse of tuberculosis in HIV-infected individuals is associated with nonadherence to treatment, use of intermittent regimens, and with low plasma drug concentrations, all of which also contribute to the emergence of rifamycin resistance [9, 59–62, 250]. Reinfection with a new strain of *M. tuberculosis* is well documented in patients with HIV infection and occurs in settings where transmission is more common, such as in countries with high rates of tuberculosis or congregate living facilities (eg, prisons or hospitals) where infection control is inadequate. A study in Democratic Republic of the Congo (formerly Zaire) found that extending treatment from 6 to 12 months reduced the recurrence rate from 9% to 3% [255]. A randomized trial in Haiti found that 6-month treatment with a standard regimen

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Table 10. Suggested Pyrazinamide Doses, Using Whole Tablets, for Adults Weighing 40–90 kg[a]

	Weight, kg[b,c]		
Regimen	40–55	56–75	76–90
Daily (mg/kg)	1000 mg (18.2–25.0)	1500 mg (20.0–26.8)	2000 mg (22.2–26.3)
Thrice weekly (mg/kg)	1500 mg (27.3–37.5)	2500 mg (33.3–44.6)	3000 mg (33.3–39.5)
Twice weekly (mg/kg)	2000 mg (36.4–50.0)	3000 mg (40.0–53.6)	4000 mg (44.4–52.6)

[a] With normal renal function.

[b] Based on estimated lean body weight. Optimal doses for obese patients are not established.

[c] Numbers in parentheses are the calculated mg/kg doses for patients at the highest and lowest body weights in the weight band.

followed by 12 months of INH preventive therapy reduced recurrences from 7.8 per 100 person-years to 1.4 per 100 person-years [258]. Therefore, in areas where reinfection is likely, the opinion of experts is that secondary preventive therapy with INH may be justified.

In regard to duration of treatment for drug-susceptible pulmonary tuberculosis in the presence of HIV infection, the standard regimen currently used worldwide is the 6-month regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF [10, 67, 98]. There is, however, a paucity of data on the optimal duration of tuberculosis treatment for HIV-infected patients receiving highly active antiretroviral therapy (HAART), though it is widely believed that the standard 6-month regimen is effective and achieves tuberculosis cure rates comparable to those reported for HIV-uninfected patients. In the TB-HAART (Early Versus Delayed Initiation of HAART for HIV-Infected Adults With Newly Diagnosed Pulmonary Tuberculosis) trial, patients with CD4 counts ≥220 cells/μL were randomized on timing of ART initiation [259]. All patients were treated with the standard 6-month regimen for tuberculosis and were followed for 12 months. Among patients who completed treatment, recurrence of tuberculosis occurred in 2.0%, providing indirect but supportive evidence that a 6-month regimen is effective in HIV-infected patients receiving ART. In our updated systematic review of randomized trials and cohort studies comparing various durations of tuberculosis therapy (6 months vs 8 months or longer), most of which were conducted prior to the era of HAART, we found that the risk of recurrence is lower when the continuation phase of treatment is extended. However, it is important to note that the majority of these studies were reports on nonrandomized cohorts, most were completed prior to the era of routine antiretroviral use, many tested intermittent regimens, and few distinguished between reinfection and relapse (see Supplementary Appendix B). As discussed below, based on data that show significant reductions in mortality and AIDS-defining illnesses, patients with HIV infection and tuberculosis should receive ART in conjunction with daily antituberculosis medications. For HIV-infected patients receiving ART, we suggest using the standard 6-month daily regimen consisting of an intensive phase of 2 months of INH, RIF, PZA, and EMB followed by a continuation phase of 4 months of INH and RIF for the treatment of drug-susceptible pulmonary tuberculosis (Recommendation 5a: *conditional recommendation; very low certainty in the evidence*) (see Supplementary Appendix B, Evidence Profile 12). In the uncommon situation in which an HIV-infected patient does NOT receive ART during tuberculosis treatment, we suggest extending the continuation phase with INH and RIF for an additional 3 months (ie, a continuation phase of 7 months in duration, corresponding to a total of 9 months of therapy) for treatment of drug-susceptible pulmonary tuberculosis (Recommendation 5b: *conditional recommendation; very low certainty in the evidence*). As is noted for drug-susceptible pulmonary tuberculosis in patients without HIV coinfection, the continuation phase is extended in specific situations that are known to increase risk for relapse (see "Identification and Management of Patients at Increased Risk of Relapse"), as well as for selected extrapulmonary sites of disease, namely tuberculous meningitis, and bone, joint, and spinal tuberculosis (see "Extrapulmonary Tuberculosis").

Table 11. Suggested Ethambutol Dosages, Using Whole Tablets, for Adults Weighing 40–90 kg[a]

	Weight, kg[b,c]		
Regimen	40–55	56–75	76–90
Daily (mg/kg)	800 mg (14.5–20.0)	1200 mg (16.0–21.4)	1600 mg (17.8–21.1)
Thrice weekly (mg/kg)	1200 mg (21.8–30.0)	2000 mg (26.7–35.7)	2400 mg (26.7–31.6)
Twice weekly (mg/kg)	2000 mg (36.4–50.0)	2800 mg (37.3–50.0)	4000 mg (44.4–52.6)

[a] With normal renal function.

[b] Based on estimated lean body weight. Optimal doses for obese patients are not established.

[c] Numbers in parentheses are the calculated mg/kg doses for patients at the highest and lowest body weights in the weight band.

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Use of intermittent tuberculosis treatment regimens in HIV-infected patients has been associated with high rates of relapse and the emergence of drug resistance. In TBTC Study 22, patients with HIV infection who received once-weekly RPT and INH or twice-weekly RIF and INH in the continuation phase had an unacceptably high rate of relapse: 5 of 30 (16.7%) in the former and 3/31 (9.8%) in the latter group [9]. In addition, for those receiving weekly therapy, 4 patients relapsing had acquired rifamycin resistance, which was associated with low serum concentrations of INH and was presumably the result of unopposed rifamycin exposure [59]. In a trial of RFB-based antituberculosis therapy in combination with antiretroviral drugs, patients treated with twice-weekly RFB had a relapse rate of 5.3%, but 8 of 9 relapses had acquired rifamycin resistance [60]. Relapse and resistance were associated with low CD4 lymphocyte counts, as all recurrences occurred in patients with baseline CD4 lymphocyte counts <100 cells/μL. In the pharmacokinetic substudy of the trial, lower plasma concentrations of RFB and INH were identified as key risk factors for acquiring rifamycin resistance [250]. More recently, the use of a thrice-weekly RIF-based regimen during the intensive and continuation phases of treatment was associated with a higher rate of relapse and emergence of rifamycin resistance in HIV-infected individuals not receiving antiretrovirals compared with HIV-infected patients also receiving antiretrovirals or HIV-uninfected patients [62]. Based in part on systematic reviews conducted to obtain evidence in support of this guideline, our expert opinion is that treatment of HIV-related tuberculosis be given daily in both the intensive and continuation phases to avoid recurrent disease and the emergence of rifamycin resistance (see "Recommended Treatment Regimens").

Mortality among patients with HIV and tuberculosis is high, principally due to complications of immunosuppression and occurrence of other HIV-related opportunistic diseases. In this regard, the value of co-trimoxazole (trimethoprim-sulfamethoxazole) prophylaxis in reducing morbidity and mortality in HIV-infected patients with newly diagnosed tuberculosis is well established [63–65]. Whereas the WHO recommends routine co-trimoxazole prophylaxis for all HIV-infected people with active tuberculosis disease regardless of the CD4 cell count [66], in high-income countries, co-trimoxazole prophylaxis is primarily used in tuberculosis patients coinfected with HIV with CD4 counts <200 cells/μL [67]. The use of ART during tuberculosis treatment in persons with HIV infection also reduces mortality rates significantly for those with advanced HIV disease and decreases the risk of developing AIDS-related conditions. The Starting Antiretroviral therapy at Three Points in Tuberculosis (SAPiT) trial randomized patients with tuberculosis and HIV with CD4 lymphocyte counts <500 cells/μL to initiate ART after 2 weeks (immediate), 8 weeks (early), or 6 months (deferred) of tuberculosis treatment [260]. Patients receiving immediate or early ART had a 56% reduction in the relative risk of death compared with patients receiving deferred ART (5.6 per 100 person-years vs 12.1 per 100 person-years). The benefit of ART given immediately or early was seen in patients with CD4 lymphocyte counts <200 cells/μL and 200–500 cells/μL. Subsequently, the Cambodian Early Versus Late Introduction of Antiretrovirals trial showed that initiation of ART within 2 weeks of starting antituberculosis treatment reduced mortality rate by 34% compared to starting after 8 weeks, in a population of HIV-infected individuals with very low CD4 cell counts (median, 25 cells/μL) [261]. The Immediate vs Deferred Start of Anti-HIV Therapy in HIV-Infected Adults Being Treated for Tuberculosis (STRIDE) trial and the second phase of the SAPiT study, both of which compared immediate (2 weeks) with early (8–12 weeks) ART for HIV-infected patients beginning antituberculosis treatment, showed that immediate therapy was associated with significantly lower rates of progression of HIV disease to new AIDS-defining conditions or death compared to early therapy for patients with CD4 counts <50 cells/μL, but starting ART within 2 weeks was not superior to starting at 8 weeks for individuals with CD4 counts >50 cells/μL [262, 263]. All of these studies also showed that immediate ART was associated with significantly greater rates of IRIS, most of which was not severe.

More recently, the TB-HAART trial found that among patients with HIV and CD4 counts >220 cells/μL, immediate initiation of ART did not reduce mortality compared with waiting until completion of 6 months of antituberculosis treatment to start ART [259]. Unlike the SAPiT and STRIDE trials, however, TB-HAART did not assess progression of HIV disease as a study endpoint. Although the study did not find a survival benefit in patients with HIV-related tuberculosis and higher CD4 lymphocyte counts, it did confirm the safety of co-treatment of tuberculosis and HIV infection and documented good outcomes of tuberculosis treatment in those patients receiving dual therapy.

We performed a systematic review and meta-analysis to obtain evidence in support of this guideline, which included the 4 trials above and 4 additional studies (see Supplementary Appendix B, Evidence Profile 13) [259–266]. We found that the overall reduction in mortality with ART initiated during treatment of tuberculosis was 24% (risk ratio, 0.76; 95% confidence interval [CI], .57–1.01). The overall risk of HIV disease progression was reduced by 34% with early or immediate ART (4 studies: risk ratio, 0.66; 95% CI, .47–.91). Initiation of ART during antituberculosis therapy was associated with an increased risk of IRIS (8 studies: risk ratio, 1.88; 95% CI, 1.31–2.69). Our meta-analysis identified no increase in the risk of other adverse events or poor outcome of tuberculosis therapy. Consequently, on the basis of high certainty in the evidence that the benefits outweigh the harms, we recommend that patients with tuberculosis and HIV infection receive ART during antituberculosis treatment. Antiretroviral therapy should ideally be started within 2 weeks for those patients with a CD4 count <50 cells/μL and by 8–12

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weeks for those with a CD4 count ≥50 cells/μL (Recommendation 6: *strong recommendation; high certainty in the evidence*). An important exception is HIV-infected patients with tuberculous meningitis, in whom ART should not be initiated in the first 8 weeks of antituberculosis therapy (see "Immune Reconstitution Inflammatory Syndrome").

Concurrent Administration of Antiretrovirals and Rifamycins

Interaction of RIF with antiretroviral agents is a major treatment concern (see "Drug–Drug Interactions"). RIF is a potent inducer of drug metabolizing enzymes in the CYP family and drug transporters such as P-glycoprotein [206]. Coadministration of RIF with drugs metabolized or transported by these compounds may lead to reductions in exposure and loss of efficacy [207]. HIV protease inhibitors are metabolized by CYP3A4, and their concomitant administration with RIF leads to >80% reductions in serum concentrations of the protease inhibitors and loss of therapeutic benefit. RIF also increases the metabolism of nonnucleoside reverse transcriptase inhibitors (NNRTIs), integrase strand transfer inhibitors (INSTIs), and CCR-5 inhibitors. Detailed recommendations for coadministration of rifamycins and antiretroviral drugs have been published by the CDC, and we support these guidelines [215].

The NNRTI efavirenz is the most widely used antiretroviral drug and is the preferred initial treatment for HIV (in combination with other antiretroviral drugs) in many countries. Coadministration of RIF-containing antituberculosis regimens with efavirenz results in satisfactory antiviral efficacy, despite reductions in trough efavirenz concentrations [267, 268]. INH is an inhibitor of an alternative, minor CYP pathway involved in efavirenz metabolism. Thus, when INH and RIF are given to individuals with genetic polymorphisms associated with slow efavirenz clearance, efavirenz serum concentrations may reach supratherapeutic levels. The US Food and Drug Administration (FDA) recommends that the dosage of efavirenz be increased from 600 mg/day to 800 mg/day for patients weighing >60 kg on the basis of pharmacokinetic modeling of data from healthy volunteers; however, data from clinical studies, including the STRIDE study, do not support this advice [267, 268], and many other experts believe that efavirenz should be administered at the standard dose of 600 mg/day in patients receiving standard dose RIF-containing regimens. A treatment-shortening trial evaluating high-dose daily RPT used in combination with efavirenz-based ART for HIV-infected patients is under way (ClinicalTrials.gov identifier: NCT02410772).

The NNRTI nevirapine has also been studied as an alternative treatment for HIV-infected patients with tuberculosis [269]. However, RIF also reduces concentrations of nevirapine, a drug that induces its own metabolism [270]. Due to this autoinduction, nevirapine is initially given at a dosage of 200 mg/day for 2 weeks and then increased to 200 mg/twice daily or 400 mg/once daily. When nevirapine is started during antituberculosis treatment, use of the 200 mg daily lead-in dose can lead to subtherapeutic concentrations, loss of antiviral efficacy, and emergence of drug resistance [271–273]. Therefore, expert opinion is that if nevirapine is used during treatment with RIF, the initiation dose should be at the full 400-mg daily dosage (200 mg twice daily or 400 mg daily).

The INSTIs are now considered first-line agents for HIV infection in the United States and in Europe. Raltegravir and dolutegravir are metabolized mainly by uridine 5′-diphosphoglucuronosyltransferase 1A1 [274, 275], and concomitant use of RIF reduces trough concentrations significantly. The "Raltegravir for the treatment of patients co-infected with HIV and tuberculosis" (Reflate TB) trial showed that coadministration of RIF-based antituberculosis treatment and raltegravir at 400 mg/twice daily was associated with similar antiviral effectiveness compared to coadministration of RIF-based antituberculosis treatment and raltegravir 800 mg twice daily; both were somewhat more effective than efavirenz 600 mg daily [274]. However, pharmacokinetic data favor increasing the dose to 800 mg twice daily, and expert opinion in the United States favors this strategy [276]. Pharmacokinetic studies demonstrate that coadministration of RIF and dolutegravir at a dosage of 50 mg given twice daily results in adequate trough concentrations of dolutegravir [275]. A clinical study of patients with active tuberculosis given RIF and dolutegravir is under way (ClinicalTrials.gov identifier: NCT02178592).

RFB is less potent an inducer of CYP isoenzymes and may be used in patients receiving ART; however, RFB itself is metabolized by CYP3A enzymes, and the antiretroviral agent ritonavir (used to boost protease inhibitor levels) inhibits CYP3A enzymes, which increases concentrations of RFB. High concentrations of RFB are associated with an increased risk of uveitis and other toxicities, so dose adjustment of the standard RFB dosage of 300 mg daily is necessary [215].

Expert opinion is to use RFB at a dose of 150 mg/day or 300 mg every other day as part of a combination antituberculosis regimen for patients receiving ritonavir-boosted protease inhibitors [214]. In patients receiving dose-adjusted RFB because of concomitant protease inhibitor use, frequent assessment of adherence to both medicines is prudent, as discontinuation of the protease inhibitor while continuing dose-adjusted RFB (ie, in the context of DOT tuberculosis therapy but self-administered antiretrovirals) would be expected to result in subtherapeutic concentrations of the rifamycin, possibly with consequent poor treatment outcome and acquired rifamycin resistance. Efavirenz is also a CYP3A inducer, and when RFB is coadministered with this agent the RFB dosage needs to be increased to 600 mg/day; however, indications to use RFB instead of RIF in patients receiving efavirenz are rare.

When RFB is not available and treatment with a protease inhibitor is required because of resistance to NNRTIs and/or INSTIs, use of RIF with a lopinavir/ritonavir regimen may be attempted. For adults, this generally entails increasing the

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dosage of lopinavir/ritonavir from 400 mg/100 mg twice daily to 800 mg/200 mg twice daily over 2 weeks. This so-called "double dosing" of boosted lopinavir may result in hepatotoxicity and careful clinical monitoring is necessary [215]. Alternatively, "super boosting" of lopinavir, though poorly tolerated in adults, is sometimes effective, especially in children. In this instance, the dosage of lopinavir is maintained at 400 mg twice daily, but ritonavir dosage is increased from 100 mg twice daily to 400 mg twice daily. Super boosting of ritonavir is poorly tolerated in adults, however, and the double-dosing strategy is preferred. These complicated interactions underscore the importance of expert consultation in treating individuals with concurrent HIV and tuberculosis infections. For situations involving complex drug–drug interactions, some clinicians prefer to measure the concentrations of the interacting drugs, and to dose these drugs based upon individualized data [242].

Immune Reconstitution Inflammatory Syndrome

Transient worsening of tuberculosis symptoms and lesions in response to antituberculous therapy has previously been reported in HIV-uninfected patients [277]. Patients with HIV infection and tuberculosis are at an increased risk of developing paradoxical worsening of symptoms, signs, or clinical manifestations of tuberculosis after beginning antituberculosis and antiretroviral treatments. These reactions develop as a consequence of reconstitution of immune responsiveness brought about by ART, and are designated as the IRIS. Tuberculosis IRIS has been noted to be more common in participants with earlier ART initiation and $CD4^+$ lymphocyte counts <50 cells/μL. In the STRIDE study, IRIS occurrence was infrequent at 7.6%. When tuberculosis IRIS occurred, the majority (69%) of cases were mild to moderate in severity; however, 31% were hospitalized with tuberculosis IRIS and more than half received corticosteroids [68]. Signs of IRIS may include high fevers, worsening respiratory symptoms, increase in size and inflammation of involved lymph nodes, new lymphadenopathy, expanding central nervous system (CNS) lesions, worsening of pulmonary parenchymal infiltrations, new or increasing pleural effusions, and development of intra-abdominal or retroperitoneal abscesses [69]. Such findings are attributed to IRIS only after excluding other possible causes, especially tuberculosis treatment failure from drug-resistant tuberculosis or another opportunistic disease, such as non-Hodgkin lymphoma or infection. Antiretroviral treatment of patients with incubating, subclinical tuberculosis may also result in what is called "unmasking IRIS," where tuberculosis symptoms and clinical manifestations become more pronounced, though whether this represents normal progression of untreated tuberculosis is not known [187].

The relative risk of developing IRIS for patients who receive ART during therapy for tuberculosis is 1.88 (95% CI, 1.31–2.69), and those who start ART within 2 weeks after starting tuberculosis therapy have higher rates than those who start between 8–12 weeks [261–263]. In general, development of IRIS does not worsen treatment outcomes for either tuberculosis or HIV infection, and most episodes can be managed symptomatically. An exception to this is the development of IRIS in patients with CNS tuberculosis, where IRIS may cause severe or fatal neurological complications. In a study of patients with tuberculosis meningitis and HIV infection, early initiation of ART (within 2 weeks) was associated with increased rates of adverse events and higher mortality [278]. Thus, ART is not initiated in the first 8 weeks of antituberculosis therapy for patients with HIV infection and tuberculous meningitis (or other CNS tuberculosis), even for patients with CD4 cell counts <50 cells/μL.

Management of IRIS is symptomatic. Based on expert opinion, for most patients with mild IRIS, tuberculosis and antiretroviral therapies can be continued with the addition of anti-inflammatory agents such as ibuprofen. For patients with worsening pleural effusions or abscesses, drainage may be necessary. For more severe cases of IRIS, treatment with corticosteroids is effective. In a placebo-controlled trial of prednisone for patients with moderate IRIS, prednisone 1.25 mg/kg/day significantly reduced the need for hospitalization or surgical procedures [70]. For patients who develop IRIS, prednisone may be given at a dose of 1.25 mg/kg/day (50–80 mg/day) for 2–4 weeks, with tapering over a period of 6–12 weeks or longer. Controlled trials investigating whether treatment with nonsteroidal anti-inflammatory agents or corticosteroids can prevent the development of IRIS are under way or in development.

Children

Children commonly develop tuberculosis as a complication of the initial infection with *M. tuberculosis* (primary tuberculosis). The radiographic presentation of primary tuberculosis in children is characterized by intrathoracic lymphadenopathy with or without lung opacities, occasionally presenting with lymph node enlargement to a degree that there is compression of airways with or without hyperinflation or collapse of lobe or lung; breakthrough of node(s) in the airways can manifest with lobar or segmental infiltration, and a miliary pattern [279, 280]. The diagnosis of tuberculosis in children is challenging, especially in young children (<5 years) due to the paucibacillary nature of the disease. Depending on the setting and resources, diagnosis is microbiologically confirmed in only 15%–50% of pediatric cases, and clinical case definitions for tuberculosis in children have recently been updated [281]. Children, rarely, and adolescents, more frequently, can also develop adult-type tuberculosis (upper lobe opacities and cavitation associated with sputum production). The lesions of primary tuberculosis have fewer *M. tuberculosis* organisms than those of adult-type pulmonary tuberculosis; thus, treatment failure, relapse, and development of secondary resistance are less common events among children when standard treatment regimens are initiated in a timely

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manner. However, it is often more difficult to isolate *M. tuberculosis* from a child with pulmonary tuberculosis than from an adult. Therefore, choosing appropriate treatment drugs often requires the results of specimen culture and drug susceptibility tests from the person presumed to be the source of the child's infection. Based on expert opinion, when drug resistance is suspected or no source-case isolate is available, attempts to isolate organisms are critical; approaches including obtaining 3 early morning gastric aspirations (optimally during hospitalization), sputum induction [282], bronchoalveolar lavage [283], or tissue biopsy must be considered. Any information gained from molecular and phenotypic tests conducted on these samples is used to select an individualized regimen for the patient. Because tuberculosis in infants and children <4 years of age is more likely to disseminate and result in subsequent morbidity and mortality, empiric treatment is started as soon as the diagnosis is suspected, and particular care is given to drug dosage selection as an important component of achieving adequate concentrations of bactericidal drugs in body fluids, including the cerebrospinal fluid [284].

Several controlled and many observational trials of 6-month therapy in children with known or presumed drug-susceptible pulmonary tuberculosis have been published [285]. Based on systematic reviews of the literature, both the AAP [77] and the WHO [286, 287], list a 4-drug regimen (INH, RIF, PZA, and EMB) for 2 months followed by a 2-drug (INH and RIF) regimen for 4 months as the preferred regimen for children with suspected or confirmed pulmonary tuberculosis. The AAP Red Book also states that children who are receiving EMB should be monitored monthly for visual acuity and red-green color discrimination if they are old enough to cooperate. The AAP further notes that the use of EMB in young children whose visual acuity cannot be monitored requires consideration of risks and benefits, but it can be used routinely to treat tuberculosis disease in infants and children unless otherwise contraindicated [77]. As an approach to avoiding EMB ocular toxicity, some clinicians use a 3-drug regimen (INH, RIF, and PZA) in the initial 2 months of treatment for children who are HIV uninfected, have no prior tuberculosis treatment history, are living in an area of low prevalence of drug-resistant tuberculosis, and have no exposure to an individual from an area of high prevalence of drug-resistant tuberculosis. However, because the prevalence of and risk for drug-resistant tuberculosis can be difficult to ascertain, the AAP and most experts include EMB as part of the intensive phase regimen for children with tuberculosis. Pyridoxine, 25–50 mg/day, is given to infants, children, and adolescents undergoing INH treatment if they have nutritional deficiencies, symptomatic HIV infection, or are breastfeeding. Pyridoxine is also given to breastfeeding infants of mothers who are receiving INH [42, 77, 288, 289]. The lack of approved pediatric dosage forms for most antituberculosis medications has resulted in the creation and use of improvised formulations. This has entailed crushing tablets or opening capsules to access the drug, followed by weighing or proportioning of the contents that are in turn admixed with food or prepared into a suspension. With the recent development of child-friendly antituberculosis formulations meeting the dosage guidelines set by the WHO, procedures for making such improvised formulations should no longer be needed [290].

In the United States, DOT has become the default programmatic approach to treating children with tuberculosis [17]. Based on expert opinion, parents should not supervise DOT for their children. Even when drugs are administered under DOT, tolerance of the medications must be monitored closely. When feasible, daily dosing is preferred by experts [77, 279, 287]; however, twice- or thrice-weekly dosing has also been endorsed during the continuation phase of treatment for HIV-uninfected children in settings where DOT is well established [77] (see Supplementary Appendix C and Table 3 for dosing of antituberculosis drugs in children).

Monitoring response to treatment in children can be challenging because of the difficulties in demonstrating *M. tuberculosis* in children. Clinical and radiographic worsening may not be accompanied by positive AFB smears or mycobacterial cultures. According to experts, continued child growth and development while on treatment for tuberculosis usually predicts a positive outcome of treatment. A decision to modify the drug regimen should be undertaken with caution. Changes to the regimen are usually based on clinical and radiographic grounds. However, experts note that hilar adenopathy and resultant atelectasis in children on occasion can require 1–2 years to resolve; thus, an improving but persistent abnormality on a chest radiograph in an asymptomatic child is not believed to justify an extension of therapy. If there is concern that poor treatment response may be due to possible drug-resistant tuberculosis, expert opinion is that the child should be fully reinvestigated, verifying contact history and source case drug susceptibility test results, as well as obtaining additional specimens for cultures and drug susceptibility testing.

According to expert opinion, most forms of extrapulmonary tuberculosis in children can be treated with the same regimens as pulmonary disease [77, 286]; however, for children with confirmed or suspected tuberculous meningitis or osteoarticular tuberculosis caused by a drug-susceptible organism, expert opinion is that the duration of the continuation phase should be extended (See "Tuberculous Meningitis"). For tuberculous meningitis, the AAP lists an initial 4-drug regimen of INH, RIF, PZA, and an aminoglycoside or ethionamide for 2 months, followed by 7–10 months of INH and RIF. For patients who may have acquired tuberculosis in geographic areas where resistance to streptomycin is common, kanamycin, amikacin, or capreomycin is used instead of streptomycin [77]. Fluoroquinolones have been studied in adults with tuberculous meningitis [291], and these studies provide some evidence in support of their use; however, there have been no published trials of their use for tuberculous meningitis in children.

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Extrapulmonary Tuberculosis

PICO Question 7: Does the use of adjuvant corticosteroids in tuberculous pericarditis provide mortality and morbidity benefits?

Recommendation 7: We suggest initial adjunctive corticosteroid therapy not be routinely used in patients with tuberculous pericarditis *(conditional recommendation; very low certainty in the evidence).*

PICO Question 8: Does the use of adjuvant corticosteroids in tuberculous meningitis provide mortality and morbidity benefits?

Recommendation 8: We recommend initial adjunctive corticosteroid therapy with dexamethasone or prednisolone tapered over 6–8 weeks for patients with tuberculous meningitis *(strong recommendation; moderate certainty in the evidence).*

Tuberculosis can involve virtually any organ or tissue in the body. The principles underlying the treatment of pulmonary tuberculosis also apply to extrapulmonary disease. Chemotherapy for extrapulmonary tuberculosis is initiated with INH, RIF, PZA, and EMB in an initial 2-month phase. After 2 months of 4-drug therapy, for extrapulmonary tuberculosis known or presumed to be caused by susceptible strains, PZA and EMB may be discontinued, and INH and RIF continued during a continuation phase. Increasing evidence, including randomized controlled trials, suggests that 6–9 month INH and RIF-containing regimens are effective for the majority of extrapulmonary sites of disease. The exception is tuberculous meningitis where the optimal duration of therapy has not been established through randomized controlled trials, but most experts and society guidelines prescribe 12 months of treatment [78, 292]. The opinion of experts is that the preferred frequency of dosing for extrapulmonary tuberculosis is once daily for both the intensive and continuation phases. No randomized controlled trials have studied intermittent drug administration for extrapulmonary tuberculosis. If intermittent regimens are used, experts believe that highly intermittent, once-weekly regimens should be avoided because of insufficient experience with this regimen in extrapulmonary tuberculosis. In regard to treatment monitoring, bacteriologic evaluation is often limited by the difficulty in obtaining follow-up specimens. Sputum specimens are obtained when there is concurrent pulmonary involvement, otherwise, response to treatment in extrapulmonary diseases is often judged on the basis of clinical and radiographic findings.

Lymph Node Tuberculosis

We believe a 6-month regimen is adequate for initial treatment of all patients with drug-susceptible tuberculous lymphadenitis [293–298]. Affected lymph nodes may enlarge and new nodes can appear during or after therapy without any evidence of bacteriological relapse [293, 295, 296, 299]. Therapeutic lymph node excision is not indicated except in unusual circumstances. For large lymph nodes that are fluctuant and appear to be about to drain spontaneously, aspiration has been reported by some experts to be beneficial, although this approach has not been examined systematically. Incision and drainage techniques applied to cervical lymphadenitis, however, have been reported to be associated with prolonged wound discharge and scarring [300]. Of note, the majority of lymphatic cases of mycobacterial disease in US children are caused by nontuberculous mycobacteria [301].

Bone, Joint, and Spinal Tuberculosis

Six- to 9-month regimens containing RIF for treatment of bone, joint, and spinal tuberculosis are at least as effective as 18-month regimens that do not contain RIF [302–304]. Because of the difficulties in assessing response, however, some experts tend to favor the 9-month duration, and in the setting of extensive orthopedic hardware, some experts extend the duration of treatment further to 12 months. Several trials found no additional benefit of surgical debridement in combination with chemotherapy compared with chemotherapy alone for spinal tuberculosis [80, 303–306]. As such, uncomplicated cases of spinal tuberculosis are managed with medical rather than surgical treatment. However, based on expert opinion, surgery can be considered in situations in which (1) there is poor response to chemotherapy with evidence of ongoing infection or ongoing deterioration; (2) relief of cord compression is needed in patients with persistence or recurrence of neurologic deficits; or (3) there is instability of the spine [307]. Spinal tuberculosis with evidence of meningitis is managed as tuberculous meningitis, including consideration of adjunctive corticosteroids (see Tuberculous Meningitis).

Pericardial Tuberculosis

A 6-month regimen is adequate for patients with pericardial tuberculosis. Based on small studies that have shown mortality and morbidity benefits [71–73], corticosteroids have previously been universally recommended as adjunctive therapy for tuberculous pericarditis, however, a recent placebo-controlled randomized clinical trial with 1400 participants did not find a difference in the combined primary endpoint of the trial, which included mortality, cardiac tamponade, or constrictive pericarditis, between patients treated with adjunctive corticosteroids vs placebo [74]. A subgroup analysis, however, did suggest a benefit in preventing constrictive pericarditis. Similarly, a systematic review conducted to obtain evidence in support of this guideline did not find a statistically significant benefit in terms of mortality or constrictive pericarditis from the use of corticosteroids (see Supplementary Appendix B, Evidence Profile 14) [71–75]. Therefore, we suggest that adjunctive corticosteroids should not be used routinely in the treatment of patients with pericardial tuberculosis (Recommendation 7: *conditional recommendation; very low certainty in the evidence*). However, selective use of glucocorticoids in patients who are at the highest risk for inflammatory complications might be appropriate. Such patients might include those with large pericardial effusions, those with high levels of inflammatory cells or markers in pericardial fluid, or those with early signs of constriction [76].

Pleural Tuberculosis

A standard 6-month regimen (Table 2) is also adequate for treating pleural tuberculosis. Some clinicians consider using

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adjunctive corticosteroid therapy for tuberculous pleural effusions, and a number of studies have examined the risks and benefits of this approach [308]. Four have been prospective, double blind, and randomized [309–311], one of which was conducted in patients with HIV infection [312]. In all 4 studies, prednisone (or prednisolone) administration did not confer a beneficial effect on residual pleural thickening or prevention of other long-term pleural sequelae. In one study, an increased risk for Kaposi sarcoma was noted with the use of prednisolone in HIV-associated tuberculous pleurisy [312]. Based on these randomized clinical trials and a systematic review, there is no evidence to support the routine use of adjunctive corticosteroids in patients with tuberculous pleurisy.

Tuberculous empyema, a chronic, active infection of the pleural space containing a large number of tubercle bacilli, usually occurs when a cavity ruptures into the pleural space. Treatment consists of drainage (often requiring a surgical procedure) and antituberculous chemotherapy [313]. The optimum duration of treatment for this unusual form of tuberculosis has not been established.

Tuberculous Meningitis

Tuberculous meningitis remains a potentially devastating disease associated with a high morbidity and mortality in children and adults, despite prompt initiation of adequate chemotherapy [314]. HIV-infected individuals appear to be at increased risk for developing tuberculous meningitis, but the clinical features of the disease are similar to those in tuberculous meningitis patients without HIV infection [315–317]. High short-term morbidity and mortality is reported regardless of HIV serostatus [315–317]; however, 9-month survival was further decreased in HIV-infected patients compared with HIV-uninfected patients in one cohort study [318].

Chemotherapy for tuberculous meningitis is initiated with INH, RIF, PZA, and EMB in an initial 2-month phase. After 2 months of 4-drug therapy, for meningitis known or presumed to be caused by susceptible strains, PZA and EMB may be discontinued, and INH and RIF continued for an additional 7–10 months, although the optimal duration of chemotherapy is not defined. Based on expert opinion, repeated lumbar punctures should be considered to monitor changes in cerebrospinal fluid cell count, glucose, and protein, especially early in the course of therapy. In children with tuberculous meningitis, the AAP lists an initial 4-drug regimen of INH, RIF, PZA, and ethionamide or an aminoglycoside for 2 months (in place of EMB), followed by 7–10 months of INH and RIF [77]. There are no data from controlled trials to guide the selection of EMB vs an injectable or ethionamide as the fourth drug for tuberculosis meningitis [78]. Most societies and experts recommend the use of either an injectable or EMB. For adults, based on expert opinion, our writing committee prefers using EMB as the fourth drug. Fluoroquinolones, as well as higher doses of intravenous RIF, are being evaluated in adults with tuberculous meningitis [291, 319]; a large randomized controlled trial (ISRCTN61649292) is under way to evaluate the impact on reducing mortality of levofloxacin combined with higher-dose rifampicin during the intensive phase of treatment [320]. Selected complications of tuberculous meningitis warranting neurosurgical referral include hydrocephalus, tuberculous cerebral abscess, and clinical situations in which there is paraparesis [78].

A number of studies have examined the role of adjunctive corticosteroid therapy in the treatment of tuberculous meningitis [79–91]. Our updated systematic review found a mortality benefit from the use of adjuvant corticosteroids (See Supplementary Appendix B, Evidence Profile 15). Therefore, we recommend adjunctive corticosteroid therapy with dexamethasone or prednisolone tapered over 6–8 weeks for patients with tuberculous meningitis (Recommendation 8: *strong recommendation; moderate certainty in the evidence*).

Disseminated Tuberculosis

Based on expert opinion, a standard daily 6-month regimen (Table 2) is adequate for tuberculosis at multiple sites and for miliary tuberculosis; however, supporting data from controlled clinical trials are limited. Some experts believe concurrent corticosteroid therapy is indicated for treating severe respiratory failure or adrenal insufficiency caused by disseminated tuberculosis [321–323], though the role of adjunct corticosteroid treatment in patients with miliary tuberculosis remains unclear [324]. Patients with disseminated tuberculosis may have concomitant neurologic complications, with indolent symptoms of CNS involvement, which should be appropriately worked up [325]. Treatment recommendations for tuberculous meningitis are followed when there is CNS involvement.

Genitourinary Tuberculosis

Renal tuberculosis is treated primarily with medical rather than surgical therapy, and expert opinion is that a standard daily 6-month regimen (Table 2) is adequate [326–329]. If ureteral obstruction occurs, procedures to relieve the obstruction are indicated. In cases of hydronephrosis and progressive renal insufficiency due to obstruction, renal drainage by stenting or nephrostomy is advised by experts [330]. Nephrectomy is considered when there is a nonfunctioning or poorly functioning kidney, particularly if hypertension or continuous flank pain is present. Dose adjustment is required in patients with coexistent renal failure. Tuberculosis of the female or male genital tract responds well to standard chemotherapy, although surgery may be indicated for residual, large, tubo-ovarian abscesses.

A positive urine culture for *M. tuberculosis* is a component of the diagnostic assessment of genitourinary tuberculosis [331]. A positive urine culture for *M. tuberculosis* is also sometimes seen in tuberculosis patients with advanced HIV infection, and may reflect disseminated disease and/or occult genitourinary tract involvement. Rarely, a positive culture may occur in the

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absence of any abnormalities on urinalysis and does not necessarily represent invasive genitourinary tract involvement [332].

Abdominal Tuberculosis

Expert opinion is that a 6-month regimen is adequate for patients with peritoneal or intestinal tuberculosis [333–335]. The nonspecific presentation of abdominal tuberculosis means that a high index of suspicion is an important factor in early diagnosis and initiation of treatment [336, 337]. Data on adjunctive corticosteroid therapy in the treatment of tuberculous peritonitis are limited [338]; thus, experts believe it should not be prescribed routinely.

Other Sites of Involvement

As noted above, tuberculosis can involve any organ or tissue. When treating tuberculosis in sites other than those mentioned, the basic principles of therapy apply, but experts should be consulted.

Culture-Negative Pulmonary Tuberculosis in Adults

PICO Question 9: Does a shorter duration of treatment have similar outcomes compared to the standard 6-month treatment duration among HIV-uninfected patients with paucibacillary tuberculosis (ie, smear negative, culture negative)?

Recommendation 9: We suggest that a 4-month treatment regimen is adequate for treatment of HIV-uninfected adult patients with AFB smear- and culture-negative pulmonary tuberculosis *(conditional recommendation; very low certainty in the evidence).*

Failure to isolate *M. tuberculosis* from appropriately collected sputum specimens in persons who, because of clinical or radiographic findings, are suspected of having pulmonary tuberculosis does not exclude a diagnosis of active pulmonary tuberculosis. Some causes of failure to isolate organisms include the recent use of antibiotics with bactericidal activity against *M. tuberculosis* (eg, fluoroquinolones), low bacillary populations, inadequate sputum specimens, temporal variations in the number of expelled bacilli, overgrowth of cultures with other microorganisms, and errors in specimen processing [92]. Alternative diagnoses must be considered and appropriate diagnostic studies undertaken in patients who appear to have culture-negative tuberculosis. At a minimum, patients suspected of having pulmonary tuberculosis have 2 sputum specimens (using sputum induction with hypertonic saline if necessary) for AFB smears and cultures for mycobacteria or for rapid molecular testing for *M. tuberculosis* as part of the diagnostic evaluation. Other diagnostic procedures, such as bronchoscopy with bronchoalveolar lavage and biopsy, are considered before making a presumptive diagnosis of culture-negative tuberculosis.

Patients who, on the basis of careful clinical and radiographic evaluation, are thought to have pulmonary tuberculosis should have treatment initiated with INH, RIF, PZA, and EMB even when the initial sputum smears are negative. If *M. tuberculosis* is isolated in culture or a rapid molecular test is positive, treatment for active disease is continued for a full, standard 6-month course (Table 2), if appropriate based on drug susceptibility test results. Patients who have negative cultures but who still are presumed to have pulmonary tuberculosis should have thorough clinical and radiographic follow-up after 2 months of therapy. If there is clinical or radiographic improvement and no other etiology is identified, treatment should be continued.

The optimum treatment regimens and duration for culture-negative tuberculosis have not been convincingly established. We performed a systematic review that evaluated 4- and 6-month treatment regimens using available clinical trials data in adult (>15 years of age) patients. No clinical trials data on shortened treatments in children were available. A study from Hong Kong demonstrated that for adults with smear-negative, culture-positive, and culture-negative pulmonary tuberculosis, a 4-month regimen of INH, RIF, streptomycin, and PZA given either daily or thrice weekly was highly successful [339]. In Arkansas, a 4-month INH and RIF regimen for culture-negative tuberculosis was successful with only 1.2% relapses during an average follow-up of 44 months [340]. In Singapore, a study of a small number of patients with smear-negative and either culture-positive or culture-negative tuberculosis treated with INH, RIF, and PZA daily for 2 months followed by INH and RIF either daily or thrice weekly for 2 months showed a high degree of success in both groups [341]. Overall, these 3 studies report a proportion relapsing of only 1.9% among a total of 940 patients treated for 4 months, all of whom had at least 3 negative smears/cultures prior to starting therapy. Our systematic review of available clinical trials data in adult (>15 years of age) patients did not identify a significant difference in the risk of relapse in culture-negative tuberculosis treated for either 4 or 6 months (see Supplementary Appendix B, Evidence Profile 16). Consequently, we suggest that a 4-month treatment regimen is adequate for HIV-uninfected adults with culture-negative pulmonary tuberculosis (*conditional recommendation; very low certainty in the evidence*). Operationally, treatment is initiated with an intensive phase of INH, RIF, PZA, and EMB daily and continued in all patients suspected of having pulmonary tuberculosis even when the initial bacteriologic studies are negative. If all cultures on samples deemed to be adequate are negative and there is clinical or radiographic response after 2 months of intensive phase therapy, the continuation phase with INH and RIF can be shortened to 2 months. Clinical and radiographic response, assessed at the end of treatment, is used to determine whether an extension in treatment to a full standard 6-month regimen is needed. Alternatively, if there is concern about the adequacy of workup or the accuracy of the microbiologic evaluations, a standard 6-month regimen remains preferred (Table 2) [14, 15].

On occasion, patients who are being evaluated for pulmonary tuberculosis will be found to have positive AFB smears but negative cultures. Potential causes include the possibilities that the

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acid-fast organisms are fastidious mycobacteria other than *M. tuberculosis* complex, that they are nonviable *M. tuberculosis*, or that the results are due to laboratory error (false-positive smear, or false-negative culture). The approach in such cases is individualized on the basis of clinical and radiographic findings, as well as the results of rapid molecular diagnostic studies; discussion with the microbiologist performing the cultures is prudent. If clinical suspicion of tuberculosis is high, particularly if there is clinical and radiologic improvement since the start of therapy, then therapy is continued for a minimum of 6 months as for culture-positive pulmonary tuberculosis.

Pregnancy and Breastfeeding

Treatment for tuberculosis is initiated whenever the probability of maternal disease is moderate to high because of the risk of untreated tuberculosis to a pregnant woman and her fetus [342–345]. Although antituberculosis drugs cross the placenta, they do not appear to have teratogenic effects in humans [346–349]. However, the inclusion of PZA in the treatment regimen for pregnant women is controversial in the United States. The FDA previously classified all 4 first-line drugs, INH, RIF, PZA, and EMB, as having equal potential for teratogenicity (all assigned to category C according to the previous FDA letter-based classification system, which is currently being revised [350]). We suggest that clinicians evaluate the risks and benefits of prescribing PZA on a case-by-case basis, allowing the patient to make an informed and educated decision, recognizing that for all first-line drugs, risk cannot be ruled out as there are no adequate and well-controlled studies in humans, but potential benefits warrant use of the drug in pregnant women despite potential risks. It is also important to recognize that PZA has been used extensively in high-burden countries for many years, and is recommended by the WHO for tuberculosis in pregnancy, as part of the standard treatment regimen [98]. Expert opinion is that in pregnant women with tuberculosis and HIV, extrapulmonary or severe tuberculosis, it is more beneficial to include PZA in the treatment regimen than to not include PZA. If a decision is made to exclude PZA from the regimen, a minimum of 9 months of INH, RIF, and EMB is used for most pregnant women with drug-susceptible tuberculosis. Expert consultation should be sought when first-line drugs cannot be used due to adverse effects or antibiotic resistance, when there is extensive disease and/or a risk of noncompliance. Although the fetal effects of many second-line drugs are not well established, small case series of pregnant women treated with second-line drugs (from studies in drug-resistant tuberculosis) suggest that good outcomes are achievable and that termination of the pregnancy is not necessary [351–354]. Overall, the absence of high-quality studies combined with estimates of >200 000 cases of tuberculosis in pregnant women each year highlight the need for additional research in this area [355, 356].

Breastfeeding is encouraged for women who are deemed noninfectious and are being treated with first-line agents. The small concentrations of antituberculosis drugs measured in breast milk have not been reported to produce toxic effects in the nursing infant [77]. Conversely, drugs in breast milk should not be considered to serve as effective treatment for active tuberculosis or latent tuberculosis infection in a nursing infant. Whenever INH is given to a pregnant or nursing woman, supplementary pyridoxine, 25–50 mg/day, is prescribed [42, 43, 357, 358]. According to the AAP, supplementary pyridoxine (1–2 mg/kg/day) is also prescribed to exclusively breastfed infants, even those not receiving INH [77, 289].

Renal Disease

Patients with renal insufficiency or end-stage renal disease (ESRD) are immunocompromised [359]. Tuberculosis patients with chronic renal failure have worse clinical outcomes than those without renal failure, and, thus, experts recommend close monitoring during tuberculosis treatment [360]. The pharmacokinetics of antituberculosis drugs are altered as some are cleared by the kidneys and/or removed via hemodialysis [361, 362]. Therefore, dose adjustment in patients with renal insufficiency or ESRD may be required (Table 3 and Table 12). Decreasing the dose lowers peak serum drug concentrations and can compromise treatment efficacy. Based on expert opinion, the interval between drug doses in patients with a creatinine clearance of <30 mL/minute and those receiving hemodialysis should be increased instead. In patients with borderline renal function, a 24-hour urine collection may be needed to more accurately define the degree of renal insufficiency prior to making regimen changes [242, 363]. Insufficient data exist to guide dosing recommendations for patients with a reduced but >30 mL/min creatinine clearance. In such patients, standard doses are used by experts, but measurement of serum concentrations 2 and 6 hours after timed administration can be used to assist with optimizing drug dosages.

RIF and INH are metabolized by the liver, and conventional dosing can be used in the setting of renal insufficiency. Although PZA is metabolized by the liver, its metabolites (pyrazinoic acid and 5-hydroxy-pyrazinoic acid) may accumulate in patients with renal insufficiency. EMB is approximately 80% cleared by the kidneys and may accumulate in patients with renal insufficiency. Experts suggest a longer interval between doses (ie, thrice weekly) for PZA and EMB [242, 363]. With hemodialysis, PZA and, presumably, its metabolites are cleared to a significant degree, INH and EMB are cleared to some degree, and RIF is not cleared by hemodialysis [361]. The fluoroquinolones are also cleared variably by the kidneys. Levofloxacin undergoes greater renal clearance than moxifloxacin [179]. Postdialysis administration of all antituberculosis medications is preferred to facilitate DOT and to avoid premature clearance of drugs such as PZA. Monitoring serum drug concentrations, along with careful clinical and pharmacological assessment, in patients with ESRD, may be necessary. ESRD patients are often taking other medications that interact with antituberculosis drugs or have comorbid clinical

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Table 12. Dosing Recommendations for Adult Patients With Reduced Renal Function[a]

Drug	Change in Frequency?	Recommended Dose and Frequency for Patients With Creatinine Clearance <30 mL/min, or Patients Receiving Hemodialysis
Isoniazid	No	300 mg once daily, or 900 mg 3 times/wk
Rifampin	No	600 mg once daily, or 600 mg 3 times/wk
Pyrazinamide	Yes	25–35 mg/kg/dose 3 times/wk (not daily)
Ethambutol	Yes	20–25 mg/kg/dose 3 times/wk (not daily)
Levofloxacin	Yes	750–1000 mg/dose 3 times/wk (not daily)
Moxifloxacin	No	400 mg once daily
Cycloserine	Yes	250 mg once daily, or 500 mg/dose 3 times/wk[b]
Ethionamide	No	250–500 mg/dose daily
Para-amino salicylic acid	No	4 g/dose twice daily
Streptomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Capreomycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Kanamycin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)
Amikacin	Yes	15 mg/kg/dose 2-3 times/wk (not daily)

- Standard doses are given unless there is intolerance.
- The medications should be given after hemodialysis on the day of hemodialysis.
- Monitoring of serum drug concentrations should be considered to ensure adequate drug absorption, without excessive accumulation, and to assist in avoiding toxicity.
- Data currently are not available for patients receiving peritoneal dialysis. Until data become available, begin with doses recommended for patients receiving hemodialysis and verify adequacy of dosing using serum concentration monitoring.
- In patients with 30–50 mL/min creatinine clearance, standard doses are used by experts, but measurement of serum concentrations 2 and 6 hours after timed administration can be used to assist with optimizing drug dosages.

[a] Including adult patients receiving hemodialysis.

[b] The appropriateness of 250-mg daily doses has not been established. There should be careful monitoring for evidence of neurotoxicity.

conditions that could affect drug absorption, such as diabetes mellitus with gastroparesis. For patients receiving peritoneal dialysis, there is currently a paucity of pharmacokinetic and dosing data, and the dosages in Table 12 may not apply to patients receiving peritoneal dialysis. Such patients may require close monitoring for toxicity, and measurements of the serum concentrations of antituberculosis drugs before and after peritoneal dialysis should be considered.

Hepatic Disease

Tuberculosis treatment in patients with preexisting advanced liver disease poses significant challenges. The likelihood of drug-induced hepatitis is increased with prior advanced liver disease [364], liver transplant [365], or hepatitis C infection [366, 367]. Abnormal baseline aminotransferases alone are an independent risk factor for DILI [364, 368]. Experts recommend that patients with a history of injection drug use, birth in Asia or Africa (or other hepatitis virus endemic regions), or HIV infection have hepatitis B and C virus screening at baseline (Table 7). For patients with marginal hepatic reserve, superimposed DILI [56] may be severe, even life-threatening [369]. Fluctuations of serum aminotransferases and total bilirubin from preexisting liver disease can confound monitoring for DILI. Hepatic tuberculosis may also cause elevated aminotransferases, which improve with effective tuberculosis treatment.

Regimens with fewer potentially hepatotoxic agents are selected in patients with advanced liver disease or whose serum ALT is >3 times the upper limit of normal at baseline (and not thought to be caused by tuberculosis). The crucial efficacy of INH and particularly RIF warrant their use and retention, if at all possible, even in the face of preexisting liver disease. Expert consultation is advisable. Adjustments during treatment may be necessary. Drug susceptibility testing to fluoroquinolones and injectables is indicated if use of these drugs is being considered.

Alternative regimens for use in patients with hepatic disease include:

- Treatment without PZA: PZA has often been implicated in DILI. A potential regimen could be INH, RIF, and EMB for 2 months, followed by 7 months of INH and RIF [370, 371].
- Treatment without INH and PZA: For advanced liver disease patients, RIF and EMB with a fluoroquinolone, injectable, or cycloserine for 12–18 months, depending on the extent of the disease and response could be considered [372].
- Treatment without INH: Based on outcomes of studies on INH-resistant tuberculosis, a regimen of RIF, PZA, and EMB with or without a fluoroquinolone could be considered for a total duration of at least 6 months [373]. Although this regimen has 2 potentially hepatotoxic medications, it has the advantage of retaining a treatment duration of 6 months.
- Regimens with little or no potential hepatotoxicity: For patients with severe, unstable liver disease, EMB combined with a fluoroquinolone, cycloserine, and second-line injectable for 18–24 months (similar to an multidrug-resistant tuberculosis regimen) can be considered [374]. Some experts avoid aminoglycosides in patients with severe, unstable liver disease due to concerns about renal insufficiency or bleeding from the site of injected medication due to thrombocytopenia and/or coagulopathy.

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Monitoring of Treatment in Hepatic Disease

Data to guide the monitoring of patients with preexisting severe liver disease are scarce. Clinical monitoring and patient education for manifestations of liver injury is warranted for all patients [56]. Experts in the field recommend measuring serum aminotransferases and total bilirubin concentrations every 1–4 weeks for at least the first 2–3 months of treatment. The INR may also be periodically followed for patients with severe hepatic impairment [56, 375, 376]. An increase in serum ALT is more specific for hepatocellular injury than an increase in AST, which can also signify abnormalities in muscle, heart, or kidney [56, 377]. In patients with more advanced preexisting disease, such as those with cirrhosis or encephalopathy, the ALT thresholds for treatment interruption have not been defined. Some experts recommend, in addition to weekly or twice-weekly ALT monitoring, interrupting treatment for only a 3-fold elevation of ALT, even if asymptomatic [375, 376]. Reintroduction of antituberculous treatment may entail rechallenge and/or substitution of agents, while trying to retain the most effective medications [56]. Whenever feasible, management of tuberculosis in the setting of severe hepatic disease is undertaken in consultation with experts.

Advanced Age

The risk of drug-induced hepatitis and other serious adverse effects increases with advancing age because of less efficient drug elimination due to reduced renal and hepatic clearance [56]. Because PZA is the most common culprit [378, 379], the benefits of including PZA in the initial regimen for elderly patients with modest disease and low risk of drug resistance may be outweighed by the risk of serious adverse events. Consequently, some experts avoid the use of PZA during the intensive phase among patients >75 years of age. In such cases, the initial regimen consists of INH, RIF, and EMB. If PZA is not used during the intensive phase, then the total duration of tuberculosis treatment should be extended to at least 9 months. When the elderly patient has active tuberculosis with high bacillary burden (ie, bilateral cavitation) and, thus, treatment failure or the development of drug resistance is a concern, benefits and risks of adding PZA or a fluoroquinolone (eg, levofloxacin, moxifloxacin) vs no fourth drug should be carefully considered. The risk of drug interaction is increased in the elderly and consideration may need to be given to dose adjustments or use of alternative regimens. Careful clinical monitoring to detect intolerance and adverse reactions is warranted.

Other Comorbid Conditions

As noted previously, the CDC and WHO recommend routine HIV testing and counseling to all patients with presumptive and diagnosed tuberculosis [253, 254]. Experts also recommend that patients with a history of injection drug use, HIV infection, or birth in Asia or Africa (or other hepatitis virus endemic regions) undergo hepatitis B and C virus screening at baseline. Based on limited data, some experts also suggest screening for helminthic infections, including malaria, strongyloides, and schistosomiasis in patients originating from regions hyperendemic for these diseases. In general, tuberculosis treatment for patients with diseases or conditions that alter immune responsiveness, including HIV infection, parasitic and helminthic infections, hematologic or reticuloendothelial malignancies, immunosuppressive therapy (eg, TNF-α inhibitors) [380], chronic renal failure [381], diabetes mellitus, and malnutrition is based on the standard, daily 6-month regimen (Table 2). Nonetheless, decisions regarding treatment of comorbidities and the duration of tuberculosis treatment can be individualized, taking into account disease severity, organs involved, and response to treatment. For example, based on increased rates of tuberculosis recurrence, some experts suggest extending the total duration of tuberculosis treatment to 9 months in poorly controlled diabetes mellitus [49, 50, 382, 383]. Similarly, for patients with silicotuberculosis, data demonstrate that cure rate is improved if the continuation phase is extended by at least 2 months [169, 384]. Based on data suggesting increased mortality with shorter durations of treatment, some experts also suggest extending the total duration of tuberculosis treatment to at least 9 months for all solid organ transplant recipients [385].

The management of immunosuppressive therapy in patients who develop active tuberculosis varies based on the comorbid condition. If possible, steps are taken to correct immunodeficiency. In patients with rheumatologic disease, expert opinion is that TNF-α inhibitor therapy is held if clinically feasible, when active tuberculosis is suspected or confirmed. There is no consensus on when TNF-α inhibitor therapy can be resumed. However, small case series suggest that it is safe to resume TNF-α inhibitor therapy in patients who complete at least 2 months of antituberculosis treatment and have a good clinical response [380, 386, 387]. The decision to restart TNF-α inhibitor treatment should be individualized, taking into account the clinical need for immunosuppressive therapy, the extent of tuberculosis disease, and clinical response to antituberculosis treatment. Of note, severe IRIS-like reactions in the setting of holding TNF-α inhibitor treatment have been reported [388]. In solid organ transplant recipients, significant pharmacological interactions can occur between rifamycin-based antituberculosis regimens (particularly RIF) and calcineurin inhibitors or rapamycin; on this basis, strict monitoring of serum drug concentrations is needed to prevent rejection [389].

RECURRENT TUBERCULOSIS, TREATMENT FAILURE, AND DRUG RESISTANCE

Recurrent Tuberculosis

Recurrence refers to the circumstance in which a patient whose sputa had become and remained culture negative while

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receiving antituberculosis drugs becomes culture positive or experiences clinical or radiographic deterioration consistent with active tuberculosis after completion of therapy. In such patients, vigorous efforts are made to establish a diagnosis and to obtain microbiologic confirmation of the relapse to enable testing for drug resistance. True relapses, defined as recurrent tuberculosis caused by the same strain as was identified at baseline, are thought to be due to failure of chemotherapy to sterilize the host tissues, thereby enabling endogenous recrudescence of the original infection. In high-incidence settings or where infection control is poor, however, exogenous reinfection with a new strain of *M. tuberculosis* may be responsible for the apparent recurrence (in this context, not referred to as relapse) [390, 391].

Patients at risk for relapses are those with extensive disease at baseline and whose sputum cultures remain positive after completion of the intensive phase of treatment [9, 392]. However, the sensitivity of culture-positive status at 2 months for predicting relapse is low [46]. Most relapses occur within the first 6–12 months after completion of therapy [393]. In the majority of patients with tuberculosis caused by drug-susceptible organisms who were treated by DOT with rifamycin-containing regimens, relapses occur with susceptible organisms [394, 395]. However, the risk of acquired drug resistance is substantial in patients who have a relapse after receiving SAT, a highly intermittent regimen in the setting of HIV infection, a non-rifamycin-containing regimen (including receiving only INH and EMB in the continuation phase of treatment), or a second-course of a first-line regimen reinforced by streptomycin [59, 60, 396–400]. In addition, if initial drug susceptibility testing was not performed and the patient fails or relapses with a rifamycin-containing regimen using DOT, a high likelihood exists that the organisms were resistant from the outset [399, 401, 402]. To help guide regimen selection, rapid molecular tests have been used at the time of suspected recurrence as an approach to rapidly identifying the presence of resistance-conferring mutations; however, the detection of *M. tuberculosis* DNA and RIF resistance have been reported as being false positive [403]. Experts suggest caution in interpreting results from molecular tests used at the time of suspected recurrence.

The selection of empiric treatment regimens for patients with relapses is based on the prior treatment scheme. For patients with relapse who were treated for drug-susceptible tuberculosis using DOT, experts recommend retreatment using the standard intensive phase regimen until the results of susceptibility tests are known. For patients who did not receive DOT or had irregular treatment, it is prudent to infer a higher risk of acquired drug resistance. Whenever feasible, rapid molecular and phenotypic diagnostics for detection of drug resistance should be used to inform regimen selection. When immediate treatment initiation is necessary, consider the use of an expanded empiric regimen in consultation with experts in the treatment of drug-resistant disease. If started, an expanded empiric regimen is administered until the results of susceptibility tests are known and commonly consists of the standard intensive phase regimen of daily INH, RIF, PZA, and EMB, plus a later-generation fluoroquinolone, an injectable, and depending on the severity of disease or the anticipated extensiveness of resistance, an additional second-line drug [404]. All drugs are administered using DOT. An expanded regimen is indicated especially in patients with impaired immunity, limited respiratory reserve, CNS involvement, other life-threatening circumstances, or any other situation in which treatment with an inadequate regimen could have severe consequences to the individual or the community.

When epidemiological circumstances render exogenous reinfection the most likely cause of apparent relapse, the regimen choice is influenced by the drug susceptibility pattern of the presumed source case and/or drug-resistance testing. If the presumed source case is known to have drug-resistant organisms, an expanded empiric regimen based on the resistance profile of the putative source case may be suitable.

Poor Treatment Response and Treatment Failure

In the United States, treatment failure is defined as continuously or recurrently positive cultures after 4 months (5 months in Europe and WHO guidelines [98]) of treatment in a patient receiving appropriate chemotherapy. Among patients with drug-susceptible pulmonary tuberculosis, even with extensive lung cavitation, 90%–95% will be culture negative after 3 months of treatment with a regimen that contains INH and RIF. During this time, the vast majority of patients show clinical improvement, including reduced fever, reduced cough, and weight gain. Thus, patients with persistently positive cultures after 3 months of chemotherapy, with or without ongoing symptoms, are evaluated carefully to identify the cause of delayed response.

Multiple reasons for poor treatment response and treatment failure exist. For patients not receiving DOT, one explanation may be nonadherence to the treatment regimen. Among patients receiving DOT, cryptic nonadherence (spitting out or deliberately regurgitating tablets or capsules) or failure of the healthcare system to reliably deliver the drugs may be a cause. Other potential reasons include unrecognized drug resistance (drug susceptibility testing not done, misreported, or misinterpreted; reinfection with a drug-resistant strain), malabsorption (diarrhea, or prior resection surgery of the stomach or small intestine, or taking tuberculosis medications with antacids or other drugs/substances that might bind or interfere with drug absorption), or diabetes mellitus with or without gastroparesis [198, 199, 201, 405–410]. Some experts use TDM to evaluate poor drug exposure as a contributing factor to treatment failure [242]. Laboratory error (eg, cross-contamination or mislabeling of specimens) is also a possible reason for a positive culture in a patient who is doing well clinically [411].

Clinicians should be alert, as well, to the possibility of transient clinical or radiographic worsening (paradoxical reactions), despite appropriate therapy that would eventually result in cure.

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Examples of this include ongoing inflammation at sites of lymphadenitis, worsened abnormalities on chest radiographs after several months of treatment, or the new appearance of pleural effusions during therapy for pulmonary tuberculosis. Such paradoxical worsening during treatment can occur in HIV-uninfected patients, as well as in HIV-infected patients (see "Immune Reconstitution Inflammatory Syndrome"). The diagnosis of a paradoxical reaction is made only after a thorough evaluation has excluded other etiologies, particularly tuberculosis treatment failure and drug resistance.

For patients who meet criteria for treatment failure, the possible reasons listed above should be addressed promptly. Recent mycobacterial isolates should be sent to a reference laboratory for susceptibility testing to both first-and second-line drugs. If clinicians are not familiar with the management of drug-resistant tuberculosis, immediate referral to, or consultation with a specialty center is indicated. If treatment failure is presumably due to drug resistance and the patient is seriously ill or has a positive sputum AFB smear, an empiric regimen is started immediately and continued until susceptibility tests are available to guide therapy; however, if the patient's clinical presentation is not severe, one may either initiate an empiric retreatment regimen or wait for drug susceptibility results from a recent isolate. Of note, patients who are not on the correct regimen remain infectious [102, 412].

A single new drug is never to be added to a failing regimen as it can lead to amplification of drug resistance, including acquired resistance to the newly added drug [413]. To lessen the likelihood of increasing resistance, it is generally prudent to add 2–3 new drugs to which susceptibility could logically be inferred (eg, using regional drug-resistance surveillance data and the patient's history of medication use). When drug susceptibility results are available, the regimen is adjusted accordingly.

Tuberculosis Caused by Drug-Resistant Organisms

Mycobacterium tuberculosis bacilli are continually undergoing spontaneous mutations that create resistance to individual antituberculosis drugs; however, the frequency of these mutations is sufficiently low that with appropriate combination chemotherapy that is reliably ingested, clinically significant resistance is very unlikely to develop [121, 414]. Acquired drug resistance can occur, however, when there is a large bacillary population (such as in pulmonary cavities), an inadequate drug regimen, a combined failure of both the patient and the provider to ensure that an adequate regimen is ingested, or malabsorption of one or more antituberculosis drugs [415, 416]. During extended or repeated treatment, amplification of resistance to multiple agents may occur. Patients with acquired drug resistance may transmit their strains to others who, if they develop tuberculosis, will have primary drug resistance. Notable clinical and demographic risk factors for drug-resistant tuberculosis include having a previous episode of tuberculosis treatment (in particular if the regimen was inadequate or adherence to the regimen was low), originating from or living for an extended period in a country with a high prevalence of drug-resistant tuberculosis, and having a history of exposure to an index case with drug-resistant tuberculosis.

Comprehensive guidance on the management of drug-resistant tuberculosis is beyond the scope of this document, though international guidelines exist [404]. An ATS/CDC/ERS/IDSA practice guideline for the management of drug-resistant tuberculosis is also currently under development using GRADE methodology.

RESEARCH AGENDA FOR TUBERCULOSIS TREATMENT

Much progress has been made over the last 10 years in the treatment of tuberculosis [109, 417]. The corpus of knowledge on new drug combinations, drug interaction with antiretrovirals, methods of dosing, and timing of dosing is increasing. Based on the writing of this guideline, however, several priority areas in need of additional research were identified.

New Antituberculosis Drugs and Regimens

Treatment of tuberculosis remains centered around the same 6-month, 4-drug regimen introduced >40 years ago. The identification of more potent drugs and drug regimens that permit shortening the duration of treatment remains a key priority. A number of new drugs and regimens for tuberculosis are currently being investigated in clinical trials. This includes repurposed drugs (eg, daily high-dose RPT and higher dosages of RIF, linezolid and carbapenems) and new drugs (eg, bedaquiline, delamanid, and pretomanid [formerly PA-824]). High-dose, daily RPT is being tested in a treatment-shortening phase 3 clinical trial, with dosage selected based on dose-ranging, drug-exposure optimization studies (ClinicalTrials.gov identifier: NCT02410772) [418]. Pretomanid is being tested as part of a combination regimen including moxifloxacin and PZA for the treatment of both drug-susceptible and drug-resistant tuberculosis (ClinicalTrials.gov identifier: NCT02193776). Bedaquiline, approved by the US FDA for treatment of multidrug-resistant tuberculosis in 2012, is also being investigated in drug-susceptible disease as part of a combination regimen including pretomanid and PZA and/or clofazimine in a phase 2 study (ClinicalTrials.gov identifier: NCT01691534). Broadly, the tuberculosis therapeutics development field would greatly benefit from dose-ranging and drug–drug interaction studies for new and existing drugs so as to identify the drug exposures and optimal combinations necessary to achieve maximal efficacy, while improving safety and tolerability.

Biomarkers of Treatment Effect and Individualization of Therapy

The success of therapy depends upon many diverse factors and only some are presently predictable, identifiable, or modifiable. Inclusion of biomarker substudies that assess both microbial and host biomarkers within phase 3 clinical trials will yield

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important knowledge on the factors that impact therapeutic success. Additionally, data on pharmacokinetic/pharmacodynamic properties that influence drug safety and efficacy, data on drug penetration and distribution, and the pursuit of sensitive and specific biomarkers that can reliably predict relapse will be critically important to advancing the tuberculosis therapeutics field [116, 418, 419]. New biomarkers of treatment effect that can be implemented in the field and accurately monitor response to treatment on an individual basis may also allow for the individualization of the duration of treatment [420]. However, a considerable increase in investment in fundamental research is needed to develop and validate biomarkers of durable cure [421].

Treatment of Tuberculosis in Special Situations

Based on the writing of this guideline, the need for additional research was notable for treatment of tuberculosis in special situations. In particular, there is a paucity of high-quality studies on tuberculosis in pregnant women, breastfeeding women, and children. A recent US National Institutes of Health convened workshop examining the inclusion of pregnant and postpartum women in tuberculosis drug trials has provided consensus statements to help accelerate research in this area [422]. The lack of pediatric dosage forms of most antituberculosis medications has up to now necessitated using crushed tablets or opening capsules and creating suspensions to facilitate dosing in young children, and additionally has hampered inclusion of children in drug trials. As a result of key partnerships and concerted investments in pediatric therapeutics research, an affordable, high-quality, child-friendly fixed-dose combination meeting WHO quality assurance metrics is now being produced; however, these products are not yet registered in the United States or Europe [290]. Broadly, to address the paucity of data on the optimal treatment of children with tuberculosis, the drug development field should design trials to be more inclusive of children as study participants across key stages of therapeutics research, from pharmacokinetic studies through to phase 3 clinical trials. Examples of ongoing tuberculosis treatment trials that enroll children and adolescents are the SHINE study (Shorter Treatment for Minimal TB in Children Study; ISRCTN63579542), and TBTC Study 31/ACTG A5349 (Rifapentine-Containing Tuberculosis Treatment Shortening Regimens; NCT02410772) [423].

Implementation Research

Even as new drugs and new regimens are being developed, there remains a critical need to improve the delivery of tuberculosis treatment. DOT has been the dominant mode of treatment delivery, but evidence supporting its use has been weak. Strategies that are more convenient for patients and less resource-intensive for public health programs should be further explored [424]. For example, in low-incidence countries, early studies have shown that video DOT using smartphones is feasible, has high patient uptake, and is associated with similar adherence rates as in-person DOT [131]. Research to improve tuberculosis treatment delivery strategies should be informed by behavioral studies and/or implementation science frameworks, which have been shown to increase the likelihood of identifying successful multifaceted individual behavior change and health system interventions. Finally, research on the optimal introduction of new drugs is needed (even after approval from regulatory bodies) provide data that will facilitate key implementation decisions around programmatic feasibility, cost-effectiveness, and optimal approaches to surveillance of drug resistance and prevention of emergence of new drug resistance [425].

Supplementary Data

Supplementary materials are available at http://cid.oxfordjournals.org. Consisting of data provided by the author to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the author, so questions or comments should be addressed to the author.

Notes

Acknowledgments. Our sincerest gratitude for the support provided by Kevin Wilson, MD (Chief, Documents and Patient Education, American Thoracic Society); Judy Corn (Director, Documents and Patient Education, American Thoracic Society); Jennifer Padberg (Director of Clinical Affairs, Infectious Diseases Society of America [IDSA]); and Phil LoBue, MD (Director of the Division of Tuberculosis Elimination, Centers for Disease Control and Prevention [CDC]) in the development of this guideline.

Guideline Writing Committee Chairs, Members, And Methodologists. Guideline Committee Chairs: Payam Nahid, MD, MPH, University of California, San Francisco (Chair, American Thoracic Society); Susan E. Dorman, MD, Johns Hopkins University, Maryland (Chair, IDSA); Giovanni Battista Migliori, MD, World Health Organization (WHO) Collaborating Centre for TB and Lung Diseases, Fondazione S. Maugeri Care and Research Institute, Tradate, Italy (Chair, European Respiratory Society); Andrew Vernon, MD, MHS, Division of Tuberculosis Elimination, National Center for Human Immunodeficiency Virus (HIV)/AIDS, Viral Hepatitis, Sexually Transmitted Disease (STD), and TB Prevention, CDC, Georgia (Chair, CDC).

Writing Committee Members. Narges Alipanah, MD, University of California, San Francisco; Pennan Barry, MD, MPH, California Department of Public Health; Jan Brozek, MD, PhD, McMaster University, Ontario, Canada; Adithya Cattamanchi, MD, MAS, University of California, San Francisco; Lelia Chaisson, MSc, University of California, San Francisco; Richard Chaisson, MD, Johns Hopkins University, Maryland; Charles L. Daley, MD, National Jewish Health, Colorado; Susan E. Dorman, MD, Johns Hopkins University, Maryland; Malgosia Grzemska, MD, PhD, World Health Organization, Geneva, Switzerland; Julie Higashi, MD, San Francisco Department of Public Health, TB Control, California; Christine S. Ho, MD, Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, CDC, Georgia; Philip Hopewell, MD, University of California, San Francisco; Salmaan A. Keshavjee, MD, PhD, Harvard Medical School, Massachusetts; Christian Lienhardt, MD, PhD, World Health Organization, Geneva, Switzerland; Richard Menzies, MD, McGill University, Quebec, Canada; Cynthia Merrifield, RN, University of California, San Francisco; Giovanni Battista Migliori, MD, WHO Collaborating Centre for TB and Lung Diseases, Fondazione S. Maugeri Care and Research Institute, Tradate, Italy; Payam Nahid, MD, MPH, University of California, San Francisco; Masahiro Narita, MD, Seattle and King County TB Control and University of Washington; Rick O'Brien, MD, Ethics Advisory Group, International Union against TB and Lung Disease, Paris, France; Charles Peloquin, Pharm. D., University of Florida; Ann Raftery, RN, PHN, MS, University of California, San Francisco; Jussi Saukkonen, MD, Boston University, Massachusetts; H. Simon Schaaf, MD, Department

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of Paediatrics and Child Health, Stellenbosch University, Cape Town, South Africa; Giovanni Sotgiu, MD, PhD, University of Sassari, Sassari, Italy; Jeffrey R. Starke, MD, Baylor College of Medicine, Texas; Andrew Vernon, MD, MHS, Division of Tuberculosis Elimination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, Georgia.

GRADE Methodology Group. Narges Alipanah, MD, University of California, San Francisco; Jan Brozek, MD, PhD, McMaster University, Ontario, Canada; Adithya Cattamanchi, MD, MAS, University of California, San Francisco; Lelia Chaisson, MSc, University of California, San Francisco; Richard Menzies, MD, McGill University, Quebec, Canada; Payam Nahid, MD, MPH, University of California, San Francisco; Giovanni Sotgiu, MD, University of Sassari, Sassari, Italy.

Financial support. Support for this guideline was provided by the American Thoracic Society, the IDSA, and the CDC.

Potential conflicts of interest. The authors have reported to the American Thoracic Society the following: P. M. B. reported that his spouse previously owned stocks or options of Merck. R. E. C. reported service as a consultant and ownership of stocks or options for Merck. C. L. D. received research support from Insmed and served on data and safety monitoring boards of Otsuka America Pharmaceutical and Sanofi Pasteur. C. A. P. received research support from Jacobus Pharmaceuticals. J. S. reported service on a data safety and monitoring board of Otsuka Pharmaceuticals. A. V. reported serving as the chief of a CDC clinical research branch doing clinical trials in tuberculosis, which supports and works with the TB Trials Consortium (TBTC) that collaborates with pharmaceutical companies, which may provide support such as drug supplies or laboratory funding for pharmacokinetic substudies. Specifically, Sanofi Aventis has provided approximately $2.8 million in unrestricted grants to the CDC Foundation to facilitate or support TBTC work related to rifapentine, including contract research staff, pharmacokinetic substudies, travel to TBTC scientific meetings for invited speakers, and expenses related to fulfillment of company requests for data and data formats as part of use of TBTC data in support of regulatory filings. TBTC has studies under way involving rifapentine and levofloxacin that may have relevance for future regimens for drug-susceptible tuberculosis and for multidrug-resistant tuberculosis. All other authors report no potential conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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ICE HEALTH SERVICE CORPS **OPERATIONS MEMORANDUM**

OM 19-001
Effective Date: 21 February 2019

By Order of the Assistant Director:
(b)(6); (b)(7)(C) **DHSc, MPH**

(b)(6); (b)(7)(C)

TO: **IHSC Public Health Service (PHS) Commissioned Corps Officers, Civilian Federal Employees, and Contract Personnel**

SUBJECT: **Pediatric Tuberculosis Screening and Evaluation Guidance for Family Residential Centers**

1. **APPLICABILITY.** This Operations Memorandum (OM) is applicable to all U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) personnel (federal and contract staff), supporting health care operations in ICE family residential centers (FRC).

2. **PURPOSE.** The purpose of this OM is to provide clinical guidance to screen children (less than 18 years of age) for tuberculosis (TB) in IHSC-staffed FRCs pending release of revised Family Residential Standards (FRS).

3. **AUTHORITIES AND REFERENCES:**

   3-1. American Academy of Pediatrics: Redbook 2018.

   3-2. American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children.

   3-3. American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis.

   3-4. Centers for Disease Control and Prevention: Tuberculosis.

   3-5. Curry International Tuberculosis Center | Pediatric TB Resource Page.

   3-6. For adult residents, refer to Directive 05-11 Public Health Actions for Tuberculosis Care and 05-11 Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Facilities in the IHSC policy library.

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4. PROCEDURE:

4-1. All new arriving children will receive screening for symptoms consistent with pulmonary TB, within 12 hours of intake and in accordance with Centers for Disease Control and Prevention (CDC) guidelines (www.cdc.gov/tb) and the most current American Academy of Pediatrics (AAP) Redbook.

4-1.1. For children who have been in continuous law enforcement custody, symptom screening, plus documented negative TB testing, within one year of arrival may be accepted for intake screening purposes and complete TB testing.

4-2. Further testing of children for TB will be done using the following screening recommendations; it is recommended that the same test is used consistently for a target age group with minimal exceptions.

4-2.1. All children with signs or symptoms suggestive of TB: promptly administer a test for TB infection [interferon gamma release assay (IGRA) preferred or TB skin test (TST)] and chest x-ray (CXR) with two views [anteroposterior (AP) or posteroanterior (PA) and lateral views].

4-2.2. All children accompanied by an adult identified with confirmed or suspected TB, or other known exposure to a person with TB disease: promptly administer a test for TB infection (IGRA preferred, or TST) and CXR with two views (AP or PA and lateral views).

4-2.3. Children who do not have signs and symptoms suggestive of TB and no known exposure to TB disease:

4-2.3.1. Under 2 years: no further testing unless required by state law;

4-2.3.2. Children 2–14 years of age: within 30 days of arrival, administer a test for TB infection (IGRA preferred, or TST). If a test for TB infection cannot be accomplished, then conduct screening using a CXR with two views [AP or PA and lateral views];

4-2.3.3. Children 15–17 years of age: administer a CXR (within 72 hours of arrival) with two views (AP or PA and lateral views). If a CXR cannot be accomplished promptly, then administer a test for TB infection (IGRA preferred or TST).

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4-3. Post-Screening Evaluation.

4-3.1. Children with a positive IGRA or TST:

4-3.1.1. If the test for TB infection (IGRA or TST) is positive, administer a CXR with two views (AP or PA and lateral views].

4-3.1.2. Perform a directed physical examination for all children and adolescents with a positive IGRA, TST, or CXR to assess for pulmonary or extrapulmonary disease.

4-3.2. Children with symptoms consistent with pulmonary TB or abnormal CXR results:

4-3.2.1. Refer children who have any symptom suggestive of TB disease, or any resident with an abnormal CXR suggestive of pulmonary TB disease, to a medical provider for medical consultation. If a medical provider is not on duty at the time of identification, then admit the resident with suspected TB to an airborne infection isolation (AII) room if available on-site pending prompt evaluation;

4-3.2.2. If no AII room is available on-site, then refer the resident to the nearest tertiary care facility for isolation and evaluation in consultation with the Clinical Medical Authority or designee; and

4-3.2.3. Fit the child with a tight-fitting surgical mask (without an exhalation valve) when not in an AII room until a provider determines the child is noncontagious.

4-3.2.4. Children with suspected TB disease (extrapulmonary or pulmonary) should be referred to or managed in conjunction with a specialist with expertise in childhood TB;

4-3.2.5. A pediatric TB expert should be involved in the treatment of TB in children and in the management of infants, young children, and immunocompromised children who are known to

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have been exposed to someone with infectious TB disease;

4-3.2.6. For more information about TB disease or risks for TB-drug toxicity, see *American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis,* and the *AAP Red Book.*

4-3.2.7. A medical provider should seek expert medical consultation as needed through TB Centers of Excellence.

4-4. For children with confirmed and suspected active TB, designated medical staff will:

4-4.1. Report all children to local and/or state health departments within one working day of meeting reporting criteria and in accordance with established guidelines and applicable laws. Identify the children as being in ICE custody and provide their alien numbers [A-numbers];

4-4.2. Promptly report any movement of TB patients, including hospitalizations, FRC transfers, releases, or removals/deportations to the local and/or state health department and the CDC CureTB Program.

4-4.3. Promptly notify local or state health departments and CureTB of release or removal with the intended destination address, including apartment numbers and telephone numbers.

4-4.3.1. Reporting must include names, aliases, date of birth, A-number, TB status, available diagnostic and lab results, treatment status (including drugs and dosages), treatment start date, a summary case report, and a point of contact and telephone number for follow up.

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4-5. When treatment is indicated, multi-drug, anti-TB therapy will be administered using directly observed therapy in accordance with *American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis,* and the *AAP Red Book.*

4-6. Children receiving anti-TB therapy should be provided with a 15-day supply of medications and appropriate education when transferred, discharged, or deported, in an effort to prevent interruptions in treatment until care is continued in another location.

4-7. Treatment for latent TB infection (LBTI) should not be initiated unless active TB disease is ruled out or a pediatric TB expert advises staff to initiate LTBI treatment for a child with known exposure to contagious TB.

4-8. Annual TB testing should be implemented in accordance with CDC guidelines. The annual TB screening method should be appropriately selected with consideration given to the initial screening method conducted or documented. Routine annual CXRs are not required or recommended. Evaluate all children in continuous law enforcement custody for symptoms consistent with TB within one year of the previously documented TB evaluation. In HIV positive children, health staff should perform a TST or an IGRA annually to exclude recent TB infection.

4-9. For TB reporting, the Compliance Officer (CO), or designee if the facility does not have a CO, must oversee case reporting information in the TB Case Management (TB-CM) template in the electronic health record (eHR). Health staff should refer to the 05-06-G-03, Infectious Disease Public Health Actions Guide: Surveillance and Reporting, and the IHSC eCW User Guide: TB Case Management, for detailed guidance on reporting of presumptive and verified confirmed tuberculosis using the TB-CM template in eCW.

5. HISTORICAL NOTES. This OM supplements FRS on those elements of Directive 05-11: Public Health Actions for Tuberculosis Care, and 05-11, Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics involving pediatric TB screening.

6. APPLICABLE STANDARDS

6-1. Family Residential Standards (FRS):

Part 4: Care; 4.3: Medical Care.; 2. Communicable Disease and Infection Control; b. Additional Requirements Regarding Tuberculosis.

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7. **NO PRIVATE RIGHT STATEMENT:** This OM is an internal statement of IHSC. It is not intended to, and does not create, any rights, privileges, or benefits, substantive or procedural, enforceable against the United States, its departments, agencies, or other entities; its officers or employees; or any other person.

8. **RECORDKEEPING:** All documentation should be completed in the electronic health record and retained as required for IHSC Alien Health Records.

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ICE Health Service Corps

Clinical Guidelines for the Treatment of Gender Dysphoria (formerly Gender Identity Disorder, GID)

Introduction

Gender, that is the essence of male and female, is not a clear cut distinction, but rather a spectrum on which an individual perceives themselves and is perceived by others. Transgender individuals identify with a gender which is different than their sex assignment at birth. This gender identity often manifests early in childhood but may emerge in adolescence or even adulthood. Transgender individuals may identify with the opposite sex (e.g. male to female or transwoman/girl, female to male or transman/boy) or somewhere along the gender spectrum identifying with characteristics of both genders (gender non-conforming).

Discordance between self-perception, perception of and treatment by others, and gender assignment at birth lead to conflict regarding gender identity, the most extreme of which is Gender Dysphoria (GD). Gender dysphoric individuals do not identify with their birth-assigned gender which in turn generates distress from internal discord as well as external (family and social) misunderstanding and rejection which may culminate in neglect and/or abuse.

Many patients with GD have a strong desire to modify their appearance to match the gender they identify with, and this may be achieved through hormonal supplementation as well as a vast array of surgical procedures. Both hormone treatment, as well as gender affirming (reassignment) surgery (most conservatively referring to genital reconstruction only), are covered as necessary medical treatment by major health plans as long as appropriate medical evaluation has occurred and been documented.

Basic Tenets of Managing Patients with Gender Dysphoria

1. Evaluation and treatment of detainees with GD should involve a multidisciplinary team including medical, mental health, pharmacy, nursing and administrative staff.
2. Treatment of GD is not cosmetic; denial of treatment may lead to worsening mental health and self-harm by distressed detainees.
3. Use of the pronoun corresponding to the desired gender should be utilized; slang terms ("tranny", "he-she", etc.) are derogatory and are not permissible.
4. Instituting treatment for ICE detainees with GD does **not** require previous hormone treatment. Newly diagnosed and/or previously untreated GD will be managed with the same liberality as newly diagnosed and/or previously untreated hypertension or diabetes – if treatment is clinically indicated, is desired by the patient and no medical/mental health contraindications exist, it will be initiated. Initiation of treatment does, however, require 1) evaluation by a mental health provider to officially establish the diagnosis of GD as well as evaluation for comorbid mental health illness and 2) counseling by a trained medical provider regarding the risks and benefits of treatment as well as reasonable expectations of hormone treatment. Gender affirming surgery will be considered, on a case-by-case basis, consistent with applicable medical standards.
5. Laboratory values are utilized to guide your treatment plan; corresponding physiologic

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changes are slow and variable amongst individuals and "failure to see changes" should not prompt an increase in dosage without supportive laboratory data. In addition, laboratory monitoring, pertinent review of systems, extensive counseling and physical examinations are all necessary to optimize patient safety. See **Appendix A and B** for the current treatment protocols and **Appendix E and F** for the informed consent documents which will be utilized as a counseling tool as well as documentation of the patient's understanding of the risks and benefits of hormone treatment.

6. Screening for concomitant medical conditions
    - Mental Health (MH) conditions (mood disorders, anxiety disorders, PTSD etc.) are more common in transgender individuals than the general population. All transgender individuals will be referred to a MH professional for the initial evaluation of GD as well as other concomitant MH conditions; the care plan including frequency of MH appointments will follow as deemed clinically appropriate by the MH provider. In addition, the patient should be assessed for readiness to start/continue treatment: consolidation of gender identity (if time in custody allows), progress in stabilizing mental health, and is deemed likely to take hormone treatment responsibly.
    - Blood borne pathogens and sexually transmitted infections (STIs) – HIV, syphilis, hepatitis B and C, chlamydia and gonorrhea - are common infections among transgender patients and should be actively screened for at the initial provider evaluation. Failure to diagnose may lead to untoward clinical outcomes and/or spread of infection both within and outside of the correctional environment.
7. For additional staff training and resources, see Appendix B.

Special Issues for Transgender Individuals in Custody

1. *Housing determination*

    Segregation is not required nor encouraged unless the detainee self-identifies as feeling vulnerable or at risk of harm because of their gender identity. Such concerns will be addressed during custody processing and should also be queried at the time of intake, as well as during periodic medical and mental health evaluations. Automatic assignment to administrative segregation for simple disclosure of gender dysphoria without perceived risk of harm/vulnerability may lead to the well-recognized risk of prolonged isolation, including significant self-harm and suicide.

    In facilities which have adopted or implemented best practices found in the "ICE Detention Facility Contract Modification for Transgender Care," transgender detainees may initially be placed in administrative segregation for a maximum of 72 hours (not counting weekends and holidays) to allow for the Transgender Classification and Care Committee to convene and determine a detention plan which includes housing. Housing options include: 1) general population male or female, 2) special unit housing (e.g., Gay-Bisexual-Transgender (GBT) or transgender only), or
    3) in rare cases, administrative segregation.

    Housing of transgender detainees in facilities which have not adopted or implemented this contract's best practices will be left to the discretion of the medical and custody staff. Several factors should be considered including the degree of gender expression of the

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detainee, comfort and safety of the detainee and the layout of individual units including privacy factors. Medical staff are encouraged to assist custody staff in establishing housing assignment.

2. *Gender Specific Undergarments*

   Undergarments which reflect the gender identity of the individual should be provided. Special needs forms should suffice as medical orders which custody staff shall honor.

3. *Additional support and resources*

   A correctional setting poses many challenges for a transgender person given the lack of privacy, targeted discrimination and abuse which may be amplified in close quarters and the risk of sexual assault. Resources are available to help these detainees share common experiences for support and encouragement. See **Appendix C**.

Continuity of Care Referrals

If a transgender detainee is released to the U.S., there are many regional centers of excellence as well as independent practitioners where the detainee may continue their care. See **Appendix D**. In the case of deportation, in country resources for transgender care may be limited and IHSC-directed referrals won't usually be possible. However, transgender detainees will be provided with two weeks of medication (in line with standard IHSC guidelines) to provide them with a chance to establish care once they have repatriated.

References

1. http://transhealth.ucsf.edu/trans?page=protocol-00-00
2. Tom Waddell Health Center. (2006, revised May 2013). *Protocols for Hormonal Reassignment of Gender*. Accessed online January 28, 2014 from: http://www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/TransGendprotocols122006.pdf
3. Hembree et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2009; 94(9):3132-54
4. VA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives. Transgender Cross-Sex Hormone Therapy Use. February 2012
5. Guidelines for Psychological Practice with Transgender and Gender Nonconforming People. Retrieved from http://www.apa.org/practice/guidelines/transgender.pdf

Disclaimer – Clinical guidelines have been established to provide medical providers at IHSC facilities with general information regarding the management of patients. Guidelines are not statements of policy. Medical providers should consider each case individually, in the context of good clinical judgment and within the provider's experience and comfort level. This guidance is not intended to, does not, and may not be relied upon to create any right or benefit, substantive or procedural, enforceable at law by any party in any administrative, civil, or criminal matter.

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Appendix A – Male to Female (MTF) Transgender Treatment Protocol

***Initiating MTF transgender treatment*:**

Visit 1 – assessment, referral to BH if not already done, order blood work (HIV serology, RPR, GC/chlamydia nucleic acid test, hepatitis B surface antigen, hepatitis C serology, testosterone, estradiol, lipids, cmp prolactin*), general counseling including completion of eCW informed consent document.

Visit 2 (1 week later)– if baseline lab work is normal and confirmed GD by BHP then start estradiol 2 mg / spironolactone 50 mg / aspirin 81 mg daily. Order bmp for the next visit.

Visit 3 (1 month later) – if bmp (potassium and creatinine) is normal, increase spironolactone to 100 mg daily. Order lab work (testosterone, estradiol, prolactin, cmp, lipids) for next visit.

Visit 4 (2 months later) – review lab work, PE assessment; if testosterone is not fully suppressed (<50) would increase spironolactone to 150 mg daily**; if estradiol is not at female pre-menopausal (100-200) level, increase estradiol by 2 mg daily.

Visit 5 (2-3 months later) and every 2-3 months thereafter for the first year until at goal; if 1 year of steady follow up, can reduce full blood work panel to every 6 months if hormone levels are at steady, physiologic level and no signs of end organ effects (LFTs, renal function, electrolytes).
If the patient is 60 yrs or older, please order a baseline bone mineral density scan. Perform age appropriate breast cancer screening if the patient has been on 10 years or more of hormone therapy (HT) (cumulatively).

***Continuing MTF transgender treatment*:**

Visit 1 – assessment, referral to BH if not already done, order blood work (HIV serology, RPR, GC/chlamydia nucleic acid test, hepatitis B surface antigen, hepatitis C serology, testosterone, estradiol, lipids, cmp, prolactin), general counseling including completion of eCW informed consent document.
Continue outpatient oral dose (maximum of estradiol 8 mg daily, maximum spironolactone 150 mg daily) add aspirin 81 mg daily (if not already receiving), add spironolactone if not yet receiving, start at 50 mg daily

Visit 2 (2 weeks later)– confirm GD diagnosis as per by BHP, review laboratories with patient. If was not previously on spironolactone, can increase from 50 mg to 100 mg daily if potassium and creatinine are normal. Otherwise, no need to modify treatment at this point assuming labs are within normal limits. Order lab work (testosterone, estradiol, prolactin, cmp, lipids) for next visit.

Visit 3 (2 months later) – review lab work, PE assessment; if testosterone is not fully suppressed

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(<50) would increase spironolactone to 150 mg daily; if estradiol is not at female pre-menopausal (100-200) level, increase the estradiol by 2 mg daily. Order lab work (testosterone, estradiol, prolactin, cmp, lipids) for next visit.

Visit 4 (2-3 months later) and every 2-3 months thereafter for the first year following labs above and making adjustments based on estradiol and testosterone levels (assuming monitoring labs are normal); after 1 year of steady follow up, can reduce full blood work panel to every 6 months if hormone levels are physiologic and no signs of end organ effects (LFTs, renal function, electrolytes).
If the patient is 60 yrs or older, please order a baseline bone mineral density scan. Perform age appropriate breast cancer screening if the patient has been on 10 years or more of HT (cumulatively).

*Prolactin levels are often mildly elevated and this is normal; prolactin levels should ideally be obtained in the early AM and fasting. If levels are above 50, consider decreasing the estrogen supplementation to see if prolactin declines as well as inquire about the symptoms of prolactinoma which may include galactorrhea, headaches and diplopia. If the level does not decline or rises regardless of the medication adjustment OR review of systems is positive, consider an MRI of the sella (pituitary gland) to exclude a prolactinoma.

**spironolactone can be increased to 200 mg daily if indicated, but please split dose as 100 mg 2x/day

Estrogen conversion¥

Estradiol (P.O.) daily	Premarin (P.O.) daily
2 mg	1.8 mg
4 mg	2.7 mg
6 mg	3.75 mg
8 mg	5 mg

¥ Estimated values, please use serum estradiol to adjust accordingly

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Appendix B – Female to Male (FTM) Transgender Treatment Protocol

***Initiating FTM transgender treatment*:**

Visit 1 – assessment, referral to MH if not already done, to confirm GD diagnosis and to assess for readiness to start treatment. Order blood work (HIV serology, RPR, GC/chlamydia nucleic acid test, hepatitis B surface antigen, hepatitis C serology, testosterone, estradiol, lipids, lfts, and cbc), general counseling including completion of eCW informed consent document.

Visit 2 (1 week later)– if baseline lab work and confirmed GD and demonstrates readiness to start treatment by BHP, then start testosterone cypionate 100 mg IM every 2 weeks. Order lfts, lipids, testosterone, estradiol, and cbc for 8-12 weeks after treatment has begun (to be timed 1 week after an injection; e.g., injections are day 1 and 15 of each month, the lab draw should fall on ~ day 7 or 21 of the calendar month). If a family history of osteoporosis exists or the patient is 60 yrs or older, please order a baseline bone mineral density scan.

Visit 3 (2-3 months later) – review labs, if estradiol is not suppressed and testosterone is not above 350 ng/dL, increase testosterone dose to 200 mg every 2 weeks. The serum testosterone level should not exceed 700 ng/dL.

Visit 4 etc. (2-3 months later) and every 2-3 months thereafter for the first year until at goal; if 1 year of steady follow up, can reduce full blood work panel to every 6 months if hormone levels are at steady, physiologic level and no signs of end organ effects (LFTs, renal function, electrolytes). Note, once uterine bleeding stops, estradiol levels are not necessary to obtain.

If the uterus has not been removed, pap smears should be conducted per usual preventive guidelines; likewise if mastectomy has not been performed, mammogram cancer screening is per usual guidelines.

***Continuing FTM transgender treatment*:**

Visit 1 – assessment, referral to BH if not already done to confirm GD diagnosis and to assess for readiness to continue treatment. Continue outpatient testosterone (maximum of testosterone cypionate 200 mg IM every 2 weeks), order blood work (HIV serology, RPR, GC/chlamydia nucleic acid test, hepatitis B surface antigen, hepatitis C serology, testosterone, estradiol, lipids, lfts and cbc), (to be timed 1 week after an injection; e.g. injections are day 1 and 15 of each month, the lab draw should fall on ~ day 7 or 21 of the calendar month). Provide general counseling including completion of eCW informed consent document.

Visit 2 (2 weeks later)– confirm GD diagnosis/readiness as per by BHP, review laboratories with patient. If testosterone is not above 350 ng/dL, increase testosterone dose to 200 mg every 2 weeks. The serum testosterone level should not exceed 700 ng/dL.

Visit 3 etc. (2-3 months later) and every 2-3 months for the first year until at goal; if 1 year of steady follow up, can reduce blood work to every 6 months if hormone levels are at steady,

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physiologic level and no signs of end organ effects. Note, once uterine bleeding stops, estradiol levels are not necessary to obtain.

If the uterus has not been removed, pap smears should be conducted per usual preventive guidelines; likewise if mastectomy has not been performed, mammogram cancer screening is per usual guidelines.

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Appendix C - Additional Provider and Patient Resources

1. Trans in Prison Journal, produced by the Gender Identity Center of Colorado; you can download a copy and give to your detainees; they can mail in the request form on the issue and they will receive the future publications gratis as long as they are in a correctional setting.
   https://www.gic-colorado.org/programs/trans-in-prison/

2. "Cruel and Unusual", documentary by Janet Baus and Dan Hunt, about transgender persons and the challenges they face in and out of the correctional System. ~ 1 hour long
   https://www.youtube.com/watch?v=5Yzy8oh5Fw0
   www.fandor.com/films/cruel_and_unusual

3. Resources on children diagnosed with GD, Most of our detainees will receive their hormone treatment during adolescence or adulthood but to benefit the most from this treatment, diagnosis of GD and treatment should occur during childhood.
   www.youtube.com/watch?v=YfqmEYC_rMI
   http://www.huffingtonpost.com/2014/05/30/whittington-family-ryland-___transgender-son_n_5414718.html

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Appendix D – Transgender Care Regional Centers of Excellence for Continuity of Care or Referring Challenging Cases

AOR	Facility name	Phone number	Website
Washington DC	Transgender Health Empowerment	202-636-1646	http://theincdc.org/
Boston	Fenway Health	617-267-0900	http://www.fenwayhealth.org
New York	The Center Transgender Resources	212-620-7310	https://gaycenter.org/wellness/gender-identity http://transgendercny.org/
Newark	Callen Lorde	212-271-7200	http://callen-lorde.org/our-services/sexual-health-clinic/transgender-health-services/
	City of Newark Dept of Child and Family Well Being	973-733-7635	
Philadelphia	Mazzoni Center	215-563-0658	http://mazzonicenter.org/content/transgender-services
Buffalo	Endocrinology center of Western New York	716-887-4069	
Detroit	UMHS-CGCP	734-736-0465	http://www.med.umich.edu/transgender/index.htm
Chicago	Howard Brown Health Center	773-388-1600	www.howardbrown.org
Atlanta	In-town Primary Care	404-541-0944	http://www.intownprimarycare.com/glbt-health/transgender-health.html
Miami	Care Resource	305-576-1234	http://www.careresource.org/programs/transgender-services/
New Orleans	Louisiana Trans Advocates	337-580-4615	http://www.latransadvocates.org/resources.html

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AOR	Facility name	Phone number	Website
Houston	Dr. Hammill Transgender Health Clinic	713-799-8994	http://drhammill.transhouston.com/
	Transgender Center	713-520-8586	http://www.transgenderctr.org/
San Antonio	SAGA	sagacal09@gmail.com	http://www.sagender.com/local-resources/
	Pride Center	210-370-7743	http://pridecentersa.org/resources/
Dallas	Transgender Health Clinic	214-528-2336	
	Resource Center of Dalllas	214-528-0144	http://www.rcdallas.org/family/transgender
El Paso	Trans Health Referral Line	915-532-7000	2301 N Oregon St, El Paso, TX 79902
Saint Paul	Transgender Health Services University of MN	612-625-1500	http://www.med.umn.edu/fm/phs/clinic/transgender.html
Denver	Gender Identity Center of Colorado	303-202-6466	http://www.gicofcolo.org
Salt Lake City	Susan Chasson	801-357-7930	
	D. S. Burton	385-282-2750	
	LeAnne Swenson	385-282-2000	
Phoenix	Prime Medical Clinic	602-840-3584	http://www.myprimeclinic.com/
Seattle	Gay City Health Project	206-323-5428	https://www.gaycity.org/resources/
San Francisco	The San Francisco Center	(415) 865-5555	http://www.sfcenter.org/

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AOR	Facility name	Phone number	Website
San Francisco	UCSF Center of Excellence	415-597-8198	http://www.transhealth.ucsf.edu/
Los Angeles	Western Medical Center Anaheim	714-533-6220	
	UCLA LGBT Resource Center	310-206-3628	http://www.lgbt.ucla.edu
San Diego	The Center	619-692-2077	http://www.thecentersd.org
General Resources			http://www.transgenderlynnsplace.com/transgender-medical-resources.htm

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Appendix E: Informed Consent Document for Hormone Therapy (male to female)

For Male to Female Transition: Estrogen/Antiandrogen Therapy Consent Form

Informed Consent: Information about this form.

This form refers to the use of estrogen and antiandrogens by detainees who wish to become more feminized as part of a gender transitioning process.

Your agreement or disagreement of the various statements on this form indicate that the risks as well as the changes which may occur as a result of the use of estrogen and antiandrogens have been explained and that you understand them.

If you have any questions or concerns about this information, you are encouraged to take the time you need to ask for clarification, read, research, talk with staff and think about the potential effects of this treatment before signing.

IF YOU DO NOT UNDERSTAND THIS INFORMATION STOP AND ASK FOR CLARIFICATION

---

1. I understand that estrogen may cause or contribute to depression. If I have a history of depression I will discuss this with my provider to explore treatment/therapy options that are available to me.

○ AGREE ○ DISAGREE

Some of these changes will be permanent including:

Breast development: Breast development may take years to reach full size.

There are natural variations in the size of breasts, and one person's breast development will not correlate with that of another person's.

If estrogen therapy is discontinued, there may be some breast shrinkage, but breast development will not completely disappear.

Brain structures are affected by testosterone and estrogen.

The long term effects of changing the levels of ones hormones through the use of estrogen therapy and testosterone suppressants have not been scientifically studied & are impossible to predict.

These effects may be beneficial, damaging, or both. Changes in fertility and sperm production (see information below in # 5).

These additional changes will not be permanent if I stop taking estrogen:

Decreased acne

Male pattern balding stops or slows (no hair loss will be reversed once it occurs)

Skin may become softer

Facial and body hair growth may decrease (not stop) in thickness or quantity to a greater or lesser extent.

Redistribution of body fat to a more female pattern (i.e., abdominal fat may decrease while fat on the buttocks and thighs may increase)

○ AGREE ○ DISAGREE

2. I understand the effects of estrogen will not protect me from sexually transmitted diseases or HIV and that condoms or barrier methods should be used.

○ AGREE ○ DISAGREE

3. Due to breast development with estrogen therapy, I understand that I will need to do monthly breast self-examinations, have an annual medical exam, and, once I am 40 or older, I will need to have an annual mammogram.

○ AGREE ○ DISAGREE

4. I understand that estrogen therapy will decrease hormones that support the size and function of my testicles, which may then effect overall sexual functioning and fertility.

The changes that may occur include:

a. Up to 40% shrinkage in size of the testicles.

b. Decrease in testosterone production from the testicles

c. The amount and quality of erections and ejaculation may decrease or stop entirely.

d. Sperm will still be present in the testicles, but may stop maturing which may cause infertility.

e. If estrogen therapy is stopped, the ability to make sperm healthy, mature sperm may or may not ever come back.

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f. Erections may no longer be firm enough for penetrative intercourse.

g. There may be a decrease or loss of morning and spontaneous erections. Sex drive or libido may decrease.

AGREE DISAGREE

5. I understand that taking estrogen can significantly increase the risk of blood clots (thrombosis)

This risk of blood clots can result in:

a. death

b. deep vein thrombosis (clots in large veins)

c. chronic leg vein problems

d. pulmonary embolism (blood clot in the lung, which can cause permanent lung damage or death)

e. cerebral vascular accident (stroke) which may result in permanent brain damage, blindness, paralysis, difficulty talking or death.

AGREE DISAGREE

6. I understand that the risk of blood clots, heart attack, and stroke on estrogen therapy is increased further if I smoke tobacco, especially if I am over the age of 35.

AGREE DISAGREE

7. I understand that estrogen can cause increased blood pressure. If I have existing high blood pressure it may not be controlled on my current regimen of medication and/or diet and exercise.

AGREE DISAGREE

7a. I understand that I may be able to take estrogen safely with close medical monitoring.

AGREE DISAGREE

8. I understand that estrogen use may lead to liver inflammation or liver disease. I agree that while I am on estrogen therapy I will be monitored for liver problems before and periodically during therapy.

AGREE DISAGREE

8a. I understand that there is a slight risk of long-term estrogen use causing liver cancer.

AGREE DISAGREE

9. I understand that estrogen may increase migraine headaches and that this may be a reason for me to choose to stop taking estrogen or may be a reason for estrogen to be discontinued by my provider.

AGREE DISAGREE

9a. I also understand there is a very small risk of developing a tumor at the base of the brain (pituitary gland), but that my blood tests will be monitored regularly to detect this problem early.

AGREE DISAGREE

9b. If I develop new headaches, double vision and/or breast milk production, I should inform my health care provider immediately.

AGREE DISAGREE

10. I understand that estrogen may cause nausea and vomiting, similar to morning sickness in a pregnant woman. If I experience nausea and vomiting that are severe and/or prolonged.

AGREE DISAGREE

11. I understand that the most dangerous side effects from estrogen therapy occur in connection with smoking cigarettes, being overweight, being over 40 years old & having a history of blood clots, high blood pressure, or prior estrogen dependent cancer.

AGREE DISAGREE

12. I understand that estrogen therapy may be discontinued or adjusted at any time if concerns or complications arise which are threatening to my continued physical and/or psychological well-being.

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AGREE DISAGREE

13. I understand that estrogen may cause changes in my cholesterol. My HDL (good cholesterol) may go up and my LDL (bad cholesterol) may go down.

AGREE DISAGREE

14. I understand that estrogen may prevent prostate problems. I have been informed that there is a slight chance that taking estrogen will cause overgrowth of the prostrate.

AGREE DISAGREE

14a. Prostate cancer screening is recommended for people 50 years of age and older as well as in younger people if otherwise medically indicated.

AGREE DISAGREE

15. I understand that antiandrogen side effects include dehydration, high potassium levels, breast enlargement, low blood pressure and kidney problems. My labs and blood pressure will be routinely monitored to detect changes.

AGREE DISAGREE

16. I understand that everyone's bodies will respond differently to estrogen and that there is no way to predict what will be my response to hormones.

AGREE DISAGREE

16a. I understand that the correct dosage for me may not be the same as for another person. I understand I must follow my prescribed regimen of estrogen treatment to continue to receive hormone therapy at this clinic.

AGREE DISAGREE

17. I agree to take estrogen and all other transition related medications as prescribed and to inform my provider of any problems or dissatisfactions I may have with my treatment.

AGREE DISAGREE

18. I will have a complete physical examination annually and lab tests periodically as required to make sure I am not having an adverse reaction to hormone treatment and to continue good health care.

AGREE DISAGREE

19. I understand that there are medical conditions that could make taking estrogen either dangerous or physically damaging.

AGREE DISAGREE

19a. I agree that if my provider suspects I may have any condition that could be dangerous to me, I will be evaluated for it before the decision to start or continue my hormones is made.

AGREE DISAGREE

19b. I understand that if I do not agree to be evaluated, my prescription for estrogen may be cancelled or refused.

AGREE DISAGREE

20. I understand that I can choose to stop taking estrogen at any time. I also understand that my provider can discontinue treatment for clinical reasons.

AGREE DISAGREE

20a. I agree to follow a prescribed reduction plan if either of these situations occurs to reduce negative and potentially harmful side effects that may occur if I suddenly stop my hormone therapy.

AGREE DISAGREE

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CONSENT:

Having considered all of the above counseling I would like to:

○ Begin Estrogen / Antiandrogen Therapy ○ Defer Estrogen / Antiandrogen Therapy at this time

Patient Signature:

Patient Printed Name:

Date:

Provider Information:

Provider Signature:

Provider Printed Name:

Date:

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Appendix F: Informed Consent Document for Hormone Therapy (female to male)

Androgen Therapy Consent Form

For Female to Male Transition

Informed Consent: Information about this form.

This form refers to the use of androgens by detainees who wish to become more masculinized as part of a gender transitioning process.

Your agreement or disagreement of the various statements on this form indicate that the risks as well as the changes which may occur as a result of the use of androgens have been explained and that you understand them.

If you have any questions or concerns about this information, you are encouraged to take the time you need to ask for clarification, read, research, talk with staff and think about the potential effects of this treatment before signing.

IF YOU DO NOT UNDERSTAND THIS INFORMATION STOP AND ASK FOR CLARIFICATION

1. Some changes will be permanent including:
   - Brain structures are affected by testosterone and estrogen
     - The long term effects of changing the levels of one's hormones through the use of androgen therapy have not been scientifically studied and are impossible to predict
     - These effects may be beneficial, damaging, or both
   - Deepening of the voice, which occurs after 6 to 10 weeks of androgen administration, is irreversible
   - Breast changes similar to menopausal women including loss of firmness, changed shape, smaller size, etc.
     - There are natural variations in the size and changes of breasts, and one person's breast changes will not correlate with that of another person's

   These additional changes will not be permanent if I stop taking androgen:
   - Development of sexual hair which follows the pattern of boys in puberty
     - First upper lip, then chin, then cheeks
     - The predicted pattern and degree of this hair growth can be predicted by the pattern and degree in male members of the same family.
     - Hair loss, "male pattern baldness" occurrence can also be predicted from the degree and pattern of male members of the same family
   - Menses (monthly period) will usually stop within a few months of treatment; however, sometimes bleeding may continue
   - Increase in lean body mass (average of 4kg (~9 pounds)) and an even greater increase in body weight
   - Reduction of subcutaneous fat overall but focally increased abdominal fat
   - Occurrence of acne (occurs in ~40% of patients)
   - Clitoral enlargement will occur, but the degree varies from patient to patient
   - Increased libido in most patients
   - Polycystic-like changes in ovaries

2. I understand the effects of androgen will not protect me from sexually transmitted diseases or HIV and that condoms or barrier methods should be used.
3. I understand that I will need to continue to do monthly breast self-examinations, have an annual medical exam, and, once I am 40 and older, I will need to have an annual mammogram
4. I understand that androgen therapy will decrease hormones that support the functioning of my reproductive organs which may then effect overall sexual functioning and fertility.
5. I understand that androgen use may lead to major adverse cardiovascular events. I agree that I will be monitored for cardiovascular risk factors and cardiovascular events before and periodically during therapy. These adverse events include:
   a. death
   b. myocardial infarction (heart attack)
   c. cerebral vascular accident (stroke) which may result in permanent brain damage, blindness, paralysis, difficulty talking or death
6. I understand that the most dangerous side effects from androgen therapy occur in patients with a history of cardiovascular events or cardiovascular risk factors including high blood pressure, tobacco use, elevated blood glucose (including diabetes), physical inactivity, unhealthy diet, elevated cholesterol, being over 55 years old and overweight/obesity.

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6a. I understand that androgen therapy may be discontinued or adjusted at any time if concerns or complications arise which are threatening to my current physical and/or psychological wellbeing.

7. I understand that androgen therapy can cause increased blood pressure. If I have existing high blood pressure and it is controlled with medication and/or diet and exercise:
   7a. I understand that I may be able to take androgen safely with close medical monitoring
8. I understand that androgen therapy may cause changes in my cholesterol. I agree that while I am on androgen therapy I will be monitored for changes in my cholesterol
9. I understand that androgen therapy use may lead to liver inflammation or liver disease. I agree that while I am on androgen therapy I will be monitored for liver problems before and periodically during therapy.
10. I understand that there is a risk of androgen therapy causing an abnormal increase in circulating red blood cells and an increased number of red blood cells may be a reason to stop therapy.
11. I understand that there is a slight risk of long-term androgen causing breast cancer.
12. I understand that there is a slight risk of androgen causing ovarian cancer.
13. I understand that everyone's bodies will respond differently to androgen therapy and that there is no way to predict what will be my response to hormones.
    13a. I understand that the correct dosage for me may not be the same as for another person. I understand I must follow my prescribed regimen of androgen treatment to continue o receive hormone therapy at this clinic.
14. I agree to take androgen therapy and all other transition related medications as prescribed and to inform my provider of any problems or dissatisfaction I may have with my treatment.
15. I will have a complete physical examination annually and lab tests periodically as required to make sure I am not having an adverse reaction to hormone treatment and to continue good health care.
16. I understand that there are medical conditions that could make taking androgen either dangerous or physically damaging.
    16a I agree that if my provider suspects I may have any condition that could be dangerous to me, I will be evaluated for it before the decision to start or continue my hormones is made.
    16b I understand that if I do not agree to be evaluated, my prescription for androgen may be cancelled or refused.
17. I understand that I can choose to stop taking androgen at any time. I also understand that my provider can discontinue treatment for clinical reasons.
    17a. I agree to follow a prescribed reduction plan if either of these situations occurs to reduce negative and potentially harmful side effects that may occur if I suddenly stop my hormone therapy

CONSENT:

Having considered all of the above counseling I would like to:

○ Begin Androgen Therapy ○ Defer Androgen Therapy at this time

Patient Signature:

Patient Printed Name:

Date:

Provider Information:

Provider Signature:

Provider Printed Name:

Date:

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)

Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

IHSC Environmental Health Guide

Approved by: (b)(6); (b)(7)(C)
Dr. (b)(6); (b)(7)(C) DHSc, MPH

Title: ERO-IHSC AD

Date signed: 2018

Effective updated: October 19, 2018

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Foreword

This *IHSC Environmental Health Guide* supplements the following IHSC Directive:

- IHSC Directive: 05-04, *Environmental Health.*

This Guide explains concepts, assigns responsibilities and details procedures for the implementation of environmental health activities within IHSC-staffed medical clinics.

The intended audience is IHSC health staff supporting health care operations within ICE-owned and contracted detention facilities.

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I. Overview

A. Purpose

IHSC is dedicated to promoting a healthy and safe medical clinic environment and ensures that health staff comply with the relevant laws, regulations and standards. IHSC implements activities to reduce the risks from exposure to hazardous substances, equipment, and promotes hygiene and cleanliness with safe work practices in the medical clinic. This Guide provides health staff with the procedures and resources to implement environmental health activities as required by IHSC Directive: 05-04, *Environmental Health*.

B. Responsibilities

Public Health, Safety and Preparedness (PHSP) Unit

- Provides technical guidance to medical clinics on environmental health activities.
- Annually reviews this Guide and IHSC Directive: 05-04, *Environmental Health*, and updates these documents, as necessary.
- Conducts periodic program monitoring.
- Develops, reviews and updates tools and resources to assist IHSC staff with implementing environmental health protocols.

Health Services Administrator (HSA)

- Oversees the hazardous materials program.
- Oversees the hazardous waste program.
- Supports monitoring of radiation exposures in the medical clinic.
- Supports monitoring of cleaning and decontamination of clinical working areas and notifies the facility administrator or designee of any deficiencies.
- Supports monitoring of airborne infection isolation (AII) rooms.
- Ensures maintenance of AII rooms
- Ensures health staff receive initial orientation and annual training on all environment health-related official guidance.
- Ensures that daily, weekly and monthly inspections are documented and maintained locally and submitted to the PHSP Unit or posted on SharePoint, as indicated.

Compliance Officer (CO)

- Lead accountability for all environmental health monitoring activities, including, but not limited to, hazardous materials and hazardous waste, radiation safety, cleaning and decontamination, and AII room monitoring.
- Monitors and reports problems related to environmental health to the HSA.
- Completes Radiation Safety Officer (RSO) training and is subsequently the subject matter expert (SME) for oversight of radiation safety.

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Health Staff

- Complete training and maintain knowledge of the subject matter.
- Observe the environmental health requirements specified in official guidance and training.
- Comply with all state, federal and local laws governing the disposal of hazardous waste.
- Immediately report hazards or hazardous chemical spills to the HSA or designee.
- Maintain awareness of what hazardous materials are used and where to find the safety data sheets (SDSs) for those materials.
- Wear radiation monitoring devices when conducting radiography services or while in the immediate area where radiography services are conducted.
- Promote clinic cleanliness to maintain a healthy hygienic environment.
- Wear appropriate personal protective equipment (PPE), as indicated.

C. Abbreviations Used in this Guide

ACH – Air changes per hour

AII – Airborne infection isolation

BBP – Bloodborne pathogen

CAS – Chemical Abstract Service

CDC – U.S. Centers for Disease Control and Prevention

CFM – Cubic feet per minute

FDA – U.S. Food and Drug Administration

MREM – Millirem (i.e., one thousandth of a rem)

NIOSH – National Institute for Occupational Safety and Health, CDC

OPIM – Other potentially infectious materials

OSHA – U.S. Occupational Safety and Health Administration

PPE – Personal protective equipment

REM – Roentgen equivalent in man

SDS – Safety data sheet (formerly called material safety data sheet or MSDS)

II. Hazardous Materials and Chemical Safety

The Occupational Safety and Health Administration (OSHA) requires employers to appropriately identify, inventory, label and store hazardous materials, as well as train employees and maintain SDSs on the hazardous materials found in the workplace. The

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OSHA Hazard Communication Standard provides details on these requirements. The HSA or designee develops local written procedures describing how health staff meet these requirements and identifies staff responsible for the specific components of the standard. All health staff must adhere to the local procedures.

A. Inventory

The HSA, CO, or designee performs an annual survey of the medical clinic and identifies all of the hazardous chemicals that health staff store and use in the medical clinics for inclusion in the inventory. The HSA, CO, or designee maintains a current inventory (Chemical Inventory Tool) of hazardous chemicals used by health staff in the medical clinic and their storage locations. Each inventory record must be maintained on a separate card or sheet for each substance and must be filed alphabetically. The inventory contains the organization name and location, person who oversees the inventory, chemical name and common name or trade name. The inventory must also include the purchase dates and quantities, use dates and quantities (reflecting the date and quantity of an item when they are removed from the inventory), and the current quantities on hand. OSHA does not require this inventory list to include ordinary office supply items such as copy machine toner, correcting fluid or general-purpose cleaners in very small quantities. These OSHA exemptions are based on how the product is used in the workplace, such as the duration, frequency of use and exposure of the product to the employee.

B. Safety Data Sheets

SDSs, formally known as the material safety data sheet (MSDS), are informational sheets available from the manufacturer, distributor or importer, that communicate pertinent information about the chemical in a standardized format. Some of the important sections of an SDS address measures for first aid, fire-fighting, accidental release, exposure controls, handling and storage. For more information on SDSs refer to the OSHA Hazard Communication Standard: Safety Data Sheets. Health staff must have ready and continuous access to all SDSs for hazardous substances stored and used in the facility, including the medical clinic (products in quantities of 1% or greater or 0.1% if the chemical is carcinogen). The HSA or designee must collect the SDS for each chemical identified in the medical clinic and include it in the inventory. An SDS usually arrives with the shipment of the chemical. Health staff can also locate the SDS on the internet or request it from the manufacturer. The SDSs should be stored together in a file and ordered alphabetically by common name for easy access. The HSA, CO, or designee must update the SDS file annually, and upon receipt of new products, to ensure files are kept up-to-date, and is responsible for removing SDSs for products no longer used. The HSA, CO, or designee should forward a copy of each file, along with a clinic diagram and legend of their storage location, to the facility administrator or designee. The facility maintenance supervisor should maintain a master index of all hazardous substances and SDSs in the facility and their locations.

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C. Storage, Use and Labeling

OSHA requires that hazardous chemicals are stored and used based on instructions in the SDS. Health staff who handle chemicals should be mindful of sections in the SDS that specify how and where to store a product and which products should not be stored together because of the potential for a chemical reaction. Flammable and combustible materials require special care when used and must be stored in a fire-resistant cabinet with a self-closing fire door and either a four-inch sill or a four-inch depressed floor. The cabinet must have a proper ventilation system (mechanical or gravity flow) and must be securely locked at all times. The HSA and CO must ensure that this fire-resistant hazardous material storage cabinet is conspicuously labeled "Flammable – Keep Fire Away." Health staff must store and use hazardous materials according to the manufacturer's instructions found in the SDS. The HSA and CO must ensure that health staff that handle hazardous substances are trained in accordance with OSHA standards, are knowledgeable and follow prescribed precautions, wear PPE and promptly notify the HSA or designee of any hazards or spills.

OSHA specifies that labels on hazardous materials containers cannot be defaced and must be legible, permanently displayed and written in English. The HSA and CO must ensure that all toxic and caustic materials are stored in secure areas, in their original containers, with their labels intact. Health staff must ensure that when chemicals are transferred to an unmarked container for use, that the container is labeled with the product identifier name and written in English; the written product identifier name of the chemical must be identical to how it is written in the SDS. Health staff must ensure that all hazardous substances are dispensed in single-day increments by authorized staff and must ensure that any unused portions are returned to the storage area at the end of the shift. Health staff must keep the inventory of these hazardous substances current before, during and after each use. The HSA and CO must ensure that all pipes supplying oxygen, analgesic or anesthetic gas sources into the medical clinic are labeled with their contents at the outlet.

D. Non-routine Tasks and Controlled Hazardous Materials

OSHA requires employers to provide information about the chemical hazards and safety measures that should be used when employees perform non-routine tasks. The HSA must ensure that non-routine tasks are identified and that health staff performing those activities are aware of the hazardous chemicals and the required controls to reduce or eliminate the hazard.

Controlled hazardous materials require special treatment and planning before their use; handling requirements are more comprehensive than the information provided on the warning label or within this Guide. OSHA regulations classify these controlled materials according to their type of hazard and nature of restrictions imposed for their safe use. These classifications include: Class I: Industrial Solvents; Class II: Restricted Materials; Class III: Recognized Carcinogens; and Class IV: Suspected Carcinogenic, Teratogenic, and Mutagenic Materials. Refer to the U.S. Department of Health and Human Services 14th Report on Carcinogens for an updated list of these chemical agents, substances, mixtures and exposures.

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E. Training

OSHA requires employee training on methods of detection of hazardous chemical releases, the hazards of the chemicals, protective measures, SDS, storage and labeling. The HSA and CO must ensure that health staff receive this training prior to working with hazardous chemicals, upon the introduction of new chemicals, during their initial orientation and during annual refresher training. This training must be conducted in a language and in a manner that the staff can understand. The HSA and CO must ensure that health staff understand the information on the hazardous chemical label and SDS and are able to refer to them.

III. Radiation Safety

The HSA and CO must monitor radiation exposures whenever there is radiation emitting equipment in a workplace. The HSA and CO must ensure the safe use of radiation-producing equipment in the medical clinic. Radiation exposure must be kept as low as reasonably achievable (ALARA); the maximum whole-body dose of occupational radiation exposures for a health staff member should not exceed 5 rems in any calendar year or 3 rems in any calendar quarter. The HSA and/or CO must track any occupational exposures exceeding these radiation limits. Health staff that perform radiation-related activities must receive initial and annual refresher training to maintain competency. Health staff should refer to the OSHA Standards on Ionizing Radiation which govern employee exposure to ionizing radiation.

If health staff declare pregnancy (must be in writing) to the HSA, exposure for the pregnant health staff member must be kept below 500 mrem of radiation exposure during the entire pregnancy (exposure received prior to declaration of pregnancy must be included in the exposure limit). It is the right of the employee to determine if pregnancy should and will be declared; the employee should not be asked nor forced to declare pregnancy by anyone regardless if the employee is visibly showing signs of pregnancy.

Dosimeters worn by declared pregnant employees must be sent for monthly readings throughout the pregnancy to monitor radiation exposure. Declared pregnant federal employees may request a work accommodation from the HSA and/or the Office of Human Capital (OHC). The HSA and/or CO must advise declared pregnant contract staff to contact their employer to request similar accommodations.

The HSA and/or CO must issue a dosimeter badge for radiation monitoring to all health staff that perform radiation-related activities. The HSA and/or CO must ensure that health staff are trained on the protocol for dosimeter badge use, wear and care.

A. Dosimeter Badge Use, Wear, and Storage

Health staff must wear dosimeter badges in accordance with manufacturer recommendations, and should wear them only while conducting radiography services, or while in the immediate area where radiography services are conducted, in order to

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record occupational radiation exposure. Health staff should not wear dosimeter badges during normal clinical duties, while walking outside or while outside of the workplace.

Dosimeter badges have a printed “wear date” on them. Health staff must use the dosimeter with a current wear date. At the end of the wear period, new badges are shipped by the supplier with a current “wear date” and the HSA, CO, or designee must return the expired badges to the manufacturer for processing and reading. Additionally, all dosimeter badges are sent quarterly (monthly for pregnant staff) to the assigned vendor that will compile exposure results. Upon receipt of exposure results, the HSA and CO ensures the report is reviewed for any results outside of the required limits. If any result is questionable, the HSA should go through procedure initiating an investigation by contacting PHSP unit and vendor physicist for assistance with interpreting data and instituting any recommendations.

A separate dosimeter known as a “control dosimeter” is included with each shipment of dosimeter badges to monitor radiation received in transit or storage. The HSA and CO must ensure the control dosimeter is not used for any other purpose. Upon receipt, the HSA and CO must ensure that the control dosimeter is stored away from radiation exposure along with the dosimeter badges included in that shipment. The HSA and CO must ensure that dosimeter badges are stored in a central location and are not stored near a radioactive source or in an x-ray room (including the control area). The HSA or CO must return the control dosimeter along with the accompanying dosimeter badges with the same “wear date” for processing and reading once they are expired (i.e., past the “wear date”).

B. Responsibilities

The HSA and CO must monitor for radiation outside of radiation exposure areas and ensure that radiation sources are shielded.

In areas of the medical clinic where potential radiation hazards exist, the HSA and CO must post clear and visible radiation signs on doors leading to those exposure areas. Signage must contain the phrase, “Caution, Radiation Hazard” and the radiation symbol. Radiation pregnancy signage is also recommended; signage should contain the phrase, “if you are pregnant or unsure, notify staff immediately” and the radiation symbol.

The HSA and CO must oversee the calibration checks, compliance testing and periodic maintenance of radiation-emitting equipment (checks are completed by contracted service vendor) and ensure service to meet regulatory standards.

C. Exposure Monitoring Associated with Moonlighting

If an employee (contract or federal) has a second job with another agency/company that involves using radiation emitting equipment, the HSA must include exposure levels from the other job when calculating the employee’s annual exposure limit. The HSA can request the employee obtain the dosimetry report from the other agency/company, or with contracting staff, the HSA should coordinate with the Contracting Officer

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Representative (COR) to contact the vendor to obtain a dosimetry report. In turn, if the contract vendor requests a dosimetry report for radiation exposure received while working with IHSC, the HSA should supply the report through the COR to the contracted vendor.

IV. Cleaning and Decontamination

The HSA or designee must ensure that systems are in place for cleaning surfaces and equipment in examination rooms and medical housing unit (MHU) rooms, and for terminal cleaning, in accordance with recommendations from the Centers for Disease Control and Prevention (CDC) 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities, OSHA Standards and Performance-Based National Detention Standards (PBNDS) 2011 regarding the frequency, methods, cleansers, detergents, disinfectants and cleaning equipment to maintain a clean, healthy medical clinic.

The HSA, CO, or designee must conduct a daily visual inspection of the medical clinic, noting the condition of the floors, walls, horizontal surfaces and equipment, to ensure a high standard of cleanliness. The HSA, CO, or designee should communicate with the facility administrator to ensure that general cleaning in the medical clinic is accomplished daily (including weekends) and must notify the facility administrator of any deficiencies in daily general cleaning.

A. Cleaning

Cleaning is the physical removal of organic and inorganic material from objects and surfaces. Cleaning is accomplished with water, detergent and mechanical activity such as scrubbing. After cleaning a surface or object, health staff must inspect to ensure that cleaning has been accomplished.

- Health staff must clean surfaces in examination and MHU rooms using an approved germicidal solution for general cleaning.
- Terminal cleaning refers to the physical cleaning and disinfecting of all items within a room upon detainee discharge, utilizing an approved hospital germicidal solution. The HSA or designee must establish procedures for terminal cleaning of the MHU rooms and airborne infection isolation (AII) rooms and ensure that health staff are oriented to these procedures.
- Isolation cleaning refers to the terminal cleaning of an isolation room. In facilities that use detainee staff for cleaning, the following procedures must be accomplished during isolation room cleaning:

    - Germicidal solutions are freshly prepared;
    - No items used for cleaning in one room are brought into another area;
    - Used mop heads and cleaning cloths are laundered after cleaning is complete and before being reused; and
    - All linens and waste materials are double bagged.

For facilities that use detainee staff for cleaning, any cleaning procedure issues must be report to the HSA or designee who will notify the facility administrator.

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B. Disinfectants

Cleaning must precede disinfection. Disinfection kills or inactivates microorganisms. Disinfectants vary in their efficacy based on the type, activity and level of contamination they are used for. The following are the three levels of disinfectants:

- **Low**: Inactivates some viruses, kills some fungi and kills most vegetative bacteria except tubercle bacilli or bacterial spores. Examples include:
    - Phenolic compounds
    - Iodophor
    - Quaternary ammonium compounds (QUATS)
- **Intermediate**: Kills all vegetative bacteria, some fungi, inactivates most viruses and kills tubercle bacilli. Examples include:
    - Ethyl or isopropyl alcohol (70-90%)
    - Chlorine compounds
- **High**: Kills vegetative bacteria, inactivates viruses and moderate numbers of bacterial spores. Not meant for environmental surfaces. Examples include:
    - Aldehydes (Formaldehyde, Paraformaldehyde, Glutaraldehyde)
    - Oxidizers (Hydrogen peroxide, Peroxyacetic acid)

C. Frequency of Cleaning

The HSA or designee must ensure that all patient care areas to include all surfaces touched by detainees or staff, are cleaned at minimum, at the following times:

- At the beginning and end of each shift;
- When the surface, objects or equipment is visibly soiled;
- After each patient encounter;
- Daily in MHU rooms and AII rooms; and
- After a detainee is discharged from MHU and AII rooms.

Health staff must use appropriate PPE for cleaning patient care areas and medical equipment, or when handling biohazard waste.

D. Decontamination of Medical and Dental Equipment

The decontamination process removes the pathogenic microorganism from an object to allow safe handling or disposal. Health staff must immediately sanitize surfaces and instruments in the medical clinic that become contaminated with blood or other potentially infectious materials (OPIM) using the safety methods and equipment referenced in the SDS for the chemicals used. Decontamination and sterilization (autoclaving) of all applicable medical and dental equipment must be conducted in accordance with applicable local, state and federal regulations and the manufacturer's

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instructions must also be followed. Refer to the CDC 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities for additional recommendations on sterilization guidance.

V. Pest Control

Pest control activities fall under the authority of the facility administrator. However, within the medical clinic it is extremely important for health staff to maintain a high level of cleanliness to minimize the potential for pests or vermin, and to remain constantly vigilant for the presence of pests or vermin or their droppings. The HSA must coordinate with facility staff on issues related to pest control. Health staff must notify the HSA if there are signs of pests or vermin (e.g., droppings, gnaw marks, portals of entry) or if there are actual pests or vermin (living or carcasses) in the medical clinic or other health staff work or storage areas.

VI. Hazardous Waste Management

A. Definitions

The primary type of hazardous waste generated in the medical clinic and discussed in this Guide is biohazardous or infectious waste (pharmaceutical hazardous waste management is addressed in Directive 09-02 *Pharmaceutical Services and Medication Management*). Biohazardous waste is waste known or suspected of containing pathogens of sufficient virulence or quantity to produce infectious disease in a person coming into contact with the waste which require special handling and disposal precautions (e.g., bulk blood, blood products, bloody body fluids, urine or feces, blood-soaked PPE, and medical sharps such as needles or devices).

Another type of hazardous waste is miscellaneous biomedical waste which is not specifically defined as infectious waste. These items are not designated for disposal in the biohazardous waste containers unless they are visibly soiled with blood. Examples include non-specific waste materials such as bandages, dressings, casts, catheters and disposable pads. Other examples of items not designated for disposal in the biohazardous waste containers unless soiled with blood can include examination equipment such as otoscope tips, tongue depressors and examination gloves.

B. Handling Guidelines

The disposal of biohazardous waste is strictly regulated by local county and state laws. The HSA must ensure that health staff receive training on the handling and disposal of biohazardous waste, the use of appropriate PPE, and health and safety hazards before handling, storing or disposing of any biohazardous or infectious waste. The HSA or designee must develop written procedures that specify how biohazardous waste is identified, separated from regular trash, packaged, stored and transported for disposal. These procedures must also provide details on spill clean-up, training and the use of PPE when handling biohazardous waste. The HSA and CO must maintain and implement these procedures to ensure compliance with applicable federal, state and local laws, monitor the program continually and review the program annually.

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C. Collection and Disposal

The HSA and CO must ensure that biohazardous or infectious waste, excluding sharps, is segregated from other waste at the point of origin by placing it in red, impermeable biohazardous bags, and must ensure it is handled according to the following requirements:

- Biohazardous waste bags should be contained in clearly marked red containers located near non-biomedical solid waste containers for easier segregation of waste.
- Biohazardous waste bags must be double-bagged, tied and labeled "Infectious Waste."
- The international biological hazard symbol (example below) must be at least six inches in diameter on bags 19" x 14" or larger, and at least one inch in diameter on bags smaller than 19" x 14".
- All red bags must be securely tied before removal to the secured biomedical waste room/area and must be transported in a leak-proof container.



Miscellaneous biomedical waste that is visibly soiled with blood must also be double-bagged and tied in a red, impermeable biohazardous bags.

Health staff must dispose of contaminated sharps as soon as possible after use to prevent injury and reduce the risk of infection. Sharps include disposable syringes with needles, lancets, scalpel blades and other sharp items. Health staff must discard sharps in rigid red plastic biohazardous waste sharp containers that are leak-proof, puncture resistant and approved by the National Institute of Safety and Health (NIOSH). Health staff must handle sharps and sharps containers in accordance with the following requirements:

- Syringes with needles or that contain fluid must be disposed in sharp containers.
- Needles should never be bent, recapped or broken before placing them in the container. This includes the prohibition against the removal of contaminated needles from blood tube holders following a blood draw or from medical devices, unless no feasible alternative exists, or it is necessary for a specific medical or dental procedure.
- Sharps containers must be securely closed with attached lids.
- Sharps containers must be secured in key-locked holders located close to the points of use and positioned at least 5 feet above the ground if mounted on the wall.

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- Sharps containers must be replaced when they are 3/4 full or when the fill line indicated by the manufacturer is reached.
- Before disposing of full sharps containers, ensure the containers are securely closed to prevent spilling of their contents.
- Health staff must ensure that sharps containers are placed in a red biohazard bag prior to being placed in the large biomedical waste containers awaiting transport, unless the container has already been lined with a large biohazard bag. See OSHA - Bloodborne pathogens for additional information.

Health staff must transport biomedical waste from areas where it was generated to the secured biomedical waste room/area in the clinic using the most direct route to minimize potential exposure to detainees, staff and visitors. The secured area must be well ventilated and free of pests. Health staff must use standard precautions, such as wearing PPE, when transporting biomedical waste to the secured biomedical waste room/area. Health staff must use care when transporting biomedical waste to avoid rupture of containers. Biomedical waste must remain in the designated secured biomedical waste room/area until it is picked up by the contracted waste hauler. Access to this area must be restricted to designated staff that are trained to handle hazardous waste.

Health staff must prepare red bags containing biohazardous waste or sharps containers for disposal in accordance with the following requirements:

- Red bags containing biohazardous waste or sharps containers should be sealed while wearing gloves and must be double-bagged and hand-tied using a method with a single or gooseneck knot to prevent any leakage. The bags should be placed in an approved outer container prior to removal from the facility.
- The outer container should be sealed; if using a corrugated box, seal the top of the box with 2-inch wide clear packing tape; if using an auto-locking box, engage the top flaps; if using reusable containers, secure the lid and engage all closures to lock.
- The outer containers should be labeled with the contracted waste hauler's name, address and registration number prior to transport.

The HSA or designee must ensure that a contract is in place with a qualified service provider (i.e., contracted waste hauler) for the removal and disposal of biomedical waste. The HSA or designee must also ensure that biomedical waste is picked up in a timely manner to prevent the accumulation of hazardous waste in the clinic. The HSA or designee must sign the medical waste tracking form and maintain the yellow copy until the contracted waste hauler mails the white copy which has the signed Certification of Receipt of Waste. The HSA must retain the white, signed copy of the Certification of Receipt of Waste for three years in a manifest folder as part of the clinic's permanent hazardous waste disposal records.

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D. Biohazard Infectious Waste Clean-up

Health staff must immediately clean up all spills of biomedical waste in the medical clinic using PPE and following appropriate procedures to prevent the transmission of potentially infectious organisms. The following procedures should be followed:

- Restrict access to the spill area until cleanup is complete.
- Dispose of all spill residues, including broken glass, as biomedical waste.
- Liquid spills less than 5 mL or 5 grams should be wiped with absorbent gauze pads.
- Solids should be wiped with wet absorbent gauze pads.
- The spill area should be cleaned at least twice with an approved detergent/disinfectant solution followed by clean water.
- Use the spill clean-up kit for spills greater than 5 mL or 5 grams. Spill clean-up kits may be obtained from commercial sources or may be assembled manually in accordance with directions described in PBNDS 2011.
- Pre-packaged spill kits are stored in all patient care and biohazard collection areas, and at disposal transfer locations.

The HSA and CO must ensure that biohazard training is conducted for all health staff during initial orientation and during annual trainings; this training must cover cleanup of biohazard spills and the proper use of spill clean-up kits. The following procedures should be followed when cleaning up biohazard spills:

- Put on PPE.
- Sprinkle absorbent powder over spilled area.
- Remove the material with scoop and scraper.
- Carefully place the material in red biohazard bag and clean remaining solids with absorbent towel.
- Disinfect affected surface area with germicidal wipe or hospital grade disinfectant.
- Place all contaminated materials (including PPE) in biohazardous waste bag.
- Seal and transport the bag to the secured biomedical waste room/area.
- Wipe hands with antimicrobial hand wipe.

Health staff must wash hands with soap and water as soon as possible following the cleanup of biohazardous material and before completing any further activities.

VII. Medical Clearance for Food Service Workers

A. Medical Exams and Clearances

Before any detainee is assigned to work in food service operations (i.e., food service duty), a medical provider or registered nurse must conduct a medical exam screening and clearance to evaluate the detainee's general health and check for the presence of lice, open sores, skin infections, diarrhea, illnesses transmissible by food or utensils or any other medical concerns, to ensure the protection of others from any health related harm. A detainee cannot participate in food service duty until this medical exam screening is complete and the detainee is cleared. Once medical clearance is approved, the medical provider or registered nurse must sign the IHSC Food Handler Certificate

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located in the detainee's electronic health record and must forward the certificate to the facility staff responsible for food service. The food service department shall refer to the medical department for detainees that have been absent from work for reasons of communicable illness, for a determination of medical clearance prior to resuming food service work.

If a detainee does not pass the medical exam screening, the detainee cannot participate in food service duty. However, once the detainee's condition is resolved, a medical provider must re-examine the detainee prior to starting or resuming food service duty. Once medical clearance is approved, health staff must sign the IHSC Food Handler Certificate located in the detainee's electronic health record (eHR) and must forward the certificate to the facility staff responsible for food service. Individual certificates for each detainee are required; the use of an EBO report showing clearance of all detainees does not meet this requirement.

If a detainee is injured or becomes ill and requires medical treatment due to a work-related kitchen injury or incident, the medical provider or registered nurse should examine the detainee and document the injury or related illness in the detainee's eHR and using the IHSC SharePoint within "Risk Management" of the Medical Quality Management Unit.

VIII. AII Rooms

AII rooms are designed to keep infectious air from escaping out of the room into other rooms and areas by maintaining negative pressure. The removal effect occurs when air from a room is either discharged outdoors or passed through a HEPA filter to trap the particles before recirculation. Infectious air in the room is quickly exhausted out of the building by a high ventilation rate measured in air changes per hour (ACH).

A. AII Room Monitoring

Ongoing assessment is very important to ensure the AII room is functioning properly. Some AII rooms have an electronic pressure monitor that continuously monitors the room's negative pressure. The room pressure sensor measures the differential pressure between the room and adjacent corridor or anteroom. The sensor or transmitter provides a digital or visual indication of room pressure. Health staff must follow the AII room procedures specified below to ensure negative pressure is maintained and operational.

- Keep doors to AII rooms closed except when detainees or other providers must enter or exit.
- Conduct daily visual checks of AII rooms to supplement electronic monitors and ensure negative pressure is maintained.
- Check AII rooms after a loss of power.
- Maintain records of the daily AII room negative pressure checks in a log that records both the visual check and the pressure level on the monitor. Changes in digital readings can indicate malfunction or needed maintenance. Documenting the digital

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readings provide information on negative pressure efficiency. The recording of digital readings should be a numerical value; documenting "negative" is not sufficient.

- Perform the visual check for negative pressure by holding a tissue strip parallel to the gap between the closed door and the floor from the outside. The tissue will be drawn under the door toward the room by negative air flow. Smoke testing is an option only if permitted at your facility and only if a commercially available smoke-generating kit is used and the manufacturer's instructions for conducting the testing is followed.

B. AII Room Clearance

Once a detainee is discharged from an AII room, an AII room clearance period is required to achieve the removal of >99% of infectious airborne particles before another detainee can be admitted into the AII room. The time needed for this clearance period is based on a formula that incorporates each room's ACH and removal efficiency. If the room's ACH is not known, refer to Figure 1 to determine the ACH. Once the ACH for each room is known, refer to Table 1 to estimate the time necessary to clear the air of *M. tuberculosis* after the detainee leaves the room. During the air clearance time between detainees, health staff must leave the exhaust fans servicing the rooms or enclosures on with doors closed for the removal of airborne particles. Health staff must post a sign outside the door until the clearance period has elapsed to alert staff that a respirator is required for entrance into an AII room that has not fully cleared. Health staff entering the room before the clearance period is complete must wear a fit-tested N95 respirator. Terminal cleaning guidance is referenced above in Section IV: Cleaning and Decontamination.

C. AII Room Maintenance

The HSA or designee must arrange for the maintenance of AII rooms in accordance with the manufacturer's guidelines. Health staff must fully shut off the system before any maintenance occurs. The HSA or designee must establish protocols to ensure that health staff are notified in advance of any planned maintenance affecting AII rooms. If health staff perform maintenance and/or filter replacement on AII rooms, they must wear appropriate PPE, such as a respirator and gloves, in accordance with OSHA Standards described in 29 C.F.R. §1910.132 and 29 C.F.R. 1910.134. Health staff must immediately report suspected problems with the ventilation system in an AII room to the HSA.

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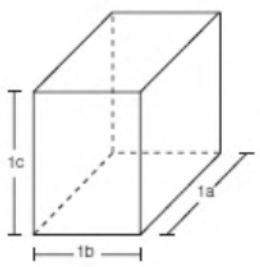
Figure 1: Airborne Infection Isolation Room Clearance Time Calculation Worksheet

CONVERSION RATE CALCULATION WORKSHEET

Room or Booth # _____

1. Calculate Room Volume



1a. Room Length	**1a.** _____ ft
1b. Room Width	**1b.** _____ ft
1c. Room Height	**1c.** _____ ft
1d. 1a x 1b x 1c = volume	**1d.** _____ ft^3

2. Calculate Air Changes Per Hour (ACH)

2a. Measured exhaust airflow rate	**2a.** _____ CFM
2b. = 2a x 60 minutes	**2b.** _____ ft^3 per hr
2c. = 2b ÷ 1d	**2c.** _____ ACH

3. Calculate Room Clearance Time

3a. Find the Uncorrected Clearance Time — **3a.** _____ min.

Using Table 1 of the CDC Guidelines (see next page), follow the first column down until the ACH value on line 2c is found. A removal efficiency of >99% is preferred; for 99% efficiency follow this row horizontally to the second column, ideally the value in the third column (99.9% removal efficiency) should be used. Record this value (the number of minutes).

This is the amount of time that should elapse before staff or other patients enter a sputum induction area (booth, hood, or room) after sputum has been induced on a person with suspected or known infectious TB and the patient has left. Table 2 of the CDC Guidelines should be consulted to ensure that your calculated ACH is appropriate for the type of setting you are working in.

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TABLE 1. Air changes per hour (ACH) and time required for removal efficiencies of 99% and 99.9% of airborne contaminants*

	Minutes required for removal efficiency†	
ACH	99%	99.9%
2	138	207
4	69	104
6	46	69
12	23	35
15	18	28
20	14	21
50	6	8
400	<1	1

* This table can be used to estimate the time necessary to clear the air of airborne *Mycobacterium tuberculosis* after the source patient leaves the area or when aerosol-producing procedures are complete.
† Time in minutes to reduce the airborne concentration by 99% or 99.9%.

Source: CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005, page 20.

IX. Construction, Renovation and Repair Work

Projects or repair activities may disrupt engineering controls in place within the medical clinic, such as AII rooms, and may introduce new sources of infection or result in failures of systems that control existing sources of infectious diseases. Additional precautions or changes in work practices may be necessary during these temporary projects. The HSA or designee must coordinate with facility staff to ensure that new construction or remodeling activities within medical clinic facilities comply with the appropriate provisions of the National Fire Protection Association (NFPA) 101 Life Safety Code (LSC), 2015 Edition, and the Rehabilitation Act. See the Rehabilitation Act of 1973 for additional information.

The HSA must coordinate with facility staff before and during construction or repair work to prepare for and implement additional precautions if the medical clinic environment will be impacted. Health staff must immediately report any workplace hazards identified during construction, renovation or repair work projects to the HSA or CO to ensure a safe and hazard-free environment. Upon the onset and throughout the duration of these projects, the HSA or designee must monitor lighting, heating, air conditioning, ventilation, plumbing, water and power to ensure they accommodate clinical activities and must arrange for temporary accommodations when necessary.

X. Clinic Inspections

The CO, with support from the HSA, must perform a monthly inspection of the medical clinic. The purpose of the inspection is to identify health and safety deficiencies or areas of concern that need corrective action. The HSA or CO should use a template to evaluate these health and safety observations addressing all deficiencies and documenting the corrective action(s) taken. This inspection requires the employer to

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identify and address any potential hazard to worker safety and may exceed those elements specified on the monthly health and safety assessment tool. This inspection is not the same as the monthly health and safety assessment tool. The monthly health and safety assessment tool does not cover all items that potentially put employees at risk for injury, illness or death. If problems are identified with the lighting, heating, air conditioning, ventilation, plumbing, water or other power systems, the HSA or CO must develop corrective action plans and request assistance from facility staff, if needed.

XI. Orientation and Training

The HSA or designee must ensure that orientation and annual training that includes environmental health is implemented and documented in accordance with *IHSC Directive 01-04 Medical Education and Development*.

XII. Program Monitoring and Evaluation

PHSP Unit staff periodically collect information from the HSA or Compliance Officer to assess the implementation of environmental health activities.

XIII. Privacy and Recordkeeping

Please refer to IHSC Directive: 05-04, *Environmental Health*, for guidance on complying with privacy and recordkeeping procedures.

XIV. Glossary

Administrative Controls – Methods of controlling employee exposures through the enforcement of policies and procedures, modification of work assignment, training in specific work practices, and other administrative measures designed to reduce exposures.

Bloodborne Pathogens – Pathogenic microorganisms that are present in human blood and can cause disease in humans (e.g., hepatitis B virus and human immunodeficiency virus (HIV)).

Body Fluid – Fluid secreted by the body including, but not limited to, blood, semen, saliva, urine and feces.

CAS Number – The unique registry number for each chemical that allows for efficient searching across databases of hazardous materials.

Disinfection – A process of killing (inactivating) most or nearly all microorganisms by various agents such as chemicals, heat, ultraviolet light, ultrasonic waves or radiation.

Exposure – The condition of being subjected to something in the working environment (noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

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Ionizing Radiation – A type of radiation that is capable of stripping electrons from atoms and breaks the chemical bonds, creating highly reactive ions. Ionizing radiation includes alpha rays, beta rays, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons and other atomic particles.

Isolation Room Cleaning – The thorough, extensive terminal cleaning and disinfection of an isolation room after the detainee is discharged.

Millirem (mrem) – A unit used to measure a dose of ionizing radiation on the human body which is one thousandth of a rem. The mrem is often used for the radiation dosage measure received from medical x-rays and background sources.

N95 Respirator – An air-purifying, filtering-facepiece respirator that is ≥95% efficient at removing 0.3 μm particles and is not resistant to oil; worn to protect the wearer from exposures in the air; not to be worn by a patient.

Other Potentially Infectious Materials (OPIM) –Includes 1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) unfixed tissue or organ (other than intact skin) from a human (living or dead); 3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and 4) blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Rem – A measure of a dose of ionizing radiation to body tissue in terms of the energy absorbed per unit of mass of the tissue.

Personal Protective Equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation and infectious diseases, and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats and steel toe boots.

Respirator – A form of personal protective equipment with filtering capability that fits snug on the face over the nose and mouth to prevent the wearer from inhaling hazardous airborne particles.

Surgical Mask – A protective device that covers the patient's nose and mouth to protect health care workers from exposures to wearer-generated microorganisms.

Terminal Cleaning – The thorough physical cleaning and disinfecting of all items within a room after a detainee is discharged, to remove germs utilizing an approved hospital germicidal solution.

Work Practice Controls – Controls that reduce the likelihood of exposure by altering the way a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

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XV. References and Resources

1) ICE Performance-Based National Detention Standards 2011.

2) Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee.

3) ICE Family Residential Standards.

4) National Institute for Occupational Safety and Health (NIOSH).

5) Occupational Safety and Health Administration (OSHA) Hazard Communication: Small Entity Compliance Guide for Employers That Use Hazardous Chemicals.

6) Occupational Safety & Health Administration (OSHA) Injury and Illness Recordkeeping and Reporting Requirements.

7) Occupational Safety and Health Standards Bloodborne Pathogens.

8) Rehabilitation Act of 1973

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The Management of Latent TB Infection (LTBI) for Adults in IHSC-staffed facilities*

Background

Mycobacterium tuberculosis (TB) is a pathogenic bacterium that primarily infects the lungs, however, it can affect any body system. TB disease is a worldwide public health problem, and in 2017 was responsible for 1.3 million deaths around the globe.[1]. It is acquired by inhaling organisms that are expelled through the air in people who have active disease. There are certain risk factors that can increase susceptibility for developing TB disease such as HIV infection, diabetes, chronic kidney disease, and other immunocompromising conditions.[2] For example, a person with no major underlying risk factors that is exposed to TB will have a 10% chance of developing active disease in their lifetime. In comparison, an individual with HIV infection has a 10% risk *per year* of developing TB disease[3]. In those who do not develop active disease, TB will be contained in an inactive form called latent TB infection (LTBI). It is asymptomatic and non-contagious. LTBI can be treated to reduce the risk of progression to TB disease. Because LTBI is not a reportable disease in every U.S. jurisdiction, it is difficult to estimate how many people are infected with TB. Based on CDC estimations (NHANES), approximately 13 million people (4.7%) in the United States have latent TB infection.[4] This number does not include individuals who are institutionalized, incarcerated, or detained. Studies have found the prevalence of LTBI in correctional facilities to be as high as 25%.[5] Individuals in ICE custody are at a high risk for LTBI because of higher TB disease rates in their countries of citizenship.[6]

However, not all adults with LTBI in ICE custody should receive treatment while detained. Developing countries' national TB programs generally restrict TB treatment to active disease only, and LTBI treatment would not be continued if detainees repatriate. Furthermore, many detainees will have had LTBI for greater than two years and are past the window of greatest risk for progression (assuming they continue to have an intact immune system). Therefore, the goal of this guidance is to screen and treat the highest risk patients and to restrict treatment of lower risk patients identified at other facilities to those who are most likely to complete treatment.

*Disclaimer –Clinical guidelines have been established to provide medical providers at IHSC facilities with general information regarding the management of patients. Guidelines are not statements of policy. Medical providers should consider each case individually, in the context of good clinical judgment and within the provider's experience and comfort level. This guidance is not intended to, does not, and may not be relied upon to create any right or benefit, substantive or procedural, enforceable at law by any party in any administrative, civil, or criminal matter.

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How to screen for LTBI:

LTBI can be diagnosed with a purified protein derivative (PPD) test (also known as tuberculin skin test (TST)) or a blood test known as an Interferon Gamma Release Assay (IGRA). The PPD is generally the method used and preferred in the IHSC setting due to its low cost and high adherence to follow-up for the interpretation 48-72 hours later. However, it should be noted that if a person has a baseline IGRA documented, follow up IGRA testing with the same test is favored over a PPD. See Appendix A for PPD interpretation.

Who to screen for LTBI:

- Patients with a known history of:
  - HIV infection
  - Diabetes
  - Chronic Kidney Disease (CKD) Stage IV-V (eGFR <30 ml/min).
  - Other conditions requiring chronic immunosuppressive drug therapy (i.e. DMARDs, chemotherapy, prolonged steroid use)
- These individuals can be identified at the PE-C and offered screening if they have no record of prior TST or IGRA.

Who to consider for LTBI treatment:

1. Patients with HIV, DM, CKD (eGFR <30ml/min), or other conditions requiring chronic immunosuppressive drug therapy, or those who are identified through a contact investigation as a new converter (PPD recently turned positive and with a previously documented negative PPD and known recent infection), or patients entering the facility already on LTBI treatment, ***regardless of anticipated length of stay.***
2. Patients without the above-mentioned chronic conditions, with a **documented** positive PPD or IGRA, TB disease has been excluded, are anticipated to stay in custody or the US for 3 months or more and are agreeable to treatment, and have **at least one** of the following risk factors:
   a. History of IV drug use (ever)
   b. BMI <19 or history of gastrectomy or gastric bypass surgery
   c. Daily tobacco use ≥1 pack per day (within the last year)
3. These individuals should also have a known negative screening CXR and negative TB symptom screen
   a. Treating a patient for LTBI who in actuality has TB disease should be avoided to prevent selection for drug resistant mycobacteria. In order to safely proceed, ensure the patient has a normal chest radiograph (CXR) (or 3 negative AFB sputum **cultures** if the CXR is abnormal) as well as a negative review of systems prior to prescribing LTBI treatment.

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Choosing a Regimen

Several recommended regimens exist (see Appendix B). For the majority of situations, the patient and provider have a choice of two equivalent regimens: INH + rifapentine (also known as 3HP) once a week for 12 weeks, or rifampin daily for 120 doses (4 months)*. In a minority of cases isoniazid (INH) may be a good choice because of drug-drug interactions with a patient's pre-existing medications (see Appendix C). If you are considering INH alone, please confer with the ID Team. Note, if a patient completes 56 doses of RIPE during management of suspected TB disease, treatment of LTBI is also satisfied.

*If you need guidance with selection of a regimen, please seek assistance from a physician, pharmacist or the IHSC ID consultant.

Step by Step Guide; How to manage LTBI patients – See Appendices F and G

Scenario 1: Patient arrives for **PE-C.**

1. Provider will assess need for LTBI screening and/or treatment using the IHSC LTBI Screening and Treatment Flowsheet (see appendix F)
2. Provider will be prompted by the PE-C template to inquire with the patient if they have one of the following chronic conditions that may increase their risk of developing TB:
    a. HIV infection
    b. Diabetes
    c. Chronic Kidney Disease (CKD) Stage IV-V (eGFR <30 ml/min).
    d. Other condition requiring chronic immunosuppressive drug therapy (i.e. DMARDs, chemotherapy, prolonged steroid use).
3. If yes, provider will be prompted if they have a documented PPD or IGRA. If the patient does not have a documented PPD or IGRA, they will be offered screening.
4. If screening indicated and patient agrees, appointments for a PPD plant and read will be made and if results positive, follow up AC appointment with provider in 2 weeks to review results. Follow up appointment will use template titled "LTBI evaluation: eligibility for treatment." (See Appendix G for samples of templates).
5. If patient already has a documented PPD/IGRA, an AC appointment will be made with the provider in 2 weeks to further assess need for treatment (i.e. has other, less concerning risk factors like low BMI). This appointment will use the same template as mentioned above.
6. If patient is already being treated for LTBI, provider will continue Rx and make follow up appointment within 30 days (sooner if issues arise). This appointment will use template titled "LTBI Treatment: monthly follow up".
7. Baseline labs only if clinically indicated.

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Scenario 2: Patient arrives for **PE-S.**

1. Provider will assess need for LTBI screening and/or treatment using the IHSC LTBI Screening and Treatment Flowsheet (see appendix F)
2. Provider or nurse will be prompted by the PE-S template to inquire if the patient has a documented positive PPD or IGRA. If yes, will be prompted to ask if patient has any of the following risk factors that my increase their risk for developing TB disease:
    a. History of IV drug use
    b. BMI <19 or history of gastrectomy or gastric bypass surgery
    c. Daily tobacco use ≥1 pack per day (within the last year)
3. If yes, RN or provider will schedule AC appointment with a provider within the next 30 days for further evaluation of LTBI.
4. At AC appointment, provider will use template titled: "LTBI Evaluation: Eligibility for Treatment"

Other things to consider and/or to discuss with patients:

- Educate patient on potential dangers of untreated LTBI in your own words and in the patient's language of choice (phone interpretation, as indicated). Example of content to discuss with patients:
    - Certain conditions can put stress on components of the immune system and increase the risk for developing active TB disease such as diabetes, kidney disease, HIV, and smoking. In addition, being detained increases those risks[5]. By treating LTBI now, you are protecting you, your family and others in your community from developing a preventable and dangerous disease.
    - Patients may relate to other personal stories. CDC has several videos that can help explain to patients why treatment of LTBI is important: https://www.cdc.gov/tb/topic/basics/personalstories.htm
- Inquire with the patient if they would be willing to adhere to weekly pill line treatment for LTBI for at least 12 weeks (if choosing 3HP) or daily RIF regimen x 4 months (KOP; *note, provider must write "KOP" in the "take" field because of eCW defaults*).
- If PPD ≥ 20 mm recommend obtaining an in-house urinalysis (UA); if UA is abnormal, recommend ID consult before proceeding with treatment of presumed LTBI.
- Monthly follow up appointment with provider while patient on LTBI treatment:
    - Screen for adverse drug reactions: Fever, chills, fatigue, weakness, nausea, vomiting, anorexia, abdominal pain, paresthesia, syncope, rash
    - Symptoms of hepatitis (abdominal pain, jaundice, nausea, vomiting) warrants holding treatment until further laboratory testing (LFTs). Submit an ID consult.
    - Assess need for follow up lab monitoring on a case by case basis
- When patient is finished with LTBI treatment, provide completion pocket card and scan into medical record. (See Appendix E)

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Contraindications / Special Populations:

The 12-dose regimen (3HP) should **NOT** be used in the following individuals:

- People living with HIV whose ARV regimen has significant drug-drug interactions and changing the regimen is not desired or feasible
- Pregnant women
- People presumed to be infected with INH or RIF resistant TB

These individuals can still be treated for LTBI. Please consult with the ID Consult service for further guidance.

Laboratory Testing and Ongoing Monitoring

Baseline CBC and/or LFT testing is NOT generally recommended before initiating LTBI therapy unless the patient has any of the following:

- HIV infection
- Liver disease
- Heavy alcohol use (>14 drinks / week in men or > 7 drinks per week females)
- Pregnancy or immediate post-partum (within 3 months)

Any of the above conditions will warrant further lab testing. Please consult with the ID consult service for further guidance.

Routine periodic testing only recommended for persons with abnormal initial results and/or those at risk for hepatic disease.

Laboratory testing and holding treatment is recommended for any patient who has symptoms suggestive of hepatitis or appears jaundiced.

Monthly chronic care appointment with provider is important to assess:

- Adherence to treatment
- Signs and symptoms of TB disease
- Potential adverse effects of drugs (See Appendix C)
    - Withhold treatment if LFTs are >3x the upper limit with symptoms or >5x upper limit without symptoms. Please consult with the ID consult service for further guidance.

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References

1.) CDC. Basic TB Facts. Data and Statistics. Retrieved from https://www.cdc.gov/tb/statistics/default.htm

2.) CDC. TB Risk Factors. Retrieved from https://www.cdc.gov/tb/topic/basics/risk.htm

3.) Kwan, C. K., & Ernst, J. D. (2011). HIV and tuberculosis: a deadly human syndemic. Clinical microbiology reviews, 24(2), 351–376. doi:10.1128/CMR.00042-10

4.) Latent TB infection in the U.S. – published estimates. Retrieved from https://www.cdc.gov/tb/statistics/ltbi.htm

5.) MacNeil J, Lobato MN, Moore M. An unanswered health disparity: tuberculosis among correctional inmates, 1993 through 2003. Am J Public Health 2005;95:1800—5

6.) MMWR Report; Prevention and Control of TB in Correctional and Detention Facilities. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm

Additional Resources

For more information on how to accurately plant and read PPD tests, please visit:
https://www.cdc.gov/tb/publications/posters/images/mantoux_wallchart.pdf

https://www.cdc.gov/tb/publications/ltbi/intro.htm

https://www.cdc.gov/tb/topic/basics/personalstories.htm

https://www.cdc.gov/tb/publications/ltbi/ltbiresources.htm

https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm

https://www.thoracic.org/statements/resources/tb-opi/diagnosis-of-tuberculosis-in-adults-and-children.PDF

https://www.drugs.com/drug_interactions.html

Useful ICD 10 Codes (Effective October 1, 2019)

Z20.1 - Contact / Exposure to TB

Z53.2 - Pt refusing treatment

(Effective October 1, 2019)

Z11.7 - Encounter for LTBI testing

Z22.7 - LTBI

Z86.15 - Personal history of LTBI

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Appendix A- PPD Interpretation

PPD Test Interpretation*

TB Test Interpretation Center for Disease Control **A tuberculin skin test should be considered positive and reported IF:**		
≥ 5 mm induration AND any of the following:	≥ 10 mm induration AND any of the following:	≥ 15 mm induration:
• HIV infection • Recent contacts with TB infected persons • Chest x-ray findings suspicious for TB • Organ transplant recipient • Persons with immunosuppression	• Recent immigrants from high-prevalence countries (within 5 years) • Injection drug users/needle sharing • Residents or employees of high-risk congregate settings (long term care, shelters, prisons) • Mycobacteriology lab personnel • Children less than 4 years old • Persons with OR children/infants exposed to persons at high-risk for TB	• Any person with NO known risk factors for TB

https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

*Generally, most individuals in IHSC custody would be considered positive for TB infection if their PPD measures ≥10 mm of induration. Note- ≥15 mm category does **NOT** apply to the vast majority of our detainees.

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Appendix B- Recommended Treatment Regimens per CDC Guidelines

Isoniazid (INH) + Rifapentine (RPT) the preferred regimen due to shortened treatment duration, and lower rates of side effects. This is also called 3HP. Please see contraindications section for more information on who should not receive this regimen.

Drug(s)	Duration	Dosing	Frequency	Total doses
Isoniazid (INH) and Rifapentine (RPT) (3HP)	3 months	**INH:** 15 mg/kg* rounded up to the nearest 50 or 100 mg; 900 mg maximum **RPT:** ≥50.0 kg* 900 mg maximum	Once weekly (pill line only)	12
Rifampin (RIF)	4 months	10mg/kg*. Max dose: 600mg	Daily (May be KOP)	120
Isoniazid^	9 months	5mg/kg*. Max dose: 300mg	Daily (May be KOP)	270

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Appendix C- Adverse Effects and Drug-Drug Interactions

All medications have side effects and it is important to discuss this with patients prior to initiating treatment so they know what to expect. The most common side effects are:

Isoniazid (INH) – Asymptomatic elevations in transaminases, hepatotoxicity, peripheral neuropathy (administer with Vitamin B6 to reduce toxicity)

Rifampin (RIF) and Rifapentine (RPT)- Cutaneous reactions (rash, flushing) with or without itching, GI symptoms (nausea, anorexia, abdominal pain), central nervous system effects (headache, fever), and orange discoloration of body fluids (tears, sweat) which is expected and harmless.

Drug-Drug Interactions

It is always important to check drug to drug interactions when starting LTBI treatment. There are helpful websites such as https://www.drugs.com/drug_interactions.html that can allow you to check interactions for multiple drugs. If the provider has any questions or concerns please utilize your pharmacy team for guidance.

Isoniazid (INH) –INH may increase the concentrations of certain cytochrome P450 enzyme substrates including phenytoin and carbamazepine.

Rifampin (RIF) – Can have several drug interactions which may include (but are not limited to) oral contraceptives, glucocorticoids, cyclosporine, HMG-CoA reductase inhibitors ("statins"), macrolide antibiotics, tacrolimus, warfarin, direct oral anticoagulants (eg, dabigatran), phenytoin, levothyroxine, azole antifungal agents, oral sulfonylurea hypoglycemics, several antimalarials, quinidine, verapamil, methadone, beta-blockers, and antiretrovirals (most notably protease inhibitors, select nonnucleoside reverse-transcriptase inhibitors (eg, etravirine and rilpivirine) and integrase inhibitors (eg, raltegravir, dolutegravir, and elvitegravir).

Rifapentine (RPT) – Use caution in those receiving antiretroviral therapy.

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Appendix D- Release from Custody Procedures

If patient is deported or transferred to another facility, pharmacy should prepare the following medications to travel with them:

1. **If on 3HP regimen:**
    a. Pharmacy will pack the remaining weekly doses, up to 4 weeks worth. Clear labeling/packaging with additional instructions is encouraged to improve patient adherence.

2. **If on RIF or INH regimens:**
    a. Pharmacy will pack up to a 30 day supply of the medication and instruct the patient to follow up with their outside medical provider for further management.

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Appendix E- LTBI completion cards

These cards can be printed out one or two sided and given to the patient once they complete LTBI treatment. LTBI completion card template

Front:

LATENT TB INFECTION (LTBI) TEST & TREATMENT COMPLETION CARD

- Show this card to the doctor, so they know about your past LTBI testing and treatment
- Call your doctor if you have any of the following symptoms for 2 or more weeks:

☐ Cough
☐ Fever and chills
☐ Coughing up blood
☐ Feeling weak and tired
☐ Weight loss without trying
☐ Night sweats

Back:

Name: _____

TST _____ mm induration **Date Read:** _____

IGRA ☐ Pos. ☐ Neg. **Date:** _____

Latent TB infection treatment completed: ☐ Yes ☐ No

Drug(s): _____ **Duration:** _____

Clinic: _____

City, State: _____

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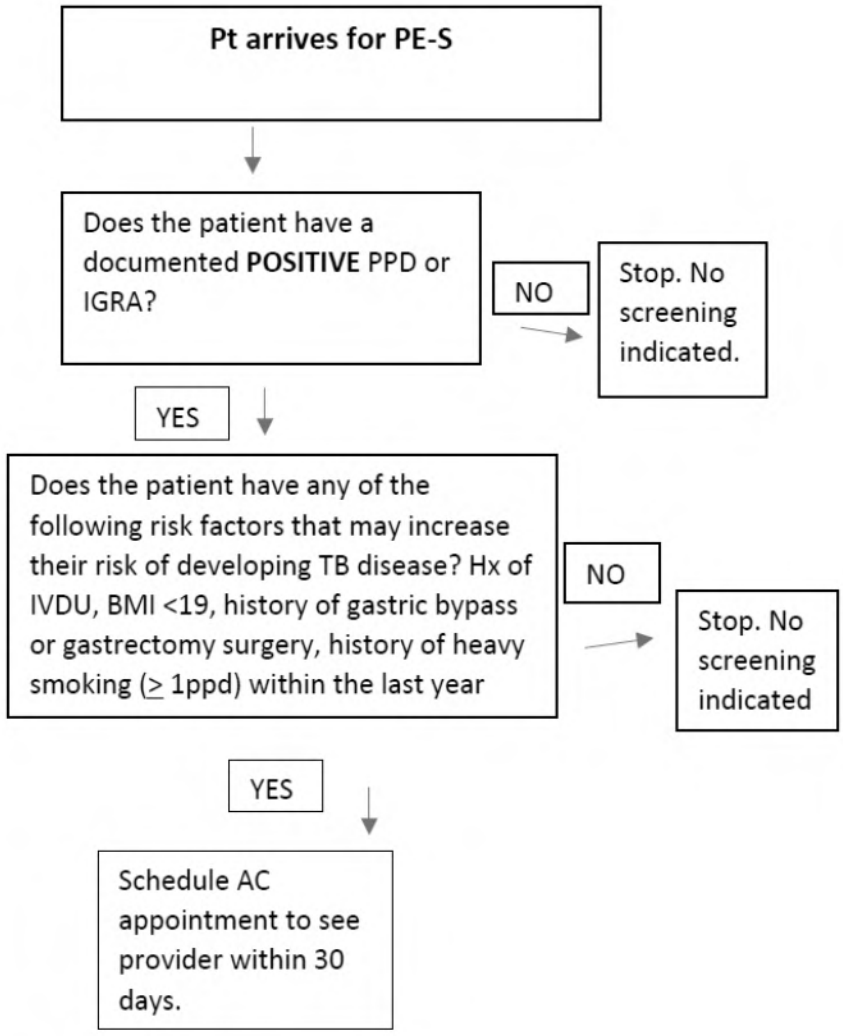
Appendix F:

Flow chart (PE-S)



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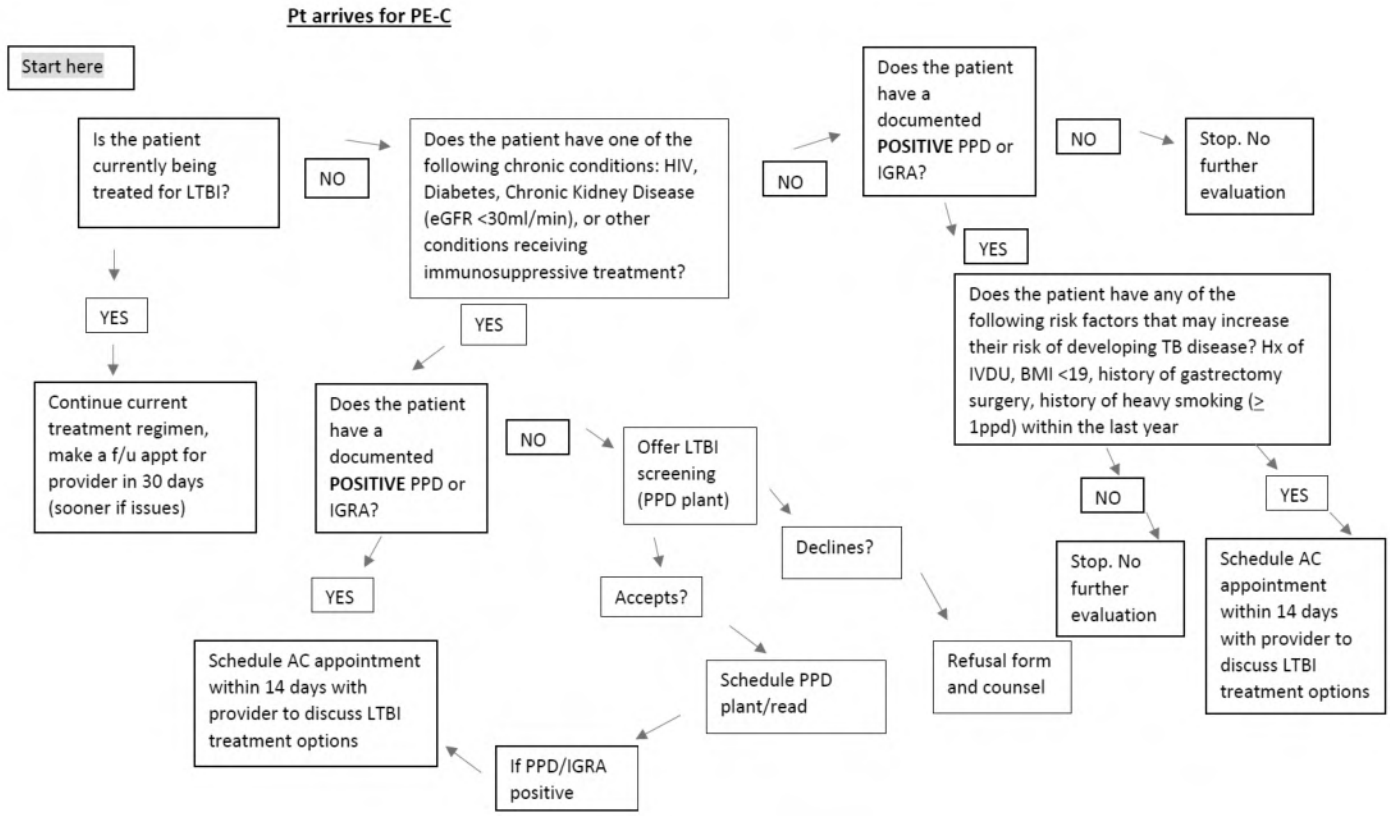
Flow Chart- PE-C



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Appendix G: Templates – screen shots

(b)(7)(E)



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U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

INFECTIOUS DISEASE PUBLIC HEALTH ACTIONS

IHSC Directive: 05-06
ERO Directive Number: 11781.1
Federal Enterprise Architecture Number: 306-112-002b
Effective Date: June 7, 2019

By Order of the Assistant Director
(b)(6); (b)(7)(C) **DHSc, MPH**

(b)(6); (b)(7)(C)

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1. **PURPOSE:** The purpose of this issuance is to set forth the policies and procedures for infectious disease public health actions.

2. **APPLICABILITY:** This directive applies to all U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) personnel, including but not limited to, U.S. Public Health Service (PHS) officers, civil service employees, and contract personnel. It is applicable to IHSC personnel supporting health care operations in ICE-owned or contracted detention facilities, and to IHSC Headquarters (HQ) staff. This directive applies to contract personnel when supporting IHSC in detention facilities and at HQ. Federal contractors are responsible for the management and discipline of its employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES**:

   3-1. Title 8, Code of Federal Regulations, Section 235.3 (8 CFR § 235.3), Inadmissible Aliens and Expedited Removal.

   3-2. Section 232 of the Immigration and Nationality Act, as amended, Title 8, U.S. Code, Section 1222 (8 U.S.C. § 1222), Detention of Aliens for Physical and Mental Examination.

   3-3. Title 8, Code of Federal Regulations, Part 232 (8 CFR 232), Detention of Aliens for Physical and Mental Examination.

   3-4. Section 322 of the Public Health Service Act, as amended, Title 42, U.S. Code, Section 249(a) (42 U.S.C. § 249(a)), Medical Care and Treatment of Quarantined and Detained Persons.

   3-5. Title 42, U.S. Code, Section 252 (42 U.S.C. § 252), Medical Examination of Aliens.

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3-6. The Privacy Act of 1974, Title 5, U.S. Code, Section 552(a) (5 U.S.C. § 252), as applied in DHS Privacy Policy Memorandum: 2007-1: "DHS Privacy Policy Regarding Collection, Use, Retention, and Dissemination of Information on Non-U.S. Persons," January 7, 2009.

3-7. ICE Policy No. 11014.1: "Continuity of Care Requirements for Adult Detainees Diagnosed with Active Tuberculosis," May 14, 2004.

3-8. Appendix A: Compliance indicators, standards, and federal regulations referenced in IHSC official guidance covering public health, safety, and preparedness functional areas.

4. POLICY: This directive addresses measures for IHSC-staffed medical clinics to prevent, control, or limit the spread of infectious diseases and minimize the impact to operations.

4-1. **Scope.** Infectious disease public health actions include a broad range of public health activities and interventions to promote and protect health, and prevent or mitigate infectious disease transmission.

4-2. **Infectious Disease Public Health Actions Plan**

4-2.1 IHSC-staffed medical clinics should maintain a written plan (see associated IHSC Guides) that addresses the public health actions for the management of the following infectious diseases:

4-2.1.a Hepatitis A, Hepatitis B, and Hepatitis C (IHSC Guide 05-06-G-04).

4-2.1.b Human Immunodeficiency Virus (HIV) (IHSC Guide 05-06-G-09).

4-2.1.c Tuberculosis (TB) (IHSC Directive 05-11 and Guides 05-11-G-01 and 05-11-G-02).

4-2.1.d Varicella and Herpes Zoster (IHSC Guide 05-06-G-06).

4-2.1.e Influenza (IHSC Guide 05-06-G-05).

4-2.2 A medical provider is responsible for the clinical management of detainees diagnosed with an infectious disease.

4-2.3 A medical provider provides urgent, non-occupational post-exposure prophylaxis (nPEP) for detainees following an exposure to an infectious disease in accordance with Centers for Disease Control and Prevention (CDC) guidelines. Refer to the IHSC 05-02-G-04 Occupational Health Guide: Workforce Health regarding occupational post-exposure prophylaxis (oPEP) for IHSC staff.

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4-3. Screening and Detection

4-3.1 Health staff conduct an intake medical screening for detainees inclusive of infectious diseases.

4-3.2 Health staff examine detainees new to, or resuming, food service duty for general health, diarrheal diseases, respiratory infections, open sores, skin infections, and illnesses transmissible by food or utensils.

4-3.3 Health staff document detainees cleared for food service duty in the IHSC medical record and provide documentation to the facility staff responsible for food service.

4-4. Medical Holds and Alerts

4-4.1 Health staff should use the IHSC Global Alert/Medical Hold to document the action in the health record. The IHSC Global Alert/Medical Hold in the health record is a tool to restrict movement of detainees diagnosed with infectious diseases of public health significance. A medical hold does not confer ICE authority to detain.

4-4.2 Health staff must not specify a detainee's confidential medical information in the Enforcement Integrated Database (EID), Enforcement CaseTracking System (ENFORCE) Alert/ Medical Alert or in an IHSC Medical Hold. The EID/ENFORCE Alert/Medical Alert and IHSC Medical Hold are tools to inform ICE Enforcement and Removal Operations (ERO) of a requested action for medical or public health reasons, such as notification prior to transfer, release, or removal. A medical hold does not confer ICE authority to detain.

4-4.3 Medical holds may be needed for detainees diagnosed with infectious diseases that pose a public health threat to detainees, staff, visitors, and the community, until the detainee is rendered non-contagious. The Facility Healthcare Program Manager (FHPM), other designated health staff, Public Health Safety and Preparedness (PHSP) Unit staff, or field medical coordinators (FMCs) should enter the EID/ENFORCE Alert, type IHSC Medical Hold. Alternatively, the FHPM, or designated staff, should notify and coordinate locally with ICE ERO to implement a medical hold. Medical holds give IHSC staff time to facilitate necessary arrangements for continuity of care prior to transfer, release, or removal.

4-4.4 Health staff, PHSP Unit staff, or FMCs should enter the EID/ENFORCE Alert, type Medical, or health staff coordinate locally with ICE ERO, to implement an alert and identify a detainee not requiring the more restrictive Medical Hold.

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4-5. **Isolation and Management of Detainees Exposed to Infectious Organisms**

4-5.1 A medical provider should order medical isolation of detainees diagnosed with infectious diseases as appropriate in accordance with guidelines on transmission-based precautions for the duration of the infectious period to prevent transmission.

4-5.1.a Health staff must document medical isolation and applicable transmission-based precautions in the health record.

4-5.2 IHSC is not responsible for establishing or implementing protocols outside of the medical clinic area. However, health staff should coordinate with the facility to mitigate risks.

4-5.2.a Health staff should recommend cohorting with restricted movement (in adult detention facilities) and social distancing (in family residential facilities) to help reduce the spread of significant infectious diseases, if appropriate.

4-5.2.b Health staff should recommend limiting close contact between known ill or exposed detainees and other detainees within the facility, if appropriate.

4-5.2.c Heath staff must monitor the condition of exposed detainees on restricted movement daily for signs or symptoms of the illness to which they were exposed.

4-5.2.d Health staff must document the exposure and restricted movement in an initial note in the health record, and reference daily monitoring tools that will be used for daily observations during the period of restriction.

4-5.2.e Health staff must use separate monitoring tools to facilitate daily observation of large numbers of exposed detainees. Health staff must maintain these monitoring tools systematically so they can be referenced and retrieved.

4-5.2.f Health staff must document the completion of the restricted movement period in the health record.

4-6. **Environmental Inspection**

4-7. **Continuity of Care**

4-7.1 Human Immunodeficiency Virus (HIV).

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4-7.1.a PHSP Unit staff research and provide health staff with referral and continuity of care resources for detainees diagnosed with HIV.

4-7.1.b Health staff provide location-specific resources to detainees diagnosed with HIV prior to their release or removal.

4-7.2 Tuberculosis – See IHSC Directive 05-11, Public Health Actions for TB Care located in the IHSC policy library.

4-7.3 Health staff should consider continuity of care needs for detainees with other infectious diseases of public health significance in consultation with the Regional Clinical Director, PHSP Unit staff, and the IHSC Infectious Disease Consultant.

4-8. Contact and Outbreak Investigations

4-8.1 The FHPM should coordinate and implement contact and outbreak investigations within the scope of detainee health services and in collaboration with the local or state health department.

4-8.2 Health staff should implement clinical and infection prevention interventions to promptly identify, investigate, and control infectious disease outbreaks within the scope of detainee health services.

4-8.3 Health staff should collaborate with facility, law enforcement, and local health department staff on contact and outbreak investigations for infectious diseases of public health significance that have the potential for serious morbidity or mortality.

4-8.4 Health staff should report contact and outbreak investigations to PHSP Unit staff and the local health department.

4-8.5 Health staff should inform detainees of the voluntary and confidential nature of a contact investigation and provide detainee education on the condition of interest.

4-8.6 PHSP Unit staff and the IHSC Infectious Disease Consultant should provide technical guidance for the conduct, scope, and overall management of contact and outbreak investigations regarding ICE detainees.

4-8.7 Health staff must follow all applicable ICE and DHS policies addressing privacy and disclosure of law enforcement sensitive information.

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4-8.8 Health staff should not disclose information regarding an individual's legal claims or proceedings.

4-8.9 Health staff should direct questions about a detainee's legal claims or proceedings, including confidentiality, or the disclosure of information to the Office of the Principal Legal Advisor (OPLA) or local Office of Chief Counsel (OCC).

4-9. Surveillance and Reporting

4-9.1 PHSP Unit staff should monitor information disseminated through the Centers for Disease Control and Prevention (CDC) and international health organizations for announcements and advisories regarding emerging or established public health threats.

4-9.2 PHSP Unit staff should monitor detainee infectious disease surveillance data in collaboration with the FHPM to examine trends and detect infectious disease outbreaks.

4-9.3 PHSP Unit staff should utilize information available in the health record for surveillance and monitoring. PHSP Unit staff should request additional health information not available in the health record at the time it is needed for completeness, surveillance, reporting, continuity of care, or other public health intervention from the FHPM, Health Services Administrator (HSA), Assistant Health Services Administrator (AHSA), or other designee.

4-9.4 The FHPM, HSA, AHSA, and other designees should facilitate completion of information requests for surveillance, reporting, continuity of care, and other public health interventions promptly.

4-9.5 Health staff should document detainee infectious disease diagnoses in the health record using the appropriate international classification of diseases (ICD) code.

4-9.6 Health staff should report detainees with notifiable diseases to the local or state health department in accordance with local, state, and federal regulations.

4-9.7 Health staff should report events requiring contact investigations, outbreaks, or an unexpected increase in prevalence or incidence of disease among detainees to local leadership, PHSP Unit staff, and the local or state health department in accordance with local, state, and federal regulations.

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4-10. Significant Infectious Disease or Pandemic

4-10.1 The FHPM, HSA, and other designated staff should implement emergency response procedures for IHSC-staffed medical clinics in the event of a significant infectious disease threat, pandemic, or indication that an IHSC-staffed medical clinic will receive an influx of detainees with a disease of public health significance.

4-10.2 PHSP Unit staff should develop and update official guidance to address public health actions and infection control measures related to a significant infectious disease threat or pandemic among ICE detainees.

4-11. Media Relations

4-11.1 IHSC staff must refer all media inquiries and responses through the supervisory chain to the ICE Office of Public Affairs.

4-12. PHSP Unit Oversight and Monitoring

4-12.1 PHSP Unit staff provide national oversight of the public health actions for the management of infectious diseases among ICE detainees. PHSP Unit staff provide technical assistance to IHSC-staffed medical clinics on implementing infectious disease public health actions within the scope of detainee health services.

4-12.2 PHSP Unit staff serve as subject matter experts on infectious disease public health actions and the point of contact for providing guidance to FHPMs, HSAs, AHSAs, and other health staff on functions under the scope of this directive and related guides.

4-12.3 In addition to routine information requests for surveillance, reporting, continuity of care, and public health interventions, PHSP Unit staff periodically collect information from IHSC-staffed medical clinics to monitor implementation of public health activities regarding ICE detainees.

4-12.4 PHSP Unit staff review and update this directive and corresponding guides at least annually.

4-13. Training and Education

4-13.1 The HSA or designee must ensure that orientation and annual training that includes infectious disease public health actions is implemented and documented in accordance with IHSC Directive *01-04, Medical Education and Development*.

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4-13.2 Health care personnel should educate detainees diagnosed with, or exposed to, an infectious disease of public health significance about topics such as transmission, risk factors, and infection prevention and control measures.

5. **PROCEDURES:** Detailed procedures related to this directive are found in the IHSC policy library in the following guides:

5-1. *05-06-G-01, Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations.*

5-2. *05-06-G-02, Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms.*

5-3. *05-06-G-03, Infectious Disease Public Health Actions Guide: Surveillance and Reporting.*

5-4. *05-06-G-04, Infectious Disease Public Health Actions Guide: Management of Hepatitis.*

5-5. *05-06-G-05, Infectious Disease Public Health Actions Guide: Management of Influenza.*

5-6. *05-06-G-06, Infectious Disease Public Health Actions Guide: Management of Varicella and Herpes Zoster.*

5-7. *05-06-G-07, Infectious Disease Public Health Actions Guide: Management of Ectoparasites.*

5-8. *05-06-G-09, Infectious Disease Public Health Actions Guide: Management of HIV.*

5-9. *05-06-G-08, Infectious Disease Public Health Actions Guide: Zika Virus.*

5-10. *05-11-G-01, Public Health Actions for TB Care Guide: IHSC Staffed Medical Clinics.*

5-11. *05-11-G-02, Public Health Actions for TB Care Guide: IHSC Headquarters.*

5-12. *05-02, Occupational Health, and 05-02-G-01, Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials* (these official guidance documents address the Exposure Control Plan).

6. **HISTORICAL NOTES:** This directive replaces the previous version of IHSC Directive 05-06, Infectious Disease Public Health Actions.

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7. **DEFINITIONS:** See definitions for this policy in the 11-00 IHSC Glossary located in the IHSC policy library and guides related to infectious disease public health actions.

8. **APPLICABLE STANDARDS**:

See also Appendix A.

8-1. Performance-Based National Detention Standards (PBNDS)

8-1.1 PBNDS 2011:

8-1.1.a Part 4: Care; 4.3 Medical Care; C. Communicable Disease and Infection Control; Z. Continuity of Care; 2. Tuberculosis (TB) Management; 4. Transfer and Release of Detainees

8-2. **ICE Family Residential Standards**

8-2.1 Part 4: Care; 4.3 Medical Care; 2. Communicable Disease and Infection Control; b. Additional Requirements Regarding Tuberculosis

8-3. **American Correctional Association (ACA)**

8-3.1 Performance-Based Standards for Adult Local Detention Facilities, 4th edition:

8-3.1.a 4-ALDF-4C-04: Continuity of Care.

8-3.1.b 4-ALDF-4C-14-17: Communicable Disease and Infection Control Program.

8-3.1.c 4-ALDF-4D-13: Confidentiality.

8-4. **National Commission on Correctional Health Care (NCCHC)**

8-4.1 Standards for Health Services in Jails, 2018:

8-4.1.a J-B-02 Infection Prevention and Control Program.

(Compliance indicators for this standard are also addressed in the following IHSC official guidance: 05-02 Occupational Health, 05-02-G-01 Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials, 05-02-G-02 Occupational Health Guide: Personal Protective Equipment, 05-02-G-03 Occupational Health Guide: Respiratory Protection, 05-02-G-04 Occupational Health Guide: Workforce Health, 05-04 Environmental Health, 05-04-G-01 Environmental Health Guide, 05-05 Safety and Security,

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05-11 Public Health Actions for Tuberculosis Care, 05-11-G-01 Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics, 05-11-G-02 Public Health Actions for Tuberculosis Care Guide: IHSC Headquarters).

9. **PRIVACY AND RECORDKEEPING.** IHSC stores, retrieves, accesses, retains, and disposes of these records in accordance with the Privacy Act and as provided in the DHS/ICE-013: Alien Health Records System of Records Notice, 80 Federal Register 239 (Jan. 5, 2015). The records in the electronic health record (eHR)/eClinical Works (eCW) are destroyed ten (10) years from the date the detainee leaves ICE custody. Retention periods for records of minors may differ. Paper records are scanned into eHR and are destroyed after upload is complete

10. **NO PRIVATE RIGHT STATEMENT.** This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations

Approved by (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO AD – IHSC

Effective Date: June 7, 2019

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Foreword

This Infectious Disease Public Health Actions Guide: *Contact and Outbreak Investigations* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities, and details procedures for conducting contact and outbreak investigations.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this Guide is to provide guidance for conducting contact and outbreak investigations in facilities with IHSC-staffed medical clinics.

B. Responsibilities

Health Services Administrator, Compliance Officer, and Infection Prevention Officer

- Establish procedures to conduct the detainee component of contact and outbreak investigations in facilities with IHSC-staffed medical clinics.
- Oversee the detainee component of contact and outbreak investigations in facilities with IHSC-staffed medical clinics.
- Ensure that all health staff receive orientation and annual training related to contact and outbreak investigations.
- Facilitate completion of information requests for reporting, monitoring, tracking, and following up on contacts, public health actions, and implementation of infection prevention and control measures.

Medical Providers

- Provide clinical guidance regarding the conduct and scope of the contact or outbreak investigation.
- Oversee the clinical management of exposed detainee contacts and ill detainees during contact or outbreak investigations.

Health Staff

- Implement clinical interventions to promptly identify, investigate, and control transmission of infectious organisms within the scope of detainee health services.
- Participate in the conduct of the detainee component of contact and outbreak investigations in collaboration with the Compliance Officer, Infection Prevention Officer, and Health Services Administrator (HSA) to prevent the spread of infectious diseases.

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- Maintain knowledge about infection prevention and control measures applicable to work duties.

Public Health, Safety, and Preparedness Unit Staff

- Provide technical guidance and resources to IHSC staff related to the detainee component of contact and outbreak investigations.
- Develop, review, and update contact and outbreak investigation tools and templates.
- Facilitate reporting and requests for information from agency leadership and government partners.

IHSC Infectious Disease Consultant and Infectious Disease Advanced Practice Provider (APP)

- Provide clinical guidance regarding the conduct and scope of contact and outbreak investigations, and the clinical management of detainees during contact or outbreak investigations.

C. Acronyms

CDC – United States Centers for Disease Control and Prevention

CIFOR – Council to Improve Foodborne Outbreak Response

ILI – Influenza like illness

PPE – Personal protective equipment

SARS – Severe Acute Respiratory Syndrome

D. Definitions with Expanded Information

Case – An instance of a particular disease, injury, or other health condition that meets selected criteria.

Case definition – A set of uniformly applied criteria for determining whether a person should be identified as having a particular disease, injury, or other health condition.

Cohorting – Cohorting is a public health strategy used to house individuals separately as a group based on their infectious or exposure status.

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Contact – A person exposed to an infectious disease.

Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact; communicable; infectious; usually microorganisms.

Epidemic – The occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time.

Immunity – Protection against a disease. Immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.

Incubation Period – The interval between exposure to a communicable microorganism and onset of symptoms.

Infectious Period – The period during which a person might have transmitted a communicable microorganism to others.

Isolation – An infection control measure used to separate ill persons who have a communicable disease from those who are healthy. Isolation restricts the movement of ill persons to help stop the spread of significant infectious diseases.

Outbreak – The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period.

Personal protective equipment – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases and includes respirators, gloves, masks, goggles, gowns, face shields, ear plugs, hard hats, or steel toe boots.

Prophylaxis – A measure taken to maintain health and prevent the spread of disease.

Significant exposure – Exposure under conditions more likely to result in transmission of infection.

Surveillance – The timely, continuous, systematic collection, analysis and interpretation of health-related data for informing urgent and routine public health activities, including public health interventions; contact and outbreak investigations; evidence-based decision making; and planning, implementation, and evaluation of public health practices.

Susceptible – Unprotected against disease.

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Tracking tool – A type of epidemiologic database, organized similar to a spreadsheet with rows and columns in which information from cases or patients are listed, each column represents a variable, each row represents an individual case or patient.

Transmission – Any mode or mechanism by which an infectious agent is spread to a susceptible host.

II. Contact Investigations

A contact investigation is the process of identifying, evaluating and treating persons (contacts) who have sustained a significant exposure to a person with an infectious disease of public health significance. A contact investigation might be required to help control transmission within the facility and between facilities, and it is initiated for infectious diseases that have the potential for serious morbidity or mortality.

Examples of diseases that should generate a contact investigation include, but are not limited to, tuberculosis (see *05-11-G-01 Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Medical Clinics*), varicella or herpes zoster (see *05-06-G-06 Infectious Disease Public Health Actions Guide: Management of Varicella and Herpes Zoster* Guide), measles, mumps, Ebola, and Severe Acute Respiratory Syndrome (SARS) located in the IHSC policy library.

A. Purpose of Contact Investigations

Contact investigations are intended to accomplish the following:

- Identify and evaluate people who may have had significant exposure to an infectious organism.
- Identify people recently infected with an infectious organism.
- Halt transmission of disease.
- Initiate appropriate medical intervention.
- Prevent the development of disease among recently infected contacts.

B. Initiating Contact Investigations

The Compliance Officer, Infection Prevention Officer, HSA, and designated health staff should initiate a contact investigation as soon as a detainee is diagnosed with an infectious disease of public health significance that requires a contact investigation. The initiation of a contact investigation allows for rapid identification

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of contacts and secondary cases in order to initiate treatment and prevent further spread of disease. Designated health staff should document general information related to the contact investigation in a central investigation file that can be retrieved upon request. General information includes documentation of education provided to a group of exposed detainees and documentation of education provided to health staff. Health staff should document in a detainee's health record that a detainee was evaluated as a contact and any additional relevant information. Documentation should also include individual education provided to the detainee.

Health staff should consult with the Clinical Director (CD), Regional CD, Public Health, Safety, and Preparedness (PHSP) Unit staff, or the local or state health department for guidance on diseases of public health significance that require a contact investigation. Health staff must document initiation of a contact or outbreak investigation using the Contact and Outbreak Investigations reporting tool available on the PHSP Unit SharePoint page. Health staff should document relevant laboratory, treatment, and risk factor information for exposed detainees using a condition-specific contact investigation tracking tool which should be attached to the record in the Contact and Outbreak Investigations reporting tool upon completion of the investigation. In some circumstances, suspicion of a significant infectious condition may warrant initiating some components of a contact or outbreak investigation in order to expedite exposure assessments and mitigate possible transmission.

C. Education

Health care personnel should educate detainees with significant exposure about the symptoms of the disease and encourage them to notify a medical provider if they become ill. Health care personnel should also inform detainees about the contact investigation process, the voluntary and confidential nature of information that is collected during a contact investigation, and that the health department might interview them during the investigation.

Health care personnel should educate health staff about the potential for an outbreak and encourage everyone to maintain a high index of suspicion for the disease of interest when providing medical care and evaluation.

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D. Staff Considerations

The HSA, Nurse Manager, or designee, should adjust work schedules and assignments for susceptible or vulnerable staff members who, if infected with the disease of interest, have a high risk for complications. Health staff should make an effort to avoid contact with a detainee diagnosed with the disease of interest or exposed contacts within the incubation period, unless appropriate standard and transmission-based precautions are implemented. Health staff without known immunity, and who have had significant exposure, should see their personal health care provider for evaluation and management.

E. Collaborations

Health staff should collaborate with local or state health departments to conduct the detainee component of contact investigations, if needed. Health departments have expertise in conducting contact investigations and should be used as a resource to determine the scope of the contact investigation and recommended management of detainee contacts. The HSA, Compliance Officer, Infection Prevention Officer, or designee should recommend to facility staff that they accommodate local, state, or federal public health program requests to interview index patients and detainee contacts and review detainee health records, as necessary, to support the public health investigation.

The HSA, Compliance Officer, Infection Prevention Officer, or designee should provide the local, state, or federal public health program with information to support the public health investigation to the extent permissible under the Privacy Act and other applicable laws and regulations, and Department of Homeland Security (DHS) and U.S. Immigration and Customs Enforcement (ICE) policies.

IHSC does not have authority for, and is not responsible for, establishing or implementing protocols implemented outside of the medical clinic area; however, health staff should coordinate with the facility to mitigate risks. Health staff should refer health department staff to each respective employer within the facility for coordination regarding the employer's staff and areas of responsibility.

F. Contact Investigation Steps

1. Review existing information about the index patient to help the investigator accomplish the following:

    a. Estimate the infectious period.

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b. Estimate the degree of infectiousness.

c. Identify additional people with the disease of interest.

d. Identify potential exposure locations.

e. Conduct effective interviews.

2. Determine an initial estimate for the infectious period and the degree of infectiousness.

3. Interview the index patient.

a. Health staff should interview the index patient to determine where they spent time during the infectious period, what activities or events they participated in, and who they spent time with during the infectious period.

b. Health staff should discuss the contact investigation process and provide education to the detainee.

c. Health staff should confirm and expand upon information obtained.

4. Review information and develop a plan for the investigation.

5. Refine the infectious period and the degree of infectiousness.

6. Exposure Assessment.

a. Health staff should consult with the local or state health department and PHSP Unit staff to establish parameters for determining significant exposures.

b. Health staff should coordinate with facility staff to determine whether any detainees may have had a significant exposure to detainees with the disease of interest.

c. Exposed health staff without known immunity should see their primary care provider for assessment and treatment.

7. Evaluate contacts and institute isolation, cohorting, and/or social distancing, if necessary.

a. A health care provider should perform an evaluation of detainees with significant exposure to assess for symptoms of disease.

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b. A medical provider should order medical isolation of detainees with signs or symptoms of an infectious disease in accordance with applicable official guidance (see 05-06-G-02 *Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*) located in the IHSC policy library.

c. The HSA, Compliance Officer, Infection Prevention Officer, or designee should communicate to the facility administrator, the facility's designee for safety, and other on-site employers recommended public health actions for mitigating transmission following exposures to infectious organisms among staff, visitors, and detainees for the duration of the incubation period(s), as appropriate. These public health actions may include, but are not limited to, hand hygiene, cleaning, disinfection, social distancing, administrative controls, environmental controls, respiratory precautions, personal protective equipment, immunizations, and/or serologic testing to verify immunity.

d. The CD or designee may consider testing detainee contacts with significant exposure and without documented immunity or immunization to determine immune status if medically appropriate and in accordance with Centers for Disease Control and Prevention (CDC) and/or Advisory Committee on Immunization Practices (ACIP) recommendations.

e. The Compliance Officer, Infection Prevention Officer, or other designated health staff should use a tracking tool to track clinical, demographic, and exposure information. Health staff should consult with PHSP Unit staff on the availability of tracking tools specific for the infectious condition under investigation. Previously developed tracking tools are available at PHSP Unit SharePoint | PHSP Committee Collaborative Documents | Line List Templates.

8. Determine whether to expand or conclude the investigation.

   a. Contact investigations may be expanded to detainee contacts with a lower level of exposure, if necessary (i.e., if the initial phases demonstrated that transmission occurred).

   b. The Compliance Officer, Infection Prevention Officer, HSA, and other designated health staff should consult with PHSP Unit staff and the health department to determine if a contact investigation should be expanded beyond detainees with a significant exposure.

9. Enhance surveillance.

   a. Health staff should maintain a high index of suspicion for the disease of interest to facilitate prompt identification of detainees who may present as secondary cases.

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b. Timely identification of detainees with the disease of interest and implementation of infection control measures can prevent an outbreak.

10. Evaluate the contact investigation activities.

    a. The Compliance Officer, Infection Prevention Officer, or other designated health staff should document the evaluation and summary of contact investigation activities in an after action report.

III. Outbreak Investigations

An outbreak is the occurrence of more cases of disease than expected in a given area or among a specific group of persons during a specific period. Prompt identification, investigation, and control of disease outbreaks are important to stop the spread of infectious diseases in IHSC-staffed facilities. For more information and case definitions, refer to disease or situation-specific CDC guidelines.

A. Purpose of Outbreak Investigations

Outbreak investigations are intended to accomplish the following:

- Identify the source of the outbreak.
- Evaluate causes and contributing factors to outbreak.
- Stop the spread of disease.

B. Coordination and Collaboration

- Health staff should inform the following entities if an outbreak of an infectious disease of public health significance is suspected:
    - HSA, Compliance Officer, Infection Prevention Officer, or designee;
    - CD or designee;
    - Regional CD;
    - Regional HSA;
    - PHSP Unit staff; and
    - Local public health department.

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The Compliance Officer, Infection Prevention Officer, or designee should notify the local health department of an infectious disease outbreak investigation in accordance with local and state laws. Depending on the disease of interest, outbreak investigations may be a joint effort with the health department. Health departments have expertise in conducting outbreak investigations and should be used as a resource. The Compliance Officer, Infection Prevention Officer, or other designated health staff should consult with the health department to determine scope of the outbreak investigation and recommendations for conducting the investigation. The HSA or designee should provide the local, state, or federal public health program with information to support the public health investigation to the extent permissible under the Privacy Act and other applicable law and regulations, and DHS and ICE policies.

Investigations of foodborne illness and possible foodborne outbreaks are conducted in conjunction with the facility food services staff and the local public health department. For specific guidance regarding foodborne disease outbreak investigations reference the Council to Improve Foodborne Outbreak Response (CIFOR) | Guidelines for Foodborne Disease Outbreak Response.

C. Steps for the Control and Investigation of Outbreaks

The following steps are recommended to investigate and control an outbreak of an infectious disease of public health significance. Health staff should implement appropriate precautions in the medical clinic as soon as an outbreak is suspected, and consider enhancing control measures in the medical clinic if there is an increase in the number of cases of disease in the facility, even if it does not yet meet the definition of an outbreak. The Compliance Officer, Infection Prevention Officer, and other designated health staff should conduct the following steps in consultation with PHSP Unit as needed.

1. Establish the existence of an outbreak.

    a. The general definition of an outbreak is the occurrence of more cases of disease than expected in a given area or among a specific group of persons during a specific period.

    b. The number of cases of illness that defines an outbreak varies depending on the disease.

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2. Verify the diagnosis.

    a. A medical provider should verify the diagnosis suspected of causing the outbreak.

    b. A medical provider should use medical records or lab reports to verify the diagnosis, when appropriate.

    c. A medical provider should order clinical testing, if medically appropriate.

3. Define and identify cases.

    a. The CD, or designee, should develop a case definition and identifies additional cases associated with the outbreak. The CD or designee should consult with the Regional CD, Infectious Disease Consultant, or Infectious Disease APP as appropriate.

    b. During an outbreak, laboratory confirmation may be recommended.

4. Develop tracking tool.

    a. The Compliance Officer, Infection Prevention Officer, or designated health staff should use a tracking tool to document clinical, demographic, and exposure information. The Compliance Officer, Infection Prevention Officer, or designee should consult with PHSP Unit on the availability of tracking tools specific for the infectious condition under investigation. Previously developed tracking tools are available at PHSP Unit SharePoint | PHSP Committee Collaborative Documents | Line List Templates.

    b. The information collected with the tracking tool can help manage relevant health information, describe the outbreak, and develop hypotheses (i.e., type of exposure, risk factors, and disease characteristics).

    c. Information can also inform the implementation of appropriate control measures and precautions.

5. Develop, evaluate, and refine hypotheses.

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a. The Compliance Officer, Infection Prevention Officer, or designee should use the tracking tool to develop, evaluate, and refine hypotheses in coordination with PHSP Unit staff.

b. Hypotheses can inform infection prevention and control measures.

6. Enhance infection prevention and control measures.

a. Health staff should implement appropriate precautions and control measures in the medical clinic as soon as an outbreak is suspected (see the *05-02-G-01 Occupational Health Guide: Blood Borne Pathogens and Other Potentially Infectious Materials* and *05-02-G-02 Occupational Health Guide: Personal Protective Equipment*) located in the IHSC policy library.

b. The HSA, CD, Nurse Manager, or designee should consider implementing enhanced medical screening at intake, if appropriate.

c. Health staff should provide education to detainees on the nature of the outbreak and the importance of following appropriate guidelines to prevent the spread of disease.

d. The HSA, Compliance Officer, Infection Prevention Officer, or designee should recommend to the facility administrator and the facility's designee for safety, and other on-site employers recommended public health actions for mitigating transmission following exposures to infectious organisms among staff, visitors, and detainees for the duration of the incubation period(s), as appropriate. These public health actions may include, but are not limited to, hand hygiene, cleaning, disinfection, social distancing, administrative controls, environmental controls, respiratory precautions, personal protective equipment, immunizations, and/or serologic testing to verify immunity (see 05-06-G-02 Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms).

e. A medical provider should order prophylactic treatment for detainees, if medically appropriate.

f. The Compliance Officer, Infection Prevention Officer, or designated health staff should implement enhanced surveillance, if appropriate.

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7. Summarize and communicate findings in an after action report.

   a. After action reports are useful for informing prevention and control of future outbreaks.

   b. The HSA, Compliance Officer, and Infection Prevention Officer should evaluate the process and develop a plan to improve the process for investigating future outbreaks.

IV. Program Monitoring

PHSP Unit staff periodically request information from the Compliance Officer, Infection Prevention Officer, HSA, or designee to monitor contact and outbreak investigation activities in facilities with IHSC-staffed medical clinics. The HSA, Compliance Officer, and Infection Prevention Officer should facilitate prompt completion of information requests related to contact and outbreak investigations.

V. Training and Education

The Compliance Officer, Infection Prevention Officer, HSA, or designee must ensure that orientation and annual trainings that include infectious disease public health actions for contact and outbreak investigations are implemented and documented in accordance with *Directive 01-04 Medical Education and Development* located in the IHSC policy library.

VI. Privacy and Recordkeeping

Please refer to *Directive 05-06, Infectious Disease Public Health Actions*, for guidance on complying with privacy and recordkeeping procedures located in the IHSC policy library.

VII. References and Resources

(1) CDC – Foodborne Outbreaks - Guide to Confirming a Diagnosis in Foodborne Disease.

(2) Council to Improve Foodborne Outbreak Response (CIFOR) | Guidelines for Foodborne Disease Outbreak Response.

(3) Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis, Recommendations from the National Tuberculosis Controllers Association and CDC.

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

ERO AD - IHSC

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities and details procedures for detainee isolation and recommendations for social distancing in facilities with IHSC-staffed medical clinics.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this Guide is to provide guidance and highlight considerations for the isolation of detainees with a suspected, probable, or confirmed infectious disease of public health significance.

Isolation and social distancing are infection control measures intended to control or limit the spread of infectious diseases. These public health strategies limit the exposure between persons infected or potentially infected with an infectious disease, and susceptible persons.

B. Responsibilities

Health Services Administrator (HSA), Facility Healthcare Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Ensure implementation of infectious disease public health actions in the medical and dental clinics, including isolation and exposure management.
- Oversee implementation of infection control measures for preventing transmission of infectious organisms in IHSC-staffed medical clinics.
- Facilitate completion of information requests for reporting, monitoring, tracking, and following up on contacts, public health actions, and implementation of infection prevention and control measures.

Medical Providers

- Oversee the clinical management of isolated or exposed detainees.
- Order medical isolation as appropriate.

Health Staff

- Implement appropriate infection control measures to prevent the transmission of infectious diseases in IHSC-staffed medical clinics.
- Maintain current knowledge about infection prevention and control measures applicable to work duties.

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Public Health, Safety, and Preparedness (PHSP) Unit Staff

- Provide guidance to health staff on isolation and exposure management protocols.
- Monitor national guidelines and standards for updates and new releases.

IHSC Infectious Disease Consultant and Infectious Disease Advanced Practice Provider

- Provide clinical guidance for public health actions related to the isolation and exposure management of detainees

C. Acronyms

ACIP – Advisory Committee on Immunization Practices

AII – Airborne infection isolation (room)

CDC – United States Centers for Disease Control and Prevention

IDSA – Infectious Diseases Society of America

PEP – Post-exposure prophylaxis

PPE – Personal protective equipment

D. Definitions with Expanded Information

Airborne infection isolation (AII) room – A single-occupancy patient-care room; formerly called a negative pressure isolation room; environmental factors are controlled so the isolation room receives substantial air changes per hour (ACH) (≥12 ACH for new construction since 2001 and ≥6 ACH for construction before 2001) and is under negative pressure (the direction of air flow is from the outside adjacent space [the corridor] into the room); all room air is preferably exhausted to the outside, or recirculated if the return air is filtered through a high efficiency particulate air (HEPA) filter.

Airborne transmission – Dissemination of airborne particles that remain infective over time and distance.

Case – An instance of a particular disease, injury, or other health condition that meets selected criteria.

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Cohort – A well-defined group of persons who have had a common experience or exposure.

Cohorting – Cohorting is a public health strategy used to house individuals separately as a group based on their infectious or exposure status.

Contact – A person exposed to an infectious disease.

Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact; communicable; infectious; usually microorganisms.

Enforcement Integrated Database/ENFORCE – ICE ERO maintains records pertaining to arrests, detentions, and removals in the Immigration and Enforcement Operational Records (ENFORCE) System of Records, which includes the Enforcement Integrated Database (EID).

Exposure – The condition of being subjected to something (noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

General population – Detainees whose housing and activities are not specifically restricted.

Incubation period – The interval between exposure to a communicable microorganism and onset of symptoms.

Infection control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Infectious period – The period during which a person might have transmitted a communicable microorganism to others.

Isolation – An infection control measure used to separate ill persons who have a communicable disease from those who are healthy. Isolation restricts the movement of ill persons to help stop the spread of significant infectious diseases.

Medical Housing Unit (MHU) – A designated area which provides housing for detainees in need of closely observed medical or behavioral care, medical/nursing assistance and/or medically necessary supervision or equipment. The MHU must operate 24 hours/day, seven days per week. The unit must contain life support equipment and meet the staffing and treatment needs of the detainee.

Outbreak – The sudden increase in the incidence of a disease or condition, when the observed number of cases exceeds the expected number of cases of disease.

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Personal protective equipment – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, steel toe boots.

Social distancing – Measures to increase space between people and decrease the frequency of contact among people; minimize transmission by reducing contact between susceptible and infectious individuals.

Standard precautions – Infection prevention practices, including hand hygiene, that apply to all patients regardless of infectious status. Standard precautions are a combination and expansion of Universal Precautions and Body Substance Isolation, based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes contain transmissible infectious agents. Standard precautions include hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection, or face shield. Equipment or items in the patient environment likely to have been contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents, (e.g., wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).

Symptomatic – A term applied to a patient with health-related complaints (symptoms) that might indicate the presence of disease.

Transmission-based precautions – Precautions that provide additional protections beyond standard precautions to interrupt the transmission of pathogens.

II. Isolation

A. Isolation Principles

Isolation is an infection control measure used to separate ill persons who have a communicable disease from those who are healthy. Isolation restricts the movement of ill persons to help stop the spread of significant infectious diseases. For detailed guidance on recommended isolation and transmission-based precautions for specific infections and conditions, see CDC | Isolation Precautions | Guidelines, including Appendix A | Type and Duration of Precautions Recommended for Selected Infections and Conditions and Appendix A | Table 2 | Clinical Syndromes or Conditions Warranting Empiric Transmission-Based Precautions in Addition to Standard Precautions. See also Table 1.

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Table 1. Clinical Syndromes or Conditions Warranting Empiric Transmission-Based Precautions in Addition to Standard Precautions[a]

Disease	Clinical Syndrome or Condition[b]	Potential Pathogens‡[c]	Empiric Precautions (Always Includes Standard Precautions)
Diarrhea	Acute diarrhea with a likely infectious cause in an incontinent or diapered patient	Enteric pathogens[d]	Contact precautions (pediatrics and adult)
Meningitis	Meningitis	Neisseria meningitidis	Droplet precautions prior to and for first 24 hours of antimicrobial therapy; mask and face protection for intubation
Meningitis	Meningitis	Enteroviruses	Contact precautions for infants and children
Meningitis	Meningitis	M. tuberculosis	Airborne precautions if pulmonary infiltrate; airborne precautions plus contact precautions if potentially infectious draining body fluid present
Rash or Exanthems, Generalized, Etiology Unknown	Petechial/ecchymotic with fever (general)	Neisseria meningitidis	Droplet precautions for first 24 hours of antimicrobial therapy
Rash or Exanthems, Generalized, Etiology Unknown	Petechial/ecchymotic with fever (general) If positive history of travel to an area with an ongoing outbreak of VHF in the 10 days before onset of fever	Ebola, Lassa, Marburg viruses	Droplet precautions plus contact precautions, with face/eye protection, emphasizing safety sharps and barrier precautions when blood exposure likely. Use N95 or higher respiratory protection when aerosol-generating procedure performed. **Ebola Virus Disease Update [2014]:** Updated recommendations for healthcare workers can be found at https://www.cdc.gov/vhf/ebola/healthcare-us/.
Rash or Exanthems, Generalized, Etiology Unknown	Vesicular	Varicella-zoster, *herpes simplex,* orthopox viruses, enteroviruses (coxsackie)	Airborne plus contact precautions; contact precautions only if herpes simplex, localized zoster in an immunocompetent host or enteroviruses (coxsackie) most likely
Rash or Exanthems, Generalized, Etiology Unknown	Maculopapular with cough, coryza and fever	Rubeola (measles) virus	Airborne precautions
Respiratory Infections	Cough/fever/upper lobe pulmonary infiltrate in an HIV-negative patient or a patient at low risk for human immunodeficiency virus (HIV) infection	M. tuberculosis, Respiratory viruses, S. pneumoniae, S. aureus (MSSA or MRSA)	Airborne precautions plus contact precautions

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Disease	Clinical Syndrome or Condition[b]	Potential Pathogens‡[c]	Empiric Precautions (Always Includes Standard Precautions)
Respiratory Infections	Cough/fever/pulmonary infiltrate in any lung location in an HIV-infected patient or a patient at high risk for HIV infection	M. tuberculosis, Respiratory viruses, S. pneumoniae, S. aureus (MSSA or MRSA)	Airborne precautions plus contact precautions; use eye/face protection if aerosol-generating procedure performed or contact with respiratory secretions anticipated. If tuberculosis is unlikely and there are no AII rooms and/or respirators available, use droplet precautions instead of airborne precautions; consider all HIV patients at high risk for tuberculosis
Respiratory Infections	Cough/fever/pulmonary infiltrate in any lung location in a patient with a history of recent travel (10-21 days) to countries with active outbreaks of MERSCoV, avian influenza	*M. tuberculosis,* Middle Eastern acute respiratory syndrome virus (MERSCoV), avian influenza	Airborne plus contact precautions plus eye protection. If MERSCoV and tuberculosis unlikely, use droplet precautions instead of airborne precautions.
Respiratory Infections	Respiratory infections, particularly bronchiolitis and pneumonia, in infants and young children	Respiratory syncytial virus, parainfluenza virus, adenovirus, influenza virus, *Human metapneumovirus*	Contact plus droplet precautions; droplet precautions may be discontinued when adenovirus and influenza have been ruled out.
Skin or Wound Infection	Abscess or draining wound that cannot be covered	*Staphylococcus aureus* (MSSA or MRSA), group A streptococcus[e]	Contact precautions; Add droplet precautions for the first 24 hours of appropriate antimicrobial therapy if invasive Group A streptococcal disease is suspected[e]

[a] Adapted from Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

[b] Patients with the syndromes or conditions listed below may present with atypical *signs* or symptoms (e.g.neonates and adults with pertussis may not have paroxysmal or severe cough).The clinician's index of suspicion should be guided by the prevalence of specific conditions in the community, as well as clinical judgment.

[c] The organisms listed under the column "Potential Pathogens" are not intended to *represent* the complete, or even most likely, diagnoses, but rather possible etiologic agents that require additional precautions beyond standard precautions until they can be ruled out.

[d] These *pathogens* include enterohemorrhagic *Escherichia coli* O157:H7, *Shigella spp,* hepatitis A, noroviruses, rotavirus, *C. difficile*.

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[e] Outbreaks of serious invasive disease have occurred secondary to transmission among patients and healthcare personnel during deep debridement (OR setting) [162, 972, 1096-1098] Contact Precautions for draining wound as above; follow rec. for antimicrobial prophylaxis in selected conditions.

- A medical provider must order isolation with appropriate transmission-based precautions for detainees with a suspected, probable, or confirmed infectious disease of public health significance for the duration of the infectious period.
    - Preferred isolation rooms include airborne infection isolation (AII) rooms, Medical Housing Units (MHUs), single cell rooms, or rooms with restricted contact to other detainees, depending on the appropriate transmission-based precautions for the infectious disease.
- The HSA, FHPM, IPO, and designees should maintain contingency plans for alternate isolation options if the clinic exceeds its capabilities and isolation is not possible. If isolation rooms are not available, health care personnel should implement contingency procedures in consultation with the HSA, FHPM, IPO, Clinical Director (CD), or designee. A contingency procedure may include shared rooms for detainees diagnosed with the same illness or MHU placement instead of AII placement if AII is not essential.
    - The HSA, FHPM, IPO, or designee should assess the medical risks and operational impact associated with alternate detainee placement options and consult with the CD, or designee when a single medical housing room is not available.
- The HSA, CD, or designee should establish arrangements and agreements with medical facilities in the community, and should have a written plan for referring detainees with a suspected or confirmed infectious disease of public health significance to an appropriate facility, if appropriate capabilities are not available on-site.
- Health staff should follow appropriate standard and transmission-based precautions. As an example, when treating a patient who has a MRSA skin infection, contact precautions should be used. (see *05-02-G-01 Occupational Health Guide: Blood Borne Pathogens and Other Potentially Infectious Materials*).
- Health staff should use appropriate personal protective equipment (PPE) (see the *05-02-G-02 Occupational Health Guide: Personal Protective Equipment).*

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- The HSA, FHPM, and IPO should ensure appropriate signage corresponding to the transmission-based precautions needed; see also *05-02-G-01 IHSC Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials.*

- All MHUs and AII rooms should have the appropriate staffing levels (see *03-17, Medical Housing Units*).

- The CD, Regional CD, or Deputy Medical Director will approve expanded MHU accommodations in the event of an outbreak, epidemic, or pandemic.

- The HSA, Nurse Manager (NM), or designee should adjust work schedules and assignments for staff vulnerable to complications if exposed.

- A health care provider must educate detainees in isolation regarding infection prevention and control measures, the applicable infectious disease, and the reasons for isolation.

- Health staff should implement infection control measures and maintain social distancing to the extent possible to control the spread of infectious diseases of public health significance.

- Health staff should inform facility staff that precautions are recommended for staff and visitors that may come into close contact with an ill detainee during the contagious period.

B. Infectious Disease Management

- A medical provider should monitor the health status of detainees in medical isolation. The medical provider is responsible for their overall treatment and health care (see *03-17, Medical Housing Units*).

C. IHSC Global Alert/Medical Hold in the health record

The IHSC Global Alert/Medical Hold in the health record is a tool to restrict unintended movement. A medical hold in in the health record does not confer ICE authority to detain. Providers should consider a medical hold for detainees with an infectious disease of public health significance until the detainee is rendered non-contagious and to facilitate arrangements for continuity of care prior to transfer, release or removal. Health staff should use the IHSC Global Alert/Medical Hold to document the action in the health record.

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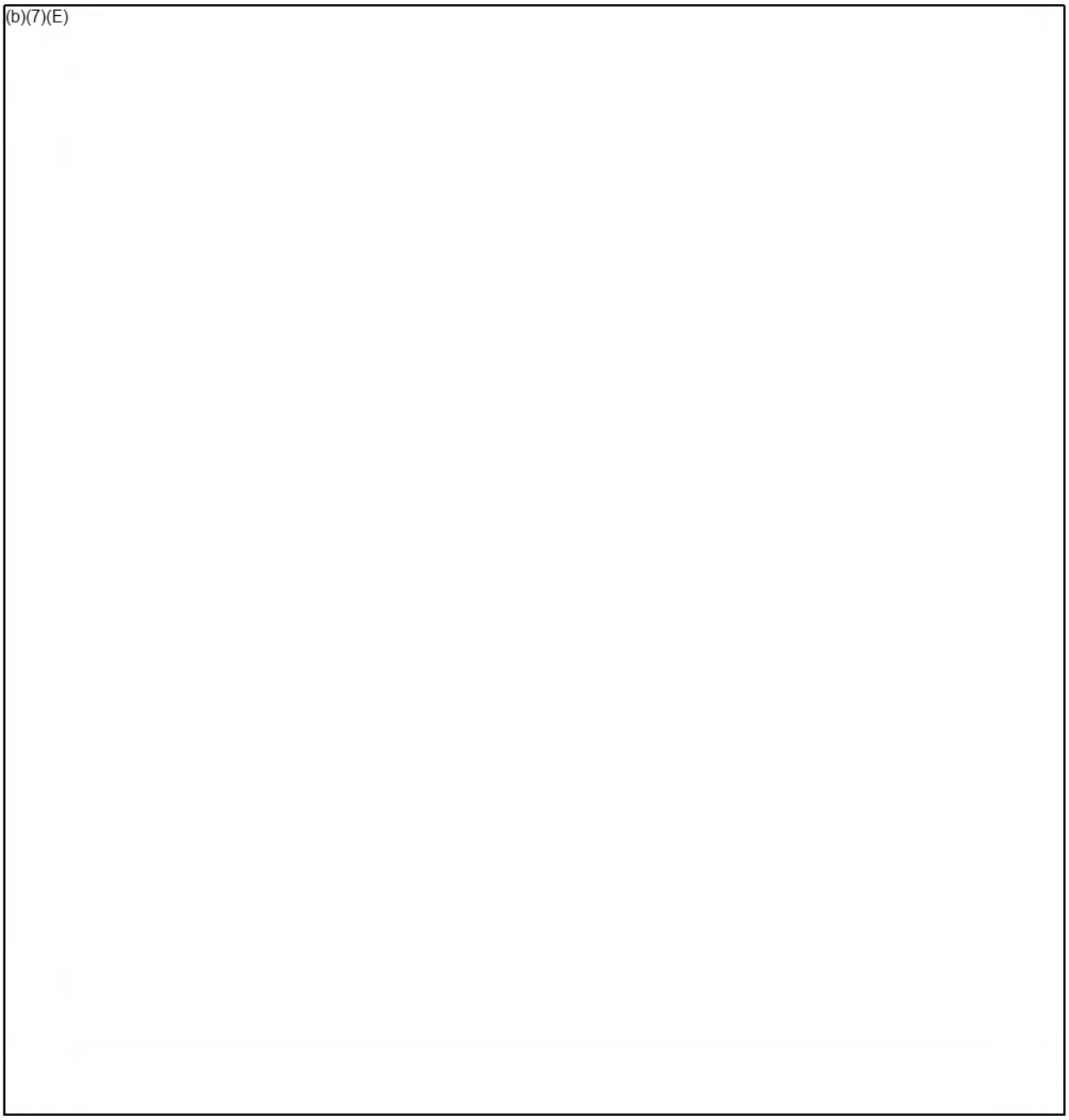

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III. Management of Detainees Exposed to Infectious Organisms

A. Social Distancing and Cohorting Principles

Social distancing refers to measures to increase the space between people and decrease the frequency of contact among people. In congregate settings, social distancing involves reducing the frequency of close contact among persons who have been exposed or potentially exposed to a person with an infectious disease, but do not show symptoms, for the duration of the incubation period. Cohorting is a strategy used to house individuals separately as a group based on their infectious or exposure status. The incubation period is unique to each disease, and should be determined in accordance with U.S. Centers for Disease Control and Prevention (CDC), or other relevant, guidelines.

The FHPM, IPO, HSA, or designee should recommend implementing social distancing to the facility administrator and the facility's designee for safety, for the duration of the incubation period and as appropriate to mitigate transmission following exposures to infectious organisms.

- In adult detention facilities, the FHPM, IPO, HSA, or designee should recommend implementing cohorting to house exposed detainees without reliable evidence of immunity together as a group with restricted movement for the duration of the incubation period for the specific disease. If a secondary case(s) is identified in a restricted housing group, the incubation period should restart from the date of the most recent exposure.

- In family residential facilities that house children, the FHPM, HSA, or designee should recommend implementing social distancing to the extent possible, to control the spread of infectious diseases of public health significance.

The HSA, or designee should implement the following:

- The HSA, NM, or designee should adjust work schedules and assignments for vulnerable health staff to limit exposure to the disease.

- Health staff must observe the condition of exposed detainees on restricted movement daily for symptoms of the illness to which they were exposed.

    - Health staff must document the exposure and restricted movement in an initial note in the health record, and reference daily monitoring tools that will be used for daily observations during the incubation periods.

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- Health staff may use separate monitoring tools to facilitate daily observation of large numbers of exposed detainees. Health staff must maintain these monitoring tools systematically so they can be referenced and retrieved.

- Health staff must document the completion of the restricted movement period in the health record.

- Health staff must educate exposed detainees on infection prevention and control measures, the applicable infectious disease and the reasons for restricted movement.

- A medical provider should consider urgent, non-occupational post-exposure prophylaxis (nPEP) for detainees, if medically appropriate, according to the Advisory Committee on Immunization Practices (ACIP), CDC, and the Infectious Diseases Society of America (IDSA) recommendations.

- The FHPM, IPO, HSA, CD, or designee should consider recommending that exposed detainees be released to the general population when immunity is confirmed (if appropriate per state public health and CDC guidelines) or the incubation periods are completed and no new cases are identified.

IV. Program Monitoring

PHSP Unit staff periodically request information from the FHPM, IPO, HSA, or designee to monitor contact and outbreak investigation activities in facilities with IHSC-staffed medical clinics. The HSA, FHPM, and IPO should facilitate prompt completion of information requests related to contact and outbreak investigations.

V. Training and Education

A. Health Staff

The HSA or designee should ensure that orientation and annual training that includes isolation and exposure management principles is implemented and documented in accordance with IHSC Directive *01-04 Medical Education and Development*.

B. Detainees

Health care personnel should educate isolated detainees, and detainees assigned to a restricted movement group, as a result of an infectious disease of public

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health significance, about topics such as transmission, risk factors, and infection prevention and control measures.

VI. Privacy and Recordkeeping

Please refer to IHSC Directive: *05-06, Infectious Disease Public Health Actions*, for guidance on complying with privacy and recordkeeping procedures.

VII. References and Resources

(1) United States Centers for Disease Control and Prevention. About Quarantine and Isolation. http://www.cdc.gov/quarantine/QuarantineIsolation.html.

(2) Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html.

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Management of Ectoparasites

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Management of Ectoparasites* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities and details procedures for public health actions for the management of ectoparasites in IHSC-staffed medical clinics.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this Guide is to provide guidance for public health actions for the management of commonly encountered ectoparasite infestations seen in ICE detainees.

A parasite is an organism that lives on or in a host organism and gets its food from or at the expense of its host. Ectoparasites are a type of parasite that refer to organisms such as ticks, fleas, lice, and mites that attach or burrow into the skin and remain there for relatively long periods of time.

B. Responsibilities

Health Services Administrator and Infection Preventionist or Facility Healthcare Program Manager

- Ensure policies and procedures related to public health actions for the management of ectoparasites in IHSC-staffed medical clinics are implemented.
- Ensure health staff orientation and annual training include public health actions for the management of ectoparasite infestations.
- Facilitate completion of information requests for monitoring and following up.

Medical Providers

- Oversee the medical care for detainees with an ectoparasite infestation.

Health Staff

- Implement infestation prevention and control measures in IHSC-staffed medical clinics.

Public Health, Safety, and Preparedness Unit

- Provide guidance to health staff regarding public health actions for the management of ectoparasite infestations.
- Periodically update the IHSC Directive: 05-06, *Infectious Disease Public Health Actions* and the *Infectious Disease Public Health Actions*

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Guide: Management of Ectoparasites.

Infectious Disease Consultant

- Provides technical guidance to health staff regarding treatment and public health actions for the management of ectoparasite infestations for ICE detainees.

C. Acronyms

CDC – United States Centers for Disease Control and Prevention

STI – Sexually transmitted infection

D. Definitions with Expanded Information

Cohort – A well-defined group of persons who have had a common experience or exposure.

Ectoparasite – A classification of animals that includes those with hard, segmented bodies and jointed appendages, such as insects which live outside the body. Ectoparasites are usually arthropods which parasitize the skin.

Incubation Period – The interval between exposure to a communicable microorganism and onset of symptoms.

Nits – Unhatched lice eggs.

Parasite – Any organism that lives in or on another organism without benefiting the host organism; commonly refers to pathogens, most commonly in reference to protozoans and helminths.

II. Scabies

A. About Scabies

Scabies are ectoparasites (parasites which live outside the body) that infest skin by the human itch mite. The scabies mite burrows into the upper layer of the skin, predominantly on the extremities (especially web spaces and underarms), lower trunk (especially the waist/buttocks), and genitals. It almost never involves the head or face. The human host develops a local allergy to the parasite proteins, leading to itching and nodules (bumps). This allergic reaction takes at least 48 to 72 hours, and sometimes up to two months, after exposure to develop. If a person previously had scabies, the incubation period can be much shorter—one to four days.

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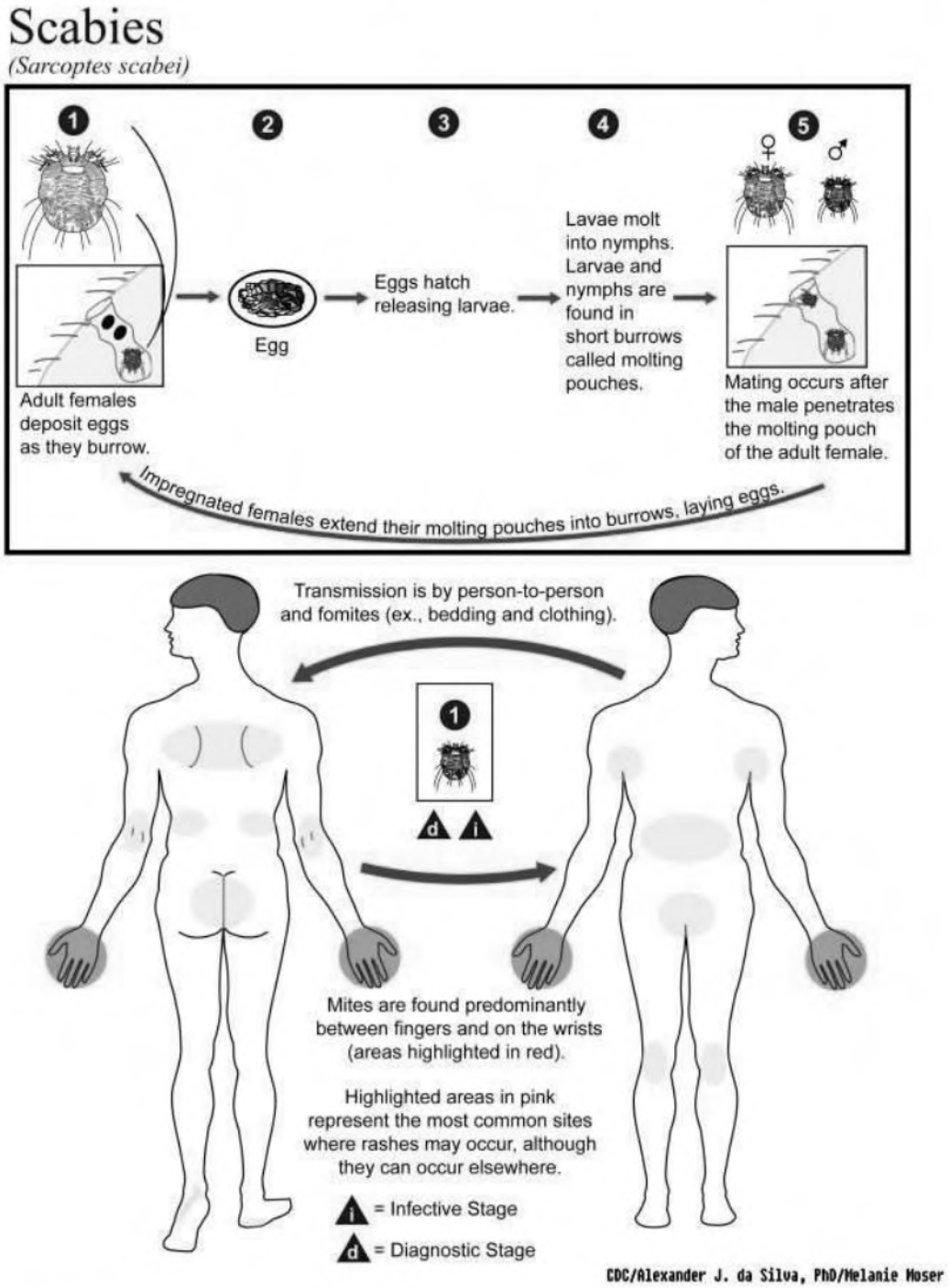
The scabies mite is usually spread by direct, prolonged, skin-to-skin contact and by the sharing of clothes, linens, and bedding with a person who has scabies. An infested person can transmit scabies even if they do not have symptoms.



For more information about scabies refer to the United States Centers for Disease Control and Prevention (CDC) - Scabies webpage.

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B. Prevention and Control

Early detection, treatment and implementation of appropriate isolation and infection control practices (e.g., gloves, gowns and avoidance of direct skin-to-skin contact) should be used when providing hands-on care to detainees who might have scabies.

Health staff should recommend that facility staff implement appropriate control measures in consultation with the facility administrator and the facility's designee for safety, including the following:

- Thoroughly clean and disinfect rooms used by a detainee with scabies after use.
- Machine wash and dry bedding and clothing worn or used next to the skin at any time during the three days before treatment, using the hot water and hot dryer cycles, or dry clean clothing and bedding items.
- Disinfect porous items that cannot be dry cleaned or laundered by storing the items in a closed plastic bag for several days to a week. Scabies mites generally do not survive more than two to three days away from human skin.
- Isolate detainees or residents being treated for scabies infestation individually, or cohort separately from unexposed detainees and common areas, until they can complete their permethrin treatment, shower, and change into fresh clothing. Isolation or cohorting duration is no more than 14 hours.

C. Clinical Management

- A medical provider oversees the clinical management of detainees with scabies and their close contacts.
- Health staff should follow contact precautions when examining detainees.
- A medical provider orders treatment for all infested detainees and their close contacts (in the same cell with infested individual(s) or known skin-to-skin contact with infested) to prevent possible re-exposure and re-infestation.

  A medical provider educates detainees on the appropriate protocols for the application of treatment, duration of treatment, side effects of treatment, personal hygiene and self-care. Health staff educate detainees to apply permethrin from the neck down, including all areas of skin (including genitals and buttocks), and leave permethrin on for eight to 14 hours before

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showering to remove the treatment. Application to mucosa (mouth, eyes, urethra, and vagina) should be avoided.

Refer to the CDC - Scabies - Resources for Health Professionals - Medications webpage for guidance on appropriate treatment to kill scabies mites.

III. Lice

A. About Lice

Lice are ectoparasites that infest the skin. There are three different types of lice. Human lice survive by feeding on human blood. Lice found on each area of the body are different from each other, although head lice and body lice are genetically very similar. The three types of lice that live on humans are:

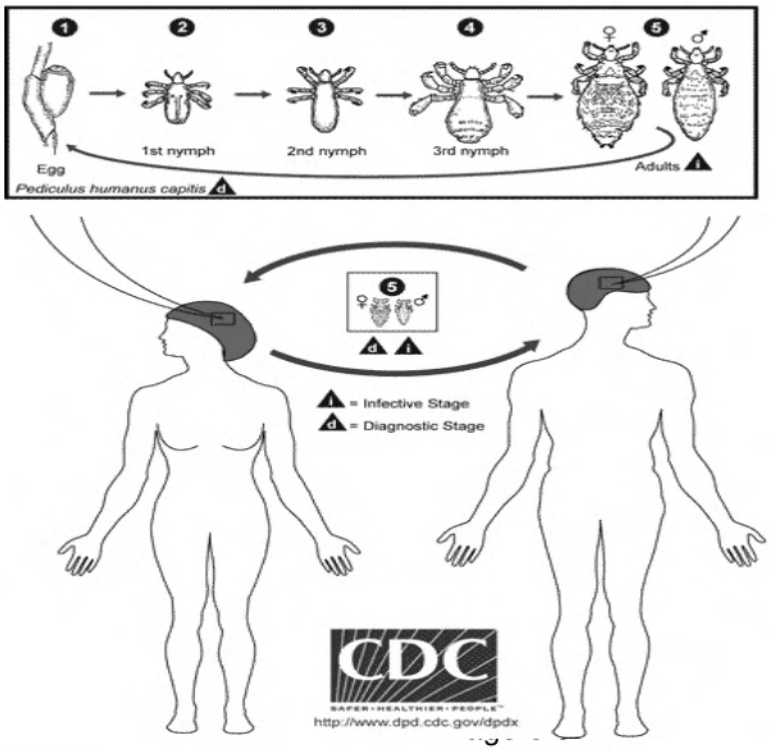
1) *Pediculus humanus capitis* (head louse)

2) *Pediculus humanus corporis* (body louse, clothes louse)

3) *Phthirus pubis* ("crab" louse, pubic louse)

Only the body louse is known to spread disease. Lice infestations (pediculosis and phthiriasis) are spread most commonly by close person-to-person contact or by sharing personal items or linens. Lice move by crawling; they cannot hop or fly.

Head Lice



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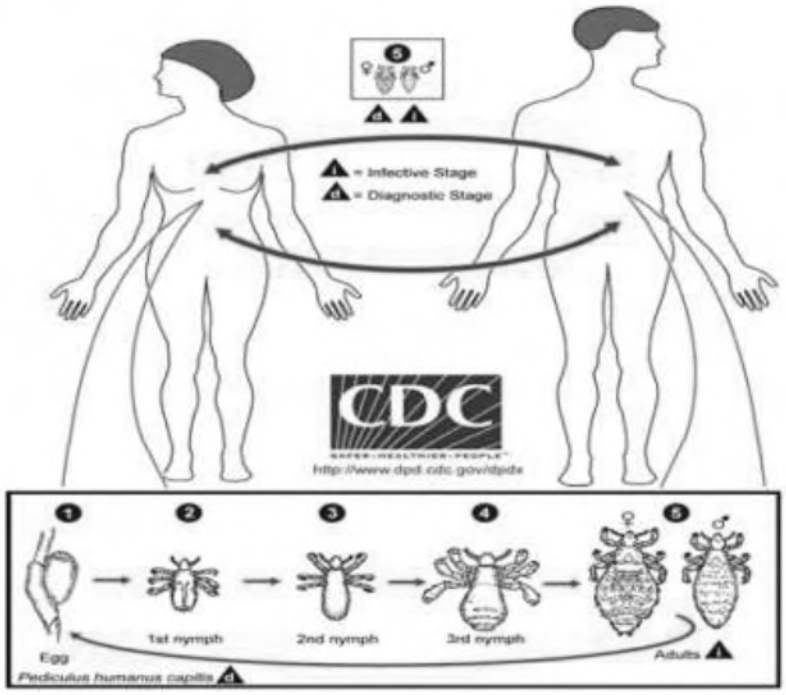
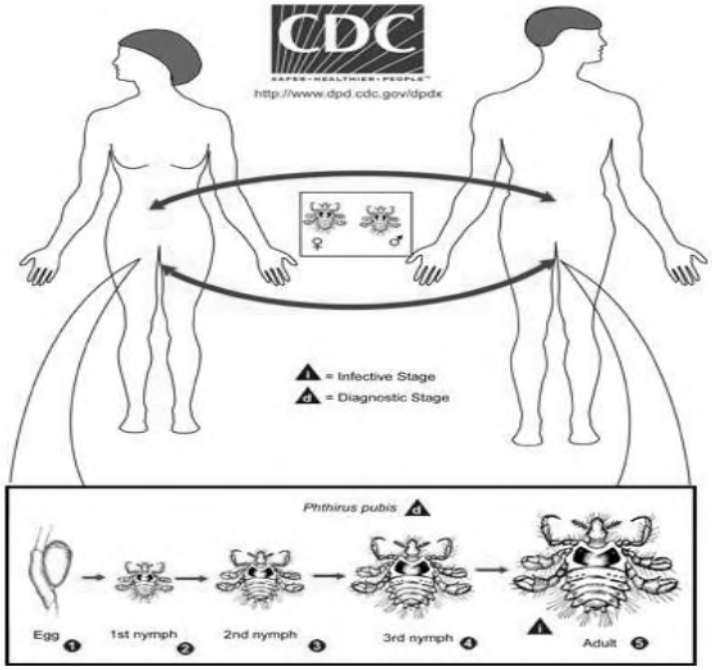
Body Lice



Pubic Lice



B. Prevention and Control

Head lice are most commonly spread by direct head-to-head (hair-to-hair) contact.

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However, much less frequently they are spread by sharing clothing or belongings. Head lice survive less than one to two days if they fall off a person and cannot feed. Nits (lice eggs) cannot hatch and usually die within a week if they are not kept at the same temperature as that found close to the scalp.

Body lice are most commonly spread by direct contact with an infested person or an infested person's clothing or bedding.

Pubic ("crab") lice are most commonly spread by sexual contact. Pubic lice, very rarely, may be spread by clothing, bedding, or a toilet seat. Although generally found attached to the coarse hair of the genitalia, they may rarely be found on other coarse hair including eyelashes, eyebrows, beard, chest and axillary hair.

Health staff should recommend that facility staff implement appropriate control measures in consultation with the facility administrator and the facility's designee for safety, including educating detainees on the importance of the following recommendations:

- Avoid head-to-head (hair-to-hair) contact during recreation and other activities.
- Bathe regularly.
- Do not share clothing such as hats, scarves, coats, uniforms, hair accessories, or barrettes.
- Do not share combs, brushes, or towels. Disinfest combs and brushes used by an infested person by soaking them in hot water (at least 130°F) for five to ten minutes.
- Do not lay on beds, couches, pillows, carpets, stuffed animals, or other fabric covered items that have recently been in contact with an infested person.

C. Clinical Management

- Health care providers should follow contact precautions when examining detainees.
- A medical provider or registered nurse should order treatment for all detainees infested with head lice and their close contacts (see Prevention and Control above) in accordance with the scope of their license and usual ordering protocols to prevent possible re-exposure and re-infestation.
    - A medical provider should order treatment for all detainees infested with

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body or pubic lice and their close contacts (see Prevention and Control above) to prevent possible re-exposure and re-infestation.

- Health care providers should educate infested detainees and their close contacts on self-care with improved personal hygiene, treatment application, duration and side effects.
- A health care provider should examine detainees with pubic lice for any other sexually transmitted infections (STIs) that may be present.
- A health care provider should recommend that detainees infested with body lice identify all sexual contacts so they may be examined.
- Permethrin may continue to kill newly hatched lice for several days after treatment.
- A second treatment is often necessary on day nine to kill any newly hatched lice before they can produce new eggs.

Refer to the CDC – Head Lice – Treatment webpage for guidance on appropriate treatment to kill head lice with over the counter or prescription strength medications. Refer to the CDC – Pubic "Crab" Lice – Treatment webpage for guidance on appropriate treatment to kill pubic lice with over the counter or prescription strength medications. Refer to the CDC – Body Lice – Treatment webpage for recommended treatment for body lice.

IV. Monitoring

The Public Health, Safety, and Preparedness Unit (PHSP Unit) staff will periodically request information from health staff to evaluate public health actions for the management of ectoparasite infestations.

V. Training and Education

The Facility Healthcare Program Manager, Infection Prevention Officer, Health Services Administrator, or designee must ensure orientation and annual training that includes infectious disease public health actions for management of ectoparasites are implemented and documented in accordance with IHSC Directive 01-04 Medical Education and Development located in the IHSC policy library.

Health staff should educate detainees with ectoparasite infestation or are evaluated for exposure to an infested detainee on personal hygiene and not sharing clothing, bedding, towels, grooming items, or hair accessories.

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VI. Privacy and Recordkeeping

Refer to IHSC Directive: 05-06, *Infectious Disease Public Health Actions*, for guidance on complying with privacy and recordkeeping procedures.

VII. References and Resources

(1) CDC - Parasites

(2) CDC - Scabies

(3) CDC - Lice

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Management of Hepatitis

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: AD-ERO, IHSC

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Management of Hepatitis* supplements the following IHSC directive:

- IHSC directive: 05-06, *Infectious Disease Public Health Actions.*

This guide explains concepts, assigns responsibilities, and details procedures for public health actions for the management of hepatitis A, hepatitis B, hepatitis C and hepatitis E in IHSC-staffed medical clinics.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

This guide assists health staff implement public health actions to manage cases of hepatitis A, hepatitis B, hepatitis C and hepatitis E in facilities with IHSC-staffed medical clinics. These actions help control and limit the spread of viral hepatitis.

B. Responsibilities

Health Services Administrator (HSA), Field Healthcare Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Responsible for ensuring implementation and oversight of Public Health, Safety, and Preparedness (PHSP) Unit activities in the medical and dental clinics, including public health actions for the management of hepatitis.
- Serve as a key liaison between the medical clinic and PHSP Unit staff.
- Facilitate completion of information requests related to public health actions for the management of hepatitis.

Medical Providers

- Oversee the clinical management of detainees diagnosed with viral hepatitis.
- Report patients with hepatitis to the health department in accordance with applicable local and state laws.

Health Staff

- Implement infection prevention and control measures to prevent transmission of viral hepatitis in IHSC-staffed medical clinics in accordance with applicable guidelines.
- Maintain knowledge about infection prevention and control measures applicable to work duties.

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- Report hepatitis to the health department in accordance with applicable local and state laws.

Public Health, Safety, and Preparedness Unit Staff

- Provide clinical guidance on activities related to public health actions for the management of hepatitis.

IHSC Infectious Disease Consultant and Infectious Disease Advanced Practice Provider

- Provide technical guidance related to clinical management and public health actions for the management of hepatitis.

C. About Viral Hepatitis

Viral hepatitis is an inflammation of the liver caused by one of five hepatitis viruses, referred to as type A, B, C, D or E. Hepatitis A, hepatitis B, hepatitis C and hepatitis E are covered in this guide. There are variations in the epidemiology, prevention, diagnosis and treatment for each type of viral hepatitis. See the Centers for Disease Control and Prevention (CDC) *The ABCs of Hepatitis Fact Sheet* and the viral hepatitis website for information and resources.

D. Acronyms

ACIP – Advisory Committee on Immunization Practices

AII – Airborne Infection Isolation (room)

BBP – Bloodborne pathogen

CDC – United States Centers for Disease Control and Prevention

ECP – Exposure control plan

HAV – Hepatitis A Virus

HBV – Hepatitis B Virus

HCV – Hepatitis C Virus

HEV – Hepatitis E Virus

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IDSA – Infectious Diseases Society of America
IG – Immune globulin

PEP – Post-exposure prophylaxis

PPE – Personal protective equipment

E. Definitions with Expanded Information

Blood-borne pathogens – Microorganisms that are present in human blood and can cause disease in humans, such as the hepatitis B virus and human immunodeficiency virus (HIV).

Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact; communicable; infectious; usually microorganisms.

Exposure – The condition of being subjected to something (e.g., noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Exposure incident – Eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials

Hepatitis – Inflammation of the liver; also refers to a group of viral infections that affect the liver.

Hepatitis A – Hepatitis caused by hepatitis A virus (HAV), a double-stranded DNA virus.

Hepatitis B – Injury to liver cells caused by hepatitis B virus (HBV), a double-stranded DNA virus.

Hepatitis C – Hepatitis caused by the hepatitis C virus (HCV).

Hepatitis E – A serious liver disease caused by the hepatitis E virus (HEV).

Immune globulin – Sterile preparation of antibodies (immunoglobulins) made from pooled human plasma that contains anti-HAV or anti-HBV and provides protection against hepatitis A or hepatitis B.

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Infection – Invasion and growth of an infectious microorganism, such as a bacterium or virus, in the body. Infection can also refer to the disease caused by the infectious microorganism.

Infection control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Infectious disease public health actions – a broad range of public health activities and interventions to promote and protect health, and prevent or mitigate infectious disease transmission.

Other potentially infectious material (OPIM) – OPIM includes: 1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) unfixed tissue or organ (other than intact skin) from a human (living or dead); 3) HIV- containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and 4) blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Outbreak – The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period.

Personal protective equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, and steel toe boots.

Post-exposure prophylaxis – Short-term treatment started as soon as possible after high-risk exposure to an infectious agent, such as HIV, HBV, or HAV. The purpose of post-exposure prophylaxis (PEP) is to reduce the risk of infection after such an exposure.

Standard precautions – Infection prevention practices, including hand hygiene, that apply to all patients regardless of infectious status. Standard precautions are a combination and expansion of universal precautions and body substance isolation, based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes contain transmissible infectious agents. Standard precautions include hand hygiene, and depending on the anticipated

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exposure, use of gloves, gown, mask, eye protection, or face shield. Equipment or items in the patient environment likely to have been contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents, (e.g., wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).

Surveillance – The timely, continuous, systematic collection, analysis and interpretation of health-related data for informing urgent and routine public health activities, including public health interventions; contact and outbreak investigations; evidence-based decision making; and planning, implementation, and evaluation of public health practices.

Transmission – Any mode or mechanism by which an infectious agent is spread to a susceptible host.

Transmission-based precautions – Precautions that provide additional protections beyond standard precautions to interrupt the transmission of pathogens.

Vaccine – A suspension containing antigenic molecules derived from a microorganism, given to stimulate an immune response to an infectious disease.

II. Hepatitis A

A. About Hepatitis A

Hepatitis A is an acute liver disease caused by the hepatitis A virus (HAV), lasting from a few weeks to several months. The route of HAV transmission is fecal-oral through person-to-person contact or ingestion of contaminated food or drink. For more information, reference CDC's hepatitis A information for health professionals.

B. Clinical Management

A medical provider oversees the clinical management of detainees diagnosed with hepatitis A. For clinical guidance reference CDC's hepatitis A professional resources.

C. Infection Prevention and Control Measures

All health staff should routinely implement infection prevention and control measures to limit and control the spread of hepatitis A. Health staff should recommend to the facility administrator, or designee, excluding detainees diagnosed with acute hepatitis A from

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food service for at least two weeks after all symptoms resolve. Health staff should also provide education regarding good hand hygiene practices to the detainee. For more information reference the IHSC directive 05-02, *Occupational Health*; 05-02-G-01, *Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials*; 05-02, *Occupational Health Guide: Personal Protective Equipment* located in the IHSC policy library; the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*; and *CDC Guidelines for Viral Hepatitis Surveillance and Case Management*.

Medical providers should consider administering urgent post-exposure prophylaxis (PEP) to detainees, hepatitis A vaccine, or immune globulin (IG), during a contact or outbreak investigation at the discretion of the clinical director (CD) or designee. Medical providers should refer to the following CDC guidance regarding the appropriate administration of PEP: *Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP)* and *Hepatitis A ACIP Vaccine Recommendations*.

III. Hepatitis B

A. About Hepatitis B

Hepatitis B is a liver disease caused by the hepatitis B virus (HBV) that ranges in severity from a mild illness lasting a few weeks (acute), to a long- term illness (chronic) that can lead to liver disease and/or liver cancer. HBV is transmitted by contact with infectious blood, semen, and other body fluids from having sex with an infected person, sharing contaminated needles, or it is transmitted from an infected mother to her newborn. There has also been documented child-to-child transmission from cuts and saliva. For more information reference CDC's hepatitis B information.

B. Clinical Management

A medical provider oversees the clinical management of detainees diagnosed with viral hepatitis. For clinical guidance reference CDC's hepatitis B information and professional resources.

C. Infection Prevention and Control Measures

Health staff implement the exposure control plan (ECP) to limit and control the spread of bloodborne pathogens (BBP) and other potentially infectious materials (OPIM), including hepatitis B. For more information reference the IHSC directive

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05-02, *Occupational Health;* 05-02-G-01*, Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials*; 05-02*, Occupational Health Guide: Personal Protective Equipment*; and the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. If a BBP exposure incident occurs among health staff, health staff should follow post-exposure procedures outlined in 05-02-G-04*, Occupational Health Guide: Workforce Health*.

A medical provider must administer PEP to detainees exposed to the hepatitis B virus as soon as possible, and no longer than 24 hours after exposure. The CD, or designee, should consider administering the hepatitis B vaccine or IG to detainees during an outbreak or contact investigation to control transmission. Medical providers should refer to the following CDC guidelines regarding the appropriate administration of PEP available at CDC's hepatitis B information, post-exposure prophylaxis page and *Hepatitis B ACIP Vaccine Recommendations*. For urgent consultation, consider calling the PEPline: http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.

IV. Hepatitis C

A. About Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) that can be an acute illness or chronic condition. HCV infection can lead to cirrhosis of the liver and liver cancer. HCV is transmitted by contact with the blood of an infected person, from mother to child, or by receipt of an infected organ. For more information see CDC's hepatitis C information.

B. Clinical Management

A medical provider oversees the clinical management of detainees diagnosed with hepatitis C. For clinical guidelines see CDC's hepatitis C information and professional resources and the Infectious Diseases Society of America (IDSA) hepatitis C website.

C. Infection Prevention and Control Measures

Health staff should implement the ECP to prevent the transmission of hepatitis C. For more information reference the IHSC directive 05-02, *Occupational Health*; 05-02-G-01, *Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials*; 05-02-G-02, *Occupational Health Guide: Personal Protective Equipment*; and the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*.

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There is no vaccine for hepatitis C. Health staff should follow post-exposure procedures outlined in 05-02-G-04, *Occupational Health Guide* located in the IHSC policy library*: Workforce Health* for bloodborne pathogen exposures among health staff. For detailed guidance, health staff should refer to CDC's recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. For urgent consultations, consider calling the PEPline: http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.

V. Hepatitis E

A. About Hepatitis E

Hepatitis E is a liver disease caused by the hepatitis E virus (HEV), similar to HAV, but poses unique risk to pregnant females (case fatality rate of ~10-30%, depending on trimester). The route of HEV transmission is fecal-oral through person-to-person contact or ingestion of contaminated food or drink. For more information reference CDC's hepatitis E information.

B. Clinical Management

A medical provider should oversee the clinical management of detainees diagnosed with hepatitis E.

C. Infection Prevention and Control Measures

All health staff should routinely implement infection prevention and control measures to limit and control the spread of hepatitis E. Health care staff should recommend to the facility administrator or designee, to exclude detainees diagnosed with acute hepatitis E from food service for at least two weeks after all symptoms resolve. Health staff should also provide education regarding good hand hygiene practices to detainee's diagnosed with hepatitis E. For more information reference the IHSC directive 05-02, *Occupational Health*; 05-02-G-01, *Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials*; 05-02-G-02, *Occupational Health Guide: Personal Protective Equipment;* the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, and CDC's hepatitis E information.

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VI. Surveillance and Reporting

A. Surveillance

Surveillance, defined as the ongoing, systematic collection, analysis, and interpretation of health data for purposes of improving health and safety, is an important public health function.

The Public Health, Safety, and Preparedness (PHSP) Unit staff monitor the number of detainees diagnosed with hepatitis at IHSC-staffed medical clinics using the electronic health record reporting tools. To ensure the accuracy of information, it is important that medical providers use the appropriate ICD codes for viral hepatitis infection. For more information refer to 05-06-G-03*, Infectious Disease Public Health Actions Guide: Surveillance and Reporting* located in the IHSC policy library.

B. Reporting

Medical providers that diagnose new cases of hepatitis are required to report specific case information to the local or state health department in accordance with local and state laws. For more information refer to the 05-06-G-03, *Infectious Disease Public Health Actions Guide: Surveillance and Reporting*.

VII. Contact and Outbreak Investigations

The FHPM, IPO, HSA, or designee, should consider implementing contact and outbreak investigations if a known exposure occurs (e.g., foodborne or fecal-oral exposure to acute HAV or HEV, tattooing, intimate contact), there is an increase in the number of cases of hepatitis, or there is more than the baseline expected occurrence at a facility or among a specific group of persons during a specified period of time. The FHPM, IPO, HSA, or designee, should consider implementing and recommending to the facility administrator, or designee, enhanced infection control measures and precautions to limit and control the transmission of hepatitis. Examples of enhanced infection control measures may include isolation, cohorting, administration of PEP and enhanced surveillance depending on the transmission route of the hepatitis virus in question. Refer to 05-06-G-01*, Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations*; 05-06-G-02, *Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*; and 05-02-G-01*, Occupational Health Guide: Blood Borne Pathogens and Other Potentially Infectious Materials* for specific guidance regarding these public health actions located in the IHSC policy library. Refer also to the CDC viral hepatitis

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outbreaks health care investigation guide for information specific to viral hepatitis outbreaks.

VIII. Program Monitoring

PHSP Unit staff monitor hepatitis information using the electronic health record reporting tools. PHSP Unit staff periodically request information from health staff to monitor public health actions for the management of hepatitis at IHSC-staffed medical clinics. The HSA, FHPM, and IPO should facilitate prompt completion of information requests.

IX. Training and Education

A. Health Staff

The HSA or designee should ensure that orientation and annual training that includes isolation and social distancing principles is implemented and documented in accordance with IHSC directive 01-04, *Medical Education and Development* located in the IHSC policy library.

B. Detainees

Medical providers educate detainees diagnosed with hepatitis about transmission, risk factors, infection prevention and control measures, and PEP, if applicable.

X. Privacy and Recordkeeping

Please refer to IHSC directive 05-06, *Infectious Disease Public Health Actions* for guidance on complying with privacy and recordkeeping procedures located in the IHSC policy library.

XI. References and Resources

1. CDC viral hepatitis website
2. CDC Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings, 2003
3. CDC Hepatitis C & Incarceration Fact Sheet

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4. CDC The ABCs of Hepatitis Fact Sheet

5. CDC Hepatitis A Patient Education Resources

6. CDC Hepatitis B Patient Education Resources

7. CDC Hepatitis C Patient Education Resources

8. Fiore, Anthony. Hepatitis A Transmitted by Food. Clinical Infectious Diseases, 2004. Vol. 38, 705-715

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Management of HIV

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Management of HIV* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities and details procedures for public health actions for the management of HIV in IHSC-staffed medical clinics.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE owned or contracted detention facilities.

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I. Overview

A. Purpose

This guide assists health staff to implement public health actions for the management of Human Immunodeficiency Virus (HIV). Topics addressed in this guide include surveillance, reporting, continuity of care and post-exposure prophylaxis.

B. Responsibilities

Health Services Administrator and Infection Prevention Officer or Facility Health Care Program Manager

- Assist with HIV continuity of care activities.
- Assist with reporting HIV cases to the health department in accordance with local and state laws.
- Ensure that health staff receive orientation and annual training related to public health actions for the management of HIV, including accessing resources to facilitate continuity of care.
- Ensure protocols are implemented to comply with all policies and standards related to public health actions for the management of HIV.
- Facilitate completion of information requests related to public health actions for HIV care and continuity of care.

Medical Providers

- Oversee the clinical management of detainees diagnosed with HIV.
- Facilitate continuity of care by providing HIV resources to detainees diagnosed with HIV specific to their country of nationality.
- Report HIV cases to the local health department in accordance with applicable local and state laws.

Health Staff

- Implement infection prevention and control measures and the exposure control plan to limit the spread of bloodborne pathogens.

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- Maintain knowledge about infection prevention and control measures applicable to work duties.

- Report patients with HIV to the local health department in accordance with applicable local and state laws.

Public Health, Safety, and Preparedness Unit Staff

- Provide guidance on activities related to public health actions for the management of HIV.

- Update and review HIV treatment center resources available to medical providers.

- Maintain relationships with public health partners and organizations to identify HIV treatment center information in foreign nations.

IHSC Infectious Disease Consultant

- Provides clinical guidance related to clinical management and public health actions for the management of HIV at the request of the medical provider or headquarters staff.

C. About Human Immunodeficiency Virus

HIV is a virus that when contracted chronically infects humans and leads to a spectrum of disease from asymptomatic carriage to acquired immunodeficiency syndrome (AIDS) and eventual death. HIV can be transmitted by blood, transplanted organs, semen, pre-seminal fluid, rectal fluids, vaginal fluids and breast milk through the following mechanisms:

- Sexual contact

- Pregnancy, childbirth or breastfeeding

- Injection drug use

- Occupational exposure

- Needle stick

- Splash to mucous membrane

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- Blood transfusion
- Organ transplant

For detailed information about HIV, including topics such as transmission, risk factors, prevention, testing and treatment, access the references and resources listed at the end of this guide.

D. Acronyms

AIDS – Acquired Immunodeficiency Syndrome

AETC – AIDS Education and Training Centers

ART – Antiretroviral therapy

ARV – Antiretroviral

CDC – United States Centers for Disease Control and Prevention

HIV – Human Immunodeficiency Virus

nPEP – Non-occupational post-exposure prophylaxis

oPEP –Occupational post-exposure prophylaxis

OPIM – Other potentially infectious materials

PAHO – Pan American Health Organization

PEP – Post-exposure prophylaxis

PHSP Unit – Public Health, Safety, and Preparedness Unit

PPE – Personal protective equipment

UMBAST – U.S.-Mexico Border AETC Steering Team

WHO – World Health Organization

E. Definitions with Expanded Information

See also: AIDS info | Glossary

Acquired Immunodeficiency Syndrome (AIDS) – A disease of the immune system due to infection with HIV.

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Adherence – Taking medications exactly as prescribed. Poor adherence to an HIV treatment regimen increases the risk for developing drug-resistant HIV and virologic failure

AIDS Education and Training Centers (AETCs) – Regional centers that conduct education and training programs for health care providers who treat people living with HIV/AIDS. Training is targeted to providers who serve minority populations, the homeless, rural communities, prisoners, community and migrant health centers, and Ryan White HIV/AIDS Program-funded sites. AIDS Education and Training Centers (AETCs) serve 50 states and many U.S. territories.

Antiretroviral (ARV) – A drug used to prevent a retrovirus, such as HIV, from replicating. The term primarily refers to antiretroviral HIV drugs.

Blood-borne pathogens – Microorganisms that are present in human blood and can cause disease in humans (e.g., hepatitis B virus and HIV).

CD4 Count – A laboratory test that measures the number of CD4 T lymphocytes (CD4 cells) in a sample of blood. In people with HIV, the CD4 count is the most important laboratory indicator of immune function and the strongest predictor of HIV disease progression.

CD4 Percentage – Percentage of white blood cells that are CD4 cells. In certain cases, such as during acute HIV infection or HIV infection in children younger than five years of age, CD4 percentage is used rather than CD4 count to assess HIV progression or response to ART. It may also inform the medical provider of "discordance" (a CD4 count which does not as accurately represent immune function) which affects the decision to provide prophylactic treatments.

Coinfection – When a person has two or more infections at the same time. For example, a person infected with HIV may be co-infected with hepatitis C (HCV) or tuberculosis (TB) or both.

Epidemiology – The study of the distribution, causes and clinical characteristics of disease or health status in a population.

Exposure – The condition of being subjected to something (noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Human Immunodeficiency Virus (HIV) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types; HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected

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body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, childbirth, or breastfeeding (through breast milk).

Immunocompromised – When the body is unable to produce an adequate immune response. A person may be immunocompromised because of a disease or an infection, such as HIV, or as the result of treatment with drugs or radiation.

Incidence – The number of new cases of a disease in a specific area during a specific time.

Infection – Invasion and growth of an infectious microorganism, such as a bacterium or virus, in the body. Infection can also refer to the disease caused by the infectious microorganism. For example, HIV infection is caused by the human immunodeficiency virus.

Other potentially infectious material (OPIM) – Body parts that have the potential to cause infection, to include: 1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; 2) unfixed tissue or organ (other than intact skin) from a human (living or dead); 3) HIV-containing cell or tissue cultures, organ cultures, and HIV or hepatitis B virus (HBV)-containing culture medium or other solutions; and 4) blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Post-Exposure Prophylaxis (PEP) – Short-term treatment started as soon as possible after high-risk exposure to an infectious agent, such as HIV, HBV or HCV. The purpose of PEP is to reduce the risk of infection after such an exposure.

Viral Load – The amount of HIV in a sample of blood. Viral load (VL) is reported as the number of HIV RNA copies per milliliter of blood.

II. Clinical Management

A physician oversees the clinical management of detainees diagnosed with HIV. For clinical management guidance, including treatment and diagnosis, see the HIV/AIDS Clinical Guidelines and CDC | HIV/AIDS Guidelines and Recommendations

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III. Infection Prevention and Control

A. Health Staff

Health staff are at risk for occupational exposure to bloodborne pathogens and should take precautions to prevent exposure to bloodborne pathogens and other potentially infectious materials (OPIM). Refer to *Directive 05-02 Occupational Health, 05-02-G-01 Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials, 05-02-G-02 Occupational Health Guide: Personal Protective Equipment, and 05-02-G-04 Occupational Health Guide: Workforce Health.*

B. Detainees

Health staff must document and report detainee blood borne pathogen exposures in accordance with IHSC Directive: 11-06, *Time Frame for Submitting Medical Incident Reports*. Medical providers should evaluate detainees for non-occupational post-exposure prophylaxis (nPEP) to detainees as soon as possible. A medical provider should also assess the baseline status of the exposed detainee and the source detainee (if known) for blood-borne pathogens and/or sexually transmitted infections, as the scenario of exposure dictates. For detailed guidance refer to CDC | Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016

1. Medical providers should evaluate detainees rapidly for nPEP after a potential nonoccupational exposure that presents a substantial risk for HIV acquisition.
2. All detainees considered for nPEP should have determination of their HIV infection status by HIV 4th generation testing. Note, there are other labs (pathogens and organ function) which should be tested for at baseline as well as in follow up so please follow established CDC guidelines, CDC | Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016.
3. If rapid HIV blood test results are unavailable or testing is delayed, and nPEP is otherwise indicated, it should be initiated without delay and can be discontinued if the patient is later determined to have HIV infection already or the source is determined not to have HIV infection.

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4. For clinical guidance, refer to CDC | Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016.

IV. Surveillance and Reporting

Surveillance, defined as the ongoing systematic collection, analysis and interpretation of health data for purposes of improving health and safety, is an important public health function. Health care personnel that newly diagnose cases of HIV are required to report specific case information to the local or state health department. Health departments, along with the CDC, use this information to inform HIV programs, policies, resources, funding, and other efforts to control the spread of HIV. For more information, refer to *05-06-G-03 Infectious Disease Public Health Actions Guide: Surveillance and Reporting.*

A. Surveillance

The Public Health, Safety, and Preparedness (PHSP) Unit staff monitor the number of detainees at IHSC-staffed facilities carrying a diagnosis of HIV in their electronic health record problem list using electronic health record reporting tools. To ensure the accuracy of information, it is important that health staff use the appropriate ICD-9 code for HIV infection, 042 or V08, or ICD-10 code B20 or Z21.

Health staff may view infectious disease surveillance and other reports relevant to PHSP activities using the Tableau Dashboard on the SharePoint | PHSP Unit. The Tableau Dashboard tool allows users to filter reports by facility and time period. The reports retrieved via Tableau Dashboard may be exported to a standard file format.

B. Reporting

HIV is a nationally notifiable condition and should be reported to the local health department in accordance with local and state laws.

V. Release Planning for Continuity of Care

Medical providers should take necessary steps to facilitate release planning for detainees diagnosed with HIV. Medical providers select resources to detainees living with HIV infection so they can follow up and access care if they are returned to their country of nationality or are released in the United States. Medical providers should initiate HIV release planning within three days of diagnosis, or as soon as

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possible to provide referral information prior to release or removal. If a detainee is released to a community in the United States, medical providers will identify resources specific to that community; the following resource should be provided to detainees, State HIV Warmlines | Updated March 2018. An online HIV service locator is available at AIDS.gov.

PHSP Unit staff maintain and update resources on treatment centers where detainees can seek care in their countries of nationality. PHSP Unit staff also collaborate with public health partners to assist in identifying treatment center resources. Examples of public health partners include the World Health Organization (WHO), Pan American Health Organization (PAHO), CDC, and AIDS Education and Training Centers (AETCs).

A. Release Planning Process

Medical providers follow these steps to facilitate release planning for detainees diagnosed with HIV. Steps might occur in a different order or at the same time.

1. HIV diagnosis (new or previous).

2. Determine where the detainee plans to live if returned to his or her country of nationality (city, state, and/or country).

   The medical provider should attempt to assess the likelihood of release in the United States; this will affect referral services as well as the anti-retroviral regimen chosen (as some may not be available in the detainee's country of nationality).

3. Access SharePoint | PHSP Unit | Infectious Disease | HIV Continuity of Care Resources to identify resources.

4. If resources are not already identified for the country or specific region, or to suggest that resources you have identified be added, click the "Suggest a new resource" box to submit a request additional resources (select Communication Type = "HIV resources".

5. Medical providers are highly encouraged to take the following action(s) and provide the following information to detainees diagnosed with HIV prior to release or removal:

   - Prescribe current HIV medications for transfer, release, or removal per usual protocols.

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- Provide a recent CD4 T lymphocytes (CD4 cell) count/percentage.
- Provide a recent viral load (HIV RNA with genotype) test result.
- Provide an antiretroviral treatment history including current regimen (preferably using generic drug names, since drug names vary in different countries).
- Provide a copy of relevant medical documentation (last chronic note or complex physical exam, whichever is most recent).
- Offer culturally and linguistically appropriate referral information.
- Offer patient education.

B. Referral Resources

International

1. AIDS Healthcare Foundation | Country Resources
2. AIDSMAP E-atlas
3. CDC - Global HIV/AIDS - Global HIV Resources
4. Pan American Health Organization (PAHO) HIV and STI Resources
5. AIDS Education and Training Centers (AETC) | National Resource Center
6. U.S.-Mexico Border AETC Steering Team (UMBAST) Resources
7. The United States President's Emergency Plan for AIDS Relief (PEPFAR)

United States

For patients released in the United States, health staff should work with the local health department to identify community resources or use the online search tool at AIDS.GOV; see also State HIV Warmlines | Updated March 2018. A medical provider provides contact information for Ryan White funded clinics in the geographic area of a detainee's sponsor to support release planning.

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VI. Program Monitoring

PHSP Unit staff monitor HIV public health activities using the electronic health record reporting tools. PHSP Unit staff periodically request information from health staff for program monitoring. The HSA and Infection Prevention Officer or Facility Healthcare Program Manager should facilitate prompt completion of information requests.

VII. Training and Education

A. Health Staff

The HSA, Infection Prevention Officer, Facility Healthcare Program Manager or designee should ensure that orientation and annual training include public health actions for the management of HIV is implemented and documented in accordance with *Directive 01-04 Medical Education and Development*.

B. Detainees

Health care personnel should educate detainees diagnosed with HIV about transmission, risk factors, infection prevention and control, medication adherence, and continuity of care.

VIII. Privacy and Recordkeeping

Health staff should refer to IHSC Directive: 05-06, *Infectious Disease Public Health Actions* for guidance on complying with privacy and recordkeeping procedures.

IX. References and Resources

1. Centers for Disease Control and Prevention - HIV/AIDS
2. HIVMA : HIV Medicine Association
3. AIDS.gov
4. AIDS Education and Training Centers (AETC) | National Resource Center
5. CDC | Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016
6. CDC | HAI | HIV in Healthcare Settings
7. HIV/AIDS Clinical Guidelines

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Management of Influenza

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Management of Influenza* supplements the following IHSC directive:

- IHSC directive: 05-06, *Infectious Disease Public Health Actions*.

This guide explains concepts, assigns responsibilities and details procedures for the prevention and control of influenza.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this guide is to assist health staff implement public health actions for the management of influenza in facilities with IHSC-staffed medical clinics. These activities must help to control and limit the spread of influenza.

B. Responsibilities

Health Services Administrator (HSA), Field Healthcare Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Ensure that health staff receive orientation and annual training related to public health actions for the management of influenza.
- Ensure procedures are in place to comply with all policies and standards related to public health actions for the management of influenza.
- Report patients with influenza to the health department in accordance with local and state laws.
- Conduct contact and outbreak investigations and assist local health department, if applicable.

Medical Providers

- Oversee the clinical management of detainees and residents diagnosed with influenza.
- Report patients with influenza to the health department in accordance with applicable local and state laws.

Health Staff

- Implement infection prevention and control measures to prevent transmission of influenza in IHSC-staffed medical clinics in accordance with applicable guidelines.
- Are knowledgeable about infection prevention and control measures applicable to work duties.

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- Notify the FHPM, IPO, or designee to report influenza to the health department in accordance with applicable local and state laws.

Public Health, Safety, and Preparedness Unit Staff

- Provide technical guidance on activities related to public health actions for the management of influenza.

IHSC Infectious Disease Consultant and Infectious Disease Advanced Practice Provider

- Provide technical guidance related to clinical management and public health actions for the management of influenza.

C. Acronyms

ACIP – Advisory Committee on Immunization Practices.

CDC – Centers for Disease Control and Prevention.

HICPAC – Healthcare Infection Control Practice Committee.

IDSA – Infectious Diseases Society of America.

ILI – Influenza-like illness.

PPE – Personal protective equipment.

RIDTs – Rapid influenza diagnostic tests.

D. Definitions with Expanded Information

Airborne infection isolation (AII) room – A single-occupancy patient-care room; formerly called a negative pressure isolation room. Environmental factors are controlled so the isolation room receives substantial air changes per hour (ACH) (≥12 ACH for new construction since 2001 and ≥6 ACH for construction before 2001) and is under negative pressure (the direction of air flow is from the outside adjacent space [the corridor] into the room). AII room air is preferably exhausted to the outside, or recirculated if the return air is filtered through a high efficiency particulate air (HEPA) filter.

Cohorting – is a public health strategy used to house individuals separately as a group based on their infectious or exposure status.

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Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact. Contagious disease are usually caused by microorganisms and termed "communicable" and "infectious."

Droplet precautions – Droplet precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions. Because these pathogens do not remain infectious over long distances in a health care facility, special air handling and ventilation are not required to prevent droplet transmission. Infectious agents for which droplet precautions are indicated are found in HICPAC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health care Settings, Appendix A. A single patient room is preferred for detainees who require droplet precautions.

Epidemic – The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a particular period of time.

Exposure – The condition of being subjected to something (e.g., noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Influenza-like illness (ILI) – Defined as fever (temperature of 100ºF or 37.8ºC or greater) and a cough or sore throat without a known cause other than influenza.

Incubation period – The interval between exposure to a communicable microorganism and onset of symptoms and infectiousness.

Infection control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Infectious period – The period during which a person can transmit a communicable microorganism to others.

Outbreak – The sudden increase in the incidence of a disease or condition, when the observed number of cases exceeds the expected number of cases of disease.

Standard precautions – Infection prevention practices, including hand hygiene, that apply to all detainees and residents regardless of infectious status. Standard precautions are a combination and expansion of universal precautions and body substance isolation, based on the principle that all blood, body fluids, secretions, non-intact skin, mucous membranes, and excretions (except sweat) contain transmissible infectious agents. Standard precautions include hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection,

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or face shield. Equipment or items in the patient environment likely to be contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents, (e.g., wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).

Surgical mask– A device worn over the nose and mouth of a person to prevent infectious particles from being released into room air.

Symptomatic – A term applied to a patient with health-related complaints (symptoms) that might indicate the presence of disease.

Vaccine – A suspension containing antigenic molecules derived from a microorganism, given to stimulate an immune response to an infectious disease.

E. About Influenza

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness. There are two main types of influenza virus: Type A and Type B. The influenza A and B viruses which routinely spread in people are responsible for seasonal flu epidemics each year. Influenza A viruses can be broken down into sub-types depending on the genes that make up the surface proteins. Over the course of a flu season, different types and subtypes of influenza A and B viruses circulate and cause illness.

Serious outcomes of flu infection can result in hospitalization or death. Some people, such as older people, young children, pregnant women, and people with certain health conditions, are at higher risk for serious flu complications.

Transmission

The influenza virus is spread by droplets made when people sneeze, cough, or talk. These droplets can land in a person's mouth or nose or can be inhaled into the respiratory tract. Transmission can also occur by touching contaminated surfaces or objects and then touching your own mouth or nose and through respiratory transmission when in close proximity of ill persons.

Incubation Period

It takes from one to four days (average is two days) after exposure to influenza for a person to develop symptoms.

Infectious Period

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A person can usually spread the virus from one day before symptoms develop and up to five to seven days after becoming ill. Children may be contagious longer than seven days. Some may be infected with the influenza virus and have no symptoms but may still spread the virus to others.

Typical Influenza Season

The flu season typically begins in October of each year and ends in late March; the peak month is February.

Symptoms

The influenza virus is different from a cold. The influenza virus usually comes on suddenly. People who have the influenza virus often feel some or all of these symptoms:

- Fever or feeling feverish/chills; not everyone with flu will have a fever.
- Cough.
- Sore throat.
- Runny or stuffy nose.
- Muscle or body aches.
- Headaches.
- Fatigue or tiredness.
- Some people may have vomiting and diarrhea, though this is more common in children than adults.

Risk Factors for Flu-Related Complications

Most people who get influenza will recover in a few days to less than two weeks. Some people will develop complications as a result of the flu, some of which can be life-threatening and result in death.

Pneumonia, bronchitis, sinus and ear infections are examples of complications from flu. The flu can make chronic health problems worse. For example, people with asthma may experience asthma attacks while they have the flu, and people with chronic congestive heart failure may experience worsening of this condition that is triggered by the flu. People considered high risk for developing flu-related complications include the following:

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- Children younger than five, but especially children younger than two years old.
- Adults 65 years of age and older.
- Pregnant women.
- American Indians and Alaskan Natives seem to be at higher risk of influenza complications.
- People who have medical conditions, including the following:
    - Asthma.
    - Neurological and neurodevelopmental conditions, including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual or developmental disability, moderate to severe developmental delay, muscular dystrophy, or spinal cord injury.
    - Chronic lung disease, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis.
    - Heart disease, such as congenital heart disease, heart failure, and coronary artery disease.
    - Blood disorders, such as sickle cell disease.
    - Chronic kidney disorders.
    - Chronic liver disorders.
    - Metabolic disorders, such as diabetes, inherited metabolic disorders, and mitochondrial disorders.
    - Weakened immune system due to disease or medication, such as people with HIV or AIDS, cancer, autoimmune disease that can cause chronic inflammation of the joints and other areas of the body including but not limited to rheumatoid arthritis and lupus, and those on chronic steroids or immunosuppressants.
    - People younger than 19 years of age who are receiving long-term aspirin therapy.

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- People who are morbidly obese, with a body mass index (BMI) of 40 or greater.

Immunization

Please refer to the following official guidance on immunizations located in the IHSC policy library:

- IHSC operations memorandum 17-005, *Adult Influenza Vaccine Protocol.*
- IHSC directive 06-05, *Pediatric Immunizations.*
- IHSC operations memorandum 15-013, *Immunization Protocol for ICE Family Residential Centers*

II. Disease Management

A medical provider is responsible for the clinical management of detainees and residents diagnosed with influenza.

A. Diagnosis and Lab Testing

- A medical provider should use influenza virus diagnostic testing when the results of such testing will influence:
  - clinical care of the detainee or resident;
  - clinical practice for other detainees and residents, such as detainees and residents at high risk for complications, and;
  - outbreak control in a detention or residential facility.
- A medical provider should consult the CDC clinical description and lab diagnosis of influenza website and the Infectious Diseases Society of America - Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza regarding considerations for influenza virus diagnostic testing and test interpretation.
- Medical providers should use reverse-transcription polymerase chain reaction (RT-PCR) or other rapid molecular assays (i.e., nucleic acid amplification tests) over rapid influenza diagnostic tests (RIDTs) to improve detection of influenza virus infection.
- Rapid influenza diagnostic tests (RIDTs) may be used to help with diagnostic and treatment decisions. However, due to the limited

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sensitivities and predictive values of RIDTs, negative results of RIDTs do not exclude influenza virus infection in detainees/residents with signs and symptoms suggestive of influenza and they should be managed as presumptive influenza until proven otherwise.

- RIDTs can be useful to identify influenza virus infection as a cause of respiratory outbreaks in any setting, but especially in institutions. Positive RIDT results from one or more ill persons with suspected influenza can support decisions to promptly implement prevention and control measures for influenza outbreaks.

- Negative RIDT results may be followed by RT-PCR to confirm or discount an outbreak due to influenza.

- Testing respiratory specimens from several persons with suspected influenza will increase the likelihood of detecting influenza virus infection, if influenza virus is the cause of the outbreak.

- Once influenza activity is documented in the facility, a clinical diagnosis of influenza can be made for detainees and residents with signs and symptoms consistent with suspected influenza, especially during periods of peak influenza activity in the community.

- Health staff should coordinate with the FHPM, IPO, or designee to notify public health authorities of any suspected institutional outbreak.

B. Treatment and Chemoprophylaxis

- A medical provider should consider ordering antiviral medications for the treatment and chemoprophylaxis of influenza in accordance with CDC's Influenza Antiviral Medications: Summary for Clinicians and Infectious Diseases Society of America - Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza and with consideration of individuals at high risk for complications.

- A medical provider should evaluate whether to treat detainees and residents with laboratory-confirmed influenza virus infection with an appropriate influenza antiviral medication.

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- A medical provider should evaluate whether to treat detainees and residents identified with ILI during suspected outbreaks with an influenza antiviral medication.

- A medical provider should order the collection of respiratory specimens from initial ill persons during institutional outbreaks and send them for testing to determine the virus type or subtype of influenza A virus associated with the outbreak to guide antiviral therapy decisions.

- Where influenza outbreaks are suspected, the antiviral medications most likely to be effective against the influenza virus that is the cause of the outbreak should be used, if known.

- During outbreaks in a detention or residential facility, the medical provider should consider ordering antiviral chemoprophylaxis for at risk detainees and residents for 14 days and continue for at least 7 days after the onset of symptoms in the last person infected.

III. Infection Prevention and Control

A. Standard and Droplet Precautions

- Health staff must institute standard and droplet precautions for detainees and residents with influenza or ILI in accordance with HICPAC Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health care Settings.

- Health staff must maintain transmission-based precautions until the patient has been determined to be noncontagious. Also see 05-02 G-01, *IHSC Occupational Health Guide: Blood Borne Pathogens and Other Potentially Infectious Materials* and 05-02 G-02, *IHSC Occupational Health Guide: Personal Protective Equipment Program*.

- For novel or epidemic strains and for which current vaccinations are inefficient, additional transmission-based precautions may be recommended to reduce transmission in the setting of vaccine inefficacy and/or higher virus pathogenicity.

- Health staff must implement standard cleaning disinfection guidelines in accordance with CDC's 2008 Disinfection & Sterilization Guideline: HICPAC. Also see 05-02 G-02, *IHSC Occupational Health Guide: Blood Borne Pathogens and Other Potentially Infectious Materials* located in the IHSC policy library.

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B. Isolation Management for detainees and residents with influenza or ILI

- When influenza or ILI is diagnosed in a detainee or resident, health staff should institute standard and droplet precautions and separate the ill detainee or resident from other detainees and residents without influenza or ILI.
- If possible, health care personnel must place detainees and residents with confirmed influenza or ILI in a single room or cell.

- When a single room is not available, health care personnel should assess the medical risks and operational impact associated with other detainee and resident placement options, such as shared rooms with other detainees or residents with influenza or ILI.

- During larger outbreaks, gender and classification separation must be maintained, and isolation capabilities may not be available. If isolation is not feasible, health care personnel should recommend that the beds of sick detainees and residents be placed at a distance of at least six feet from other detainees, to the extent possible.

- If there is widespread flu transmission within a facility, isolation as a strategy may not be feasible.

- An airborne infection isolation (AII) room is recommended when performing procedures that are more likely to generate higher concentrations of respiratory aerosols than coughing, sneezing, talking, or breathing.

- Medical providers must send detainees and residents with suspected decompensation or complications to a hospital if medically necessary.

- Health care personnel must educate detainees and residents about respiratory hygiene and cough etiquette strategies. Multilingual printable education materials can be located on the CDC's Preventing the Flu website.

- If movement is required, health care personnel must recommend that the detainee or resident with influenza or ILI, and exposed detainees and residents, wear surgical masks if tolerated.

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- Medical providers should evaluate whether to discontinue isolation of detainees and residents with seasonal influenza or ILI 24 hours after fever resolves or signs of fever without the use of fever-reducing medications.

IV. Outbreak and Exposure Management

In the event of widespread circulation of novel and/or pandemic strains of influenza, more restrictive management measures may be implemented in accordance with Advisory Committee on Immunization Practices, Centers for Disease Control, and Infectious Diseases Society of America guidance and recommendations. Health staff must be familiar with the ICE Pandemic Workforce Protection Plan.

Health staff must coordinate with the FHPM, IPO, or other designated staff to notify health departments of influenza diagnosis and outbreak investigations in accordance with local and state regulations.

A. Outbreak Management

- Health staff must consider an influenza outbreak when two or more detainees or residents in the same facility with common exposures manifest signs and symptoms of ILI within 72 hours of each other.
- A medical provider should order testing for influenza of initial detainees and residents that are clinically ill to confirm and verify outbreak with the same type.
- When influenza viruses are circulating in the facility, single positive laboratory results in conjunction with other detainees or residents with compatible illnesses are suggestive of an institutional outbreak.
- If influenza test results are positive despite antiviral chemoprophylaxis, the medical provider should consider the possibility of drug-resistant virus, the spread of influenza to previously unaffected areas of the facility where antiviral chemoprophylaxis had not been implemented, or multiple introductions of influenza from newly arriving detainees and residents.

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- If drug resistance is suspected, a medical provider should consider submitting a respiratory sample to local health authorities for consideration of susceptibility testing.

- For more information on outbreak investigations reference IHSC 05-06 G-01, *Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations* located in the IHSC policy library.

B. Cohorting of exposed, asymptomatic detainees

- During outbreak management, health care personnel should evaluate whether to recommend to facility administrators cohorting with restricted movement to help reduce the spread of influenza. Strict cohorting may not be possible depending on facility characteristics. Less restrictive social distancing measures may help decrease the likelihood of transmission.

- If cohorting is recommended and feasible, health staff should recommend to facility staff to cohort all detainees that were in close contact (within 6 feet) to the detainee with ILI from 24 hours prior to symptom onset until four days following the latest exposure, and new arrivals must not be introduced to a cohorted housing unit.

- In family residential facilities with open movement, the HSA, FHPM, or designee should recommend implementing social distancing to the extent possible, to control the spread of infectious diseases of public health significance.

- Health staff should advise facility staff to discontinue cohorting when all members of the cohort remain asymptomatic four days following the latest exposure.

- If new ILI develops among detainees in the cohort, health staff should advise facility staff to extend the cohorting period for four days after the most recent exposure and repeat the process until there is a full four-day period without any new ILI.

- A medical provider should consider antiviral prophylaxis according to CDC and IDSA recommendations.

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- Health care personnel must educate exposed detainees to maintain awareness of ILI symptoms and the importance of seeking medical attention promptly should they develop symptoms consistent with ILI.
- Health staff should recommend to facility staff that detainees wear a surgical mask when leaving the cohort area during the incubation period and if co-mingling with non-exposed persons.
- A medical provider should recommend to facility staff to avoid movement of cohorted detainees within and between facilities until the incubation period has ended.
- At least weekly, FHPMs, IPOs, or designees, and Field Medical Coordinators (FMCs) should report initial and updated status of housing units cohorted for detainee exposures to significant infectious diseases on the PHSP Unit SharePoint page.

V. Program Monitoring

PHSP Unit staff monitors influenza activity using the electronic health record reporting tools. PHSP Unit staff periodically request information from health staff at IHSC-staffed medical clinics for program monitoring.

VI. Training and Education

A. Health Staff

The HSA or designee must ensure that orientation and annual training that includes the influenza management is implemented and documented in accordance with IHSC directive 01-04, *Medical Education and Development* located in the IHSC policy library.

B. Detainees and Residents

Health care personnel should educate detainees and residents diagnosed with influenza about transmission, risk factors, and infection prevention and control. This education is documented in the detainee's or resident's electronic health record.

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VII. Privacy and Recordkeeping

Health staff should refer to IHSC directive: 05-06, *Infectious Disease Public Health Actions* located in the IHSC policy library for guidance on complying with privacy and recordkeeping procedures.

VIII. References and Resources

1. 2011 ICE Performance-Based National Detention Standards.
2. ICE Family Residential Standards.
3. American Correctional Association (ACA).
4. National Commission on Correctional Health Care.
5. CDC Influenza.
6. CDC Seasonal Influenza (Flu) | Health Professionals.
7. CDC Clinical Description & Lab Diagnosis of Influenza.
8. CDC Seasonal Influenza (Flu) | Antiviral Medications.
9. CDC HICPAC 2007 Isolation Precautions.
10. CDC HICPAC 2008 Disinfection & Sterilization Guideline.
11. CDC Preventing the Flu.
12. Infectious Diseases Society of America - Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenza.

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Management of Varicella and Herpes Zoster

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Management of Varicella and Herpes Zoster in IHSC-Staffed Medical Clinics* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities, and details procedures for the management and control of varicella and herpes zoster.

The intended audience is IHSC-staffed facilities supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

This guide assists health staff implement public health actions to manage varicella and herpes zoster and describes the procedures and resources to implement infection prevention and control measures.

B. Responsibilities

Health Services Administrator (HSA), Facility Healthcare Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Overs and implements infection prevention and control activities.
- Oversee contact and outbreak investigations.
- Ensure reporting of detainees/residents with varicella to the health department in accordance with local and state laws.
- Ensure health staff receive orientation and annual training.
- Report detainees/residents with varicella to the health department in accordance with local and state laws.
- Coordinate contact and outbreak investigations

Medical Providers

- Oversee the clinical management of detainees/residents diagnosed with varicella or herpes zoster.
- Report detainees/residents with varicella to the health department or notify the compliance officer for reporting the patient to health department in accordance with local and state laws.

Health Staff

- Implement infection prevention and control measures to stop or limit the spread of varicella and herpes zoster.
- Adhere with national guidelines, regulations, and standards.

Public Health Safety and Preparedness (PHSP) Unit staff

- Provide technical guidance to IHSC staff on varicella and herpes zoster infection prevention and control activities.

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- Review and update this Guide and IHSC Directive 05-06, *Infectious Disease Public Health Actions*.

- Monitor contact investigation and cohorting tracking information..

- Conduct surveillance for detainees/residents with varicella and herpes zoster diagnosed in IHSC-staffed medical clinics.

IHSC Infectious Disease Consultant and Infectious Disease Advanced Practice Provider (APP)

- Provide clinical guidance related to clinical management and public health actions for the management of varicella and herpes zoster at the request of the medical provider or headquarters staff.

C. About Varicella

Varicella (chickenpox) is the disease that results from primary infection with the varicella zoster virus (VZV). It is a highly contagious disease that causes a blister-like rash with itching, tiredness, and fever. Varicella most commonly causes an illness that lasts about 5–10 days.

Transmission

Varicella is transmitted from person to person. It is spread by direct contact with a persons who has either varicella or the herpes zoster virus (causes shingles) by airborne spread via respiratory secretions or aerosolized fluid from skin lesions. Exposure occurs through close contact with an infectious person, such as close indoor contact (e.g., in the same room) or face-to-face contact. Experts differ in their opinions about the duration of contact needed to contract varicella; some suggest five minutes and others up to one hour. All experts agree that significant exposure does not include transitory contact.

Incubation Period

The incubation period for varicella is 10-21 days.

Infectious Period

Persons with varicella are considered infectious from one to two days before the rash appears and until all lesions are crusted over. On average, this occurs four to seven days after rash onset. Persons with underlying medical conditions such as cancer, human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) have weakened immune systems and are especially likely to have more severe disease. In these casese, the crusting of lesions may take longer. Thus, they may shed the virus from skin lesions for a longer time period.

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Signs and Symptoms

Varicella presents as a classic rash which is initially itchy, with fluid-filled blisters that eventually form scabs. The rash may first show up on the face, chest, and back then spread to the rest of the body, usually sparing the palms and soles. It usually takes about one week for all of the blisters to become scabs.

Other typical symptoms that may begin to appear 1-2 days before the rash include:

- High fever.
- Fatigue.
- Loss of appetite.
- Headache.

Though not typical, the most common complication is a superinfection with common skin bacteria such as Staphylococcus aureus and Group A Streptococcus.

The following individuals are at increased risk of having more severe symptoms and complications, hereafter referred to as "high risk:"

- Infants.
- Pregnant women.
- Persons with health problems or treatment regimens that affect the immune system (e.g., HIV, cancer, transplant patients).

Prevention

The best way to prevent infection with varicella is to receive the vaccine. The vaccine is safe and effective at preventing the disease. Most people who get the vaccine will not get varicella. Varicella vaccination is included in routine immunization schedules in the United States. However, most developing countries do not include varicella vaccination in their national vaccine preventable disease programs.

Most detainees and residents are not previously vaccinated; therefore, the risk of exposure and susceptibility to VZV is greater.

D. About Herpes Zoster

Herpes zoster, also known as shingles, is caused by the reactivation of VZV in the body. It is the same virus that causes varicella. VZV chronically infects humans and lives dormant for the remainder of the infected person's life. As people age and/or develop a weakened immune system, they may experience an episode of shingles. For example, temporary stressors can weaken the immune system

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enough to allow VZV to reactivate. Shingles can occur more than once in a person's life time.

Anyone who has had varicella can develop shingles. However, it more commonly affects the following groups:

- Elderly. The older the individual, the more likely they are to develop post-herpetic neuralgia, a potentially lifelong and debilitating "phantom" nerve pain.
- Persons with health problems or treatment regimens that affect the immune system (e.g., HIV, cancer, transplant patients).

Transmission

A person with shingles can spread the virus when the rash is in the blister phase. A person exposed to a shingles rash and who has never been infected with VZV before will develop varicella, not shingles. The virus is spread through direct contact with fluid from the rash blister or airborne exposure. All singles patients can spread the virus through the rash blister. Those who are severely immunocompromised are at risk for airborne exposure; this includes people with AIDS or organ transplant recipients. Herpes zoster is less contagious than varicella and the risk of a person with herpes zoster spreading the virus is low if the lesions are covered.

Infectious period

The infectious period for herpes zoster begins at onset of rash and ends after all of the lesions are crusted over to form scabs.

Symptoms

Shingles commonly present as an itchy, sometimes painful rash that affects one side of the body and along nerve pathways that supply the skin (unilateral dermatomal). A general feeling of discomfort or malaise, headache, and severe neuropathic type pain or abnormal sensations may precede the rash.

Other typical symptoms that may begin to appear 1-2 days before the rash include:

- High fever.
- Fatigue.
- Appetite loss.
- Headache.

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E. Acronyms

AII – Airborne Infection Isolation.

CDC – U.S. Centers for Disease Control and Prevention.

DFA – Direct fluorescent antibody.

HICPAC – Healthcare Infection Control Practices Advisory Committee.

HIV – Human immunodeficiency virus.

IgG – Immunoglobulin G.

PCR – Polymerase chain reaction.

PPE – Personal protective equipment.

VIS – Vaccine information statement.

VZV – Varicella zoster virus.

VariZIG – Varicella zoster immune globulin.

F. Definitions with Expanded Information

Airborne infection isolation (AII) precautions – Isolates patients infected with infectious organisms spread through the air to minimize person to person transmission.

Airborne infection isolation (AII) room – A single-occupancy patient-care room, formerly called a negative pressure isolation room. Environmental factors are controlled so the isolation room receives substantial air changes per hour (ACH). ACH for AII rooms constructed since 2001 is ≥12. ACH for AII rooms constructed before 2001 is ≥6. AII rooms are under negative pressure so the direction of air flow is from the outside adjacent space (i.e., the corridor) into the room. AII room air is preferably exhausted to the outside, or recirculated if the return air is filtered through a high efficiency particulate air (HEPA) filter.

Airborne transmission – Dissemination of airborne particles that can infect people over time and distance. Airborne particles are droplet nuclei 1 to 5 µm in diameter and associated with coughing or aerosolization of contaminated fluids.

Cohorting – Cohorting is a public health strategy used to house individuals separately as a group based on their infectious or exposure status.

Contact investigation – The process of identifying, evaluating, and treating all persons (contacts) who have sustained a significant exposure to a person with suspected or confirmed infection.

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Contagious – When a disease can be transmitted from one living being to another through direct or indirect contact; communicable; infectious; usually microorganisms.

Direct contact transmission – Direct transfer of a microorganism from an infected person to another person.

Disseminated herpes zoster – Appearance of lesions outside the primary or adjacent dermatomes.

Exposure – The condition of being subjected to something in the working environment (noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Herpes Zoster (Shingles) – Primarily dermatologic disease caused by the reactivation of latent varicella zoster virus.

High efficiency particulate air (HEPA) filter – A filter that is certified to remove ≥99.97% of particles 0.3 µm in size. HEPA filters are either portable or stationary. These filters are required for AII room exhaust ventilation and requires expertise in installation and maintenance.

Incubation period – The interval between exposure to a communicable microorganism and onset of symptoms.

Infection control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Infectious period – The period during which a person might have transmitted a communicable microorganism to others.

N95 disposable respirator – An air-purifying, filtering-facepiece respirator that is ≥95% efficient at removing 0.3 µm particles and is not resistant to oil. Education and fit testing is required before wearing a respirator. N95 respirators are used to protect the wearer from exposures in the air; they are not worn by a patient.

Outbreak – The occurrence of more people with a disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period.

Shingles – The common name of the dermatomal rash caused by reactivation of varicella zoster virus.

Significant exposure – Exposure under conditions more likely to result in transmission of infection.

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Transmission-based precautions – Precautions that provide additional protections beyond Standard Precautions to interrupt the transmission of pathogens.

Varicella (chickenpox) – An acute infectious disease, usually seen in children aged less than 15 years, caused by the varicella-zoster virus.

Varicella zoster virus (VZV) – The virus that causes varicella and shingles.

II. Clinical Management

A medical provider is responsible for the clinical management of detainees/residents diagnosed with or suspected of having varicella or herpes zoster. HIV testing is recommended for detainees with herpes zoster or a history of herpes zoster. The diagnosis of VZV infection is made or supported by one or more of the following:

- Physical examination to identify the symptoms typical of VZV rash (see Figures 1 and 2), including assessment of the following:
    - Varicella: Lesions that are simultaneously in all stages of development — from vesicles on a red base, to umbilicated pustules, to crusted lesions.
    - Herpes zoster: Unilateral (on one side), dermatomal distribution of a painful vesicular rash.

Figure 1. Varicella rash in a person with a light complexion

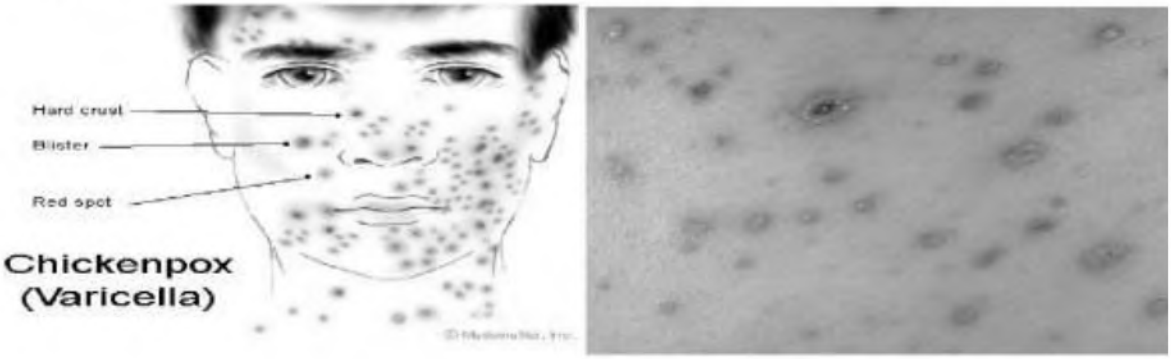

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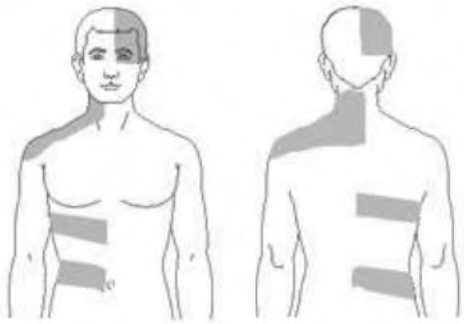
Figure 2. Common presentation of herpes zoster



Most commonly, the rash occurs in a single stripe around either the left or right side of the body. In other occurrences, the rash occurs on one side of the face. In rare occurrences, the rash may be more widespread and look similar to a varicella rash.

- History of exposure to varicella or herpes zoster within the past three weeks, in a susceptible contact.
- Laboratory tests are not routinely required but can be useful for confirmation of the diagnosis, particularly if the presentation is atypical. VZV testing includes the following methods:
    - Rapid VZV identification. Polymerase chain reaction (PCR) or direct fluorescent antibody (DFA) testing is widely available from commercial labs, with results available in several hours.
    - Viral culture is rarely necessary, and less sensitive than rapid tests above.
- Health staff should document varicella or herpes zoster diagnoses in the health record using appropriate ICD coding.

For general information about surveillance and reporting please reference 05-06-G-03 *Infectious Disease Public Health Actions Guide: Surveillance and Reporting* located in the IHSC policy library.

III. Herpes Zoster Infection Prevention and Control

Infection control measures for herpes zoster are summarized in Table 1.

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Table 1. Transmission-Based Precautions for Herpes Zoster

	Localized[a]	Disseminated[b]
Immunocompetent	• Standard precautions. • Cover lesions. Until lesions are crusted over to form scabs. If lesions cannot be effectively covered, follow contact and airborne precautions.	See immunocompromised.
Immunocompromised	• Standard precautions. • Contact precautions. • Airborne precautions. Until disseminated shingles is ruled out, then standard precautions until lesions are crusted over to form scabs.	• Standard precautions. • Contact precautions. • Airborne precautions. Until lesions are crusted over to form scabs.

[a] *Localized herpes zoster has the appearance of lesions in primary or adjacent dermatomes.*

[b] *Disseminated herpes zoster has the appearance of lesions outside the primary or adjacent dermatomes.*

IV. Varicella Infection Prevention and Control

A. Family Residential Centers

Immunization

Residents arriving at FRCs with active varicella, including residents who are pre-symptomatic, may continually introduce varicella into the family residential center (FRC) population. This presents a risk of transmission. Offering pre- and post-exposure vaccination with education should be the primary strategies for controlling transmission and managing varicella transmission.

- Vaccination is the primary strategy for mitigating varicella transmission in

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FRCs. Refer to IHSC Directive 06-05 *Pediatric Immunizations* and OM 15-013 *IHSC Immunization Protocol for ICE Family Residential Centers* for guidance on pediatric and adult immunization schedules located in the IHSC policy library.

Transmission-Based Precautions

- When active varicella is suspected or confirmed, health care personnel must institute airborne (if available) and contact precautions following the 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

- Health staff should don appropriate personal protective equipment for contact with a resident with active varicella or exposed contacts without immunity still within the incubation period; see also the *05-02-G-02 Occupational Health Guide: Personal Protective Equipment Program* and the *05-02-G-01 Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials* located in the IHSC policy library.

- The HSA or designee must adjust work schedules and assignments for susceptible or vulnerable staff members that would be at high risk for complications if exposed to and infected with varicella, including pregnant women and individuals with a weakened immune system due to health conditions or therapies.

- Health care personnel must place a surgical mask on the ill resident when in close proximity to others.

- Health care personnel must move the ill residents to a room or area that minimizes contact with other residents, especially non-family members that may not have had previous exposure. This may be an airborne infection isolation (AII) room, if available, or another room with restricted contact to other residents. Transfer to a community hospital may be considered if medically necessary.

- Parents may be placed in a room with an ill child, and children may be placed in a room with an ill parent if the room can accommodate co-habitation and the non- ill family member is not at high risk for complications.

- Health staff must implement standard cleaning and disinfection guidelines. See the Healthcare Infection Control Practices Advisory Committee (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

- It is recommended that residents with varicella not be housed with any immunocompromised persons.

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Management of Exposed Contacts

- With open movement in FRCs, residents exposed to varicella, but who are not ill, should not be housed separately.
- IHSC staff should seek consultation by the Regional Clinical Director, IHSC Infectious Disease Consultant, and/or Infectious Disease APP for post-exposure management of identified residents at high risk for complications (i.e., pregnant females, infants, and immunocompromised residents).
- Health staff must remain vigilant for additional residents potentially developing varicella following possible exposures or among recently arrived residents.
- If exposed, non-immune residents must be released or removed, health staff should implement the following prior to release or removal:
    - Educate the resident on their exposure and instruct him or her to seek medical attention if he or she develops symptoms.
    - Give the documentation of relevant medical information, including test results for VZV immunity and documentation of vaccination, if administered.

B. Adult Detention Facilities

Transmission-Based Precautions

- When active varicella is suspected or confirmed, health care personnel must institute airborne (if available) and contact precautions following the 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. See also Figure 3.
- Health staff should don appropriate personal protective equipment for contact with a detainee with active varicella or exposed contacts without immunity still within the incubation period; see also the 05-02-G-02 *IHSC Occupational Health Guide: Personal Protective Equipment Program* and the 05-02-G-01 *IHSC Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials* located in the IHSC policy library.
- The HSA or designee must adjust work schedules and assignments for susceptible or vulnerable staff members that would be at high risk for complications if exposed to and infected with varicella, including pregnant women and individuals with a weakened immune system due to health conditions or therapies.
- Health care personnel must place a surgical mask on the ill detainee when in close proximity to others.

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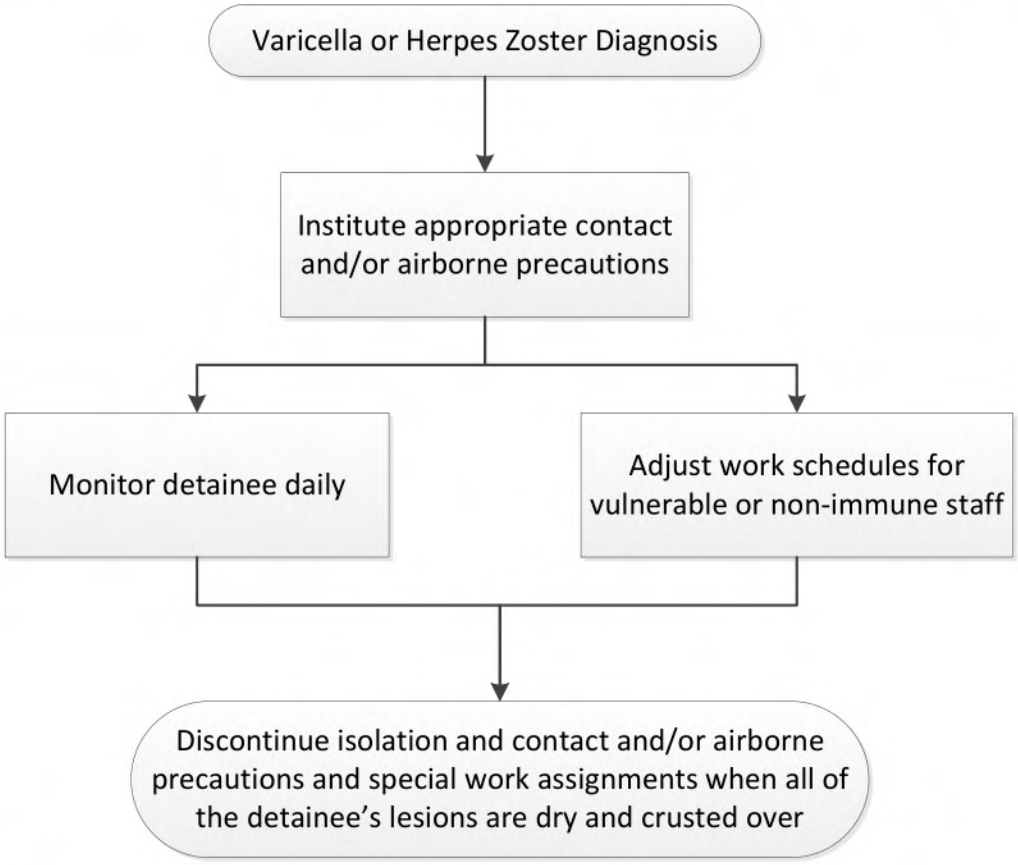
- Health care personnel must move the ill detainees to a room or area that minimizes contact with other detainees. This may be an AII room, if available, or another room with restricted contact to other detainees. Transfer to a community hospital may be considered if medically necessary.
- Health staff must implement standard cleaning and disinfection guidelines (See the HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
- It is recommended that detainees with varicella not be housed with any immunocompromised persons.

Figure 3. Varicella and Herpes Zoster Infection Control Measures



Management of Exposed Contacts

A medical provider is responsible for the overall management of susceptible contacts. Health staff should identify detainees that may have had a significant exposure to a detainee with varicella or herpes zoster. Table 2 provides guidance on establishing significant exposures.

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Table 2. Establishing Significant Exposure During the Infectious Period

Disease Exposure	Significant Exposure
Varicella	At least one-hour exposure, including any of the following: • Contact with nasopharyngeal secretion or lesions, or • Face-to-face interaction, or • Sharing indoor airspace* during the infectious period
Uncomplicated herpes zoster	Direct contact with lesions or secretions
Disseminated herpes zoster	At least one of the following: • Contact with lesions or secretions, or • Sharing indoor airspace*
Disseminated or localized herpes zoster in an immunocompromised person	At least one of the following: • Contact with lesions or secretions, or • Sharing indoor airspace*

*Sharing indoor airspace refers to being within three feet, such as in the same 2-4 bed ward, or in an adjacent bed in a large ward

- For purposes of recommending cohorting with restricted movement, health care staff may consider a detainee's self-report during the individual health assessment (i.e., prior to exposure) of having a positive history of varicella as a predictive indicator of presumptive immunity if the detainee is healthy, not immunocompromised, does not have HIV, and is not pregnant. History of varicella self-reported during the individual health assessment should be documented in the detainee's medical record. A detainee self-report of unknown history or of no history of varicella is not similarly predictive of positive or negative presumptive immunity.
- Health care personnel may consider documented immune status of contacts among detainees with a significant exposure. Evidence of presumptive immunity to VZV includes the following:
    - Documentation of varicella or herpes zoster vaccination
        - Documentation of varicella vaccination includes 2 doses of vaccine

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        - Documentation of herpes zoster vaccination includes 1 dose at age 60 or older
    - Laboratory evidence suggestive of immunity (VZV IgG positive)
    - Diagnosis or documented history of varicella disease by a healthcare provider (note: rarely a person can get varicella disease more than once).
    - Diagnosis or documented history of herpes zoster by a healthcare provider (note: rarely a person can have a second or a third episode of herpes zoster).

- If documentation of immunity is not available, or if the detainee does not self-report a positive history of varicella, a medical provider should order serologic titers (Varicella IgG) within 48 hours of exposure for exposed contacts without documented immunity to varicella.
    - Exposed detainees with a positive titer (Varicella IgG) suggestive of immunity can be released from cohorting with restricted movement.
    - It is not recommended to perform serologic titers (Varicella IgG) after vaccination, even if secondary exposures occur.
- A medical provider should evaluate exposed detainees that are immune compromised and/or pregnant with or without a history of varicella or herpes zoster as soon as possible after identification, preferably within 48 hours.
    - Exposed, immunocompromised or pregnant detainees should be housed separately from other exposed, cohorted detainees if possible.
- A medical provider should order isolation of detainees with clinical signs or symptoms.
- All health assessments and laboratory testing results for exposed detainees must be documented in the health record.

<u>Observation</u>

- Health care personnel must perform daily visual inspections on all exposed detainees to identify signs or symptoms of active varicella for 21 days from the time of latest exposure.
- Health care personnel must isolate detainees with clinical signs or symptoms of active varicella.

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Cohorting with Restricted Movement

For detainees without reliable documentation suggesting immunity who are directly exposed to a person with active varicella while contagious, the HSA or designee should recommend the following to law enforcement and custody staff:

- Maintain social distancing to the extent possible to control the spread of infectious diseases of public health significance.
- Implement cohorting (housing together as a group) with restricted movement for 21 days from the latest exposure to varicella, unless release or removal is unavoidable (see 05-06-G-02 *IHSC Infectious Disease Public Health Actions Guide: Isolation and Management of Detainees Exposed to Infectious Organisms*).
    - If an additional person(s) with varicella disease is identified in the cohorted group, the 21-day period of restricted movement begins again, with the date of latest exposure being day zero and continues until there is a full incubation period without any new disease.
- IHSC does not recommend cohorting or restricted movement for detainees exposed to an asymptomatic person who was exposed to a person with contagious varicella.
- The FHPM or IPO should document cohorted units on the Cohorted Units Weekly Update tracking tool on the PHSP Unit SharePoing page.

Documentation upon release or removal

If asymptomatic, exposed, non-immune detainees must be released or removed, health staff should implement the following prior to release or removal:

- Educate the detainee on their exposure and instruct him or her to seek medical attention if he or she develops symptoms.
- Give the documentation of relevant medical information, including test results for VZV immunity and documentation of vaccination, if administered.

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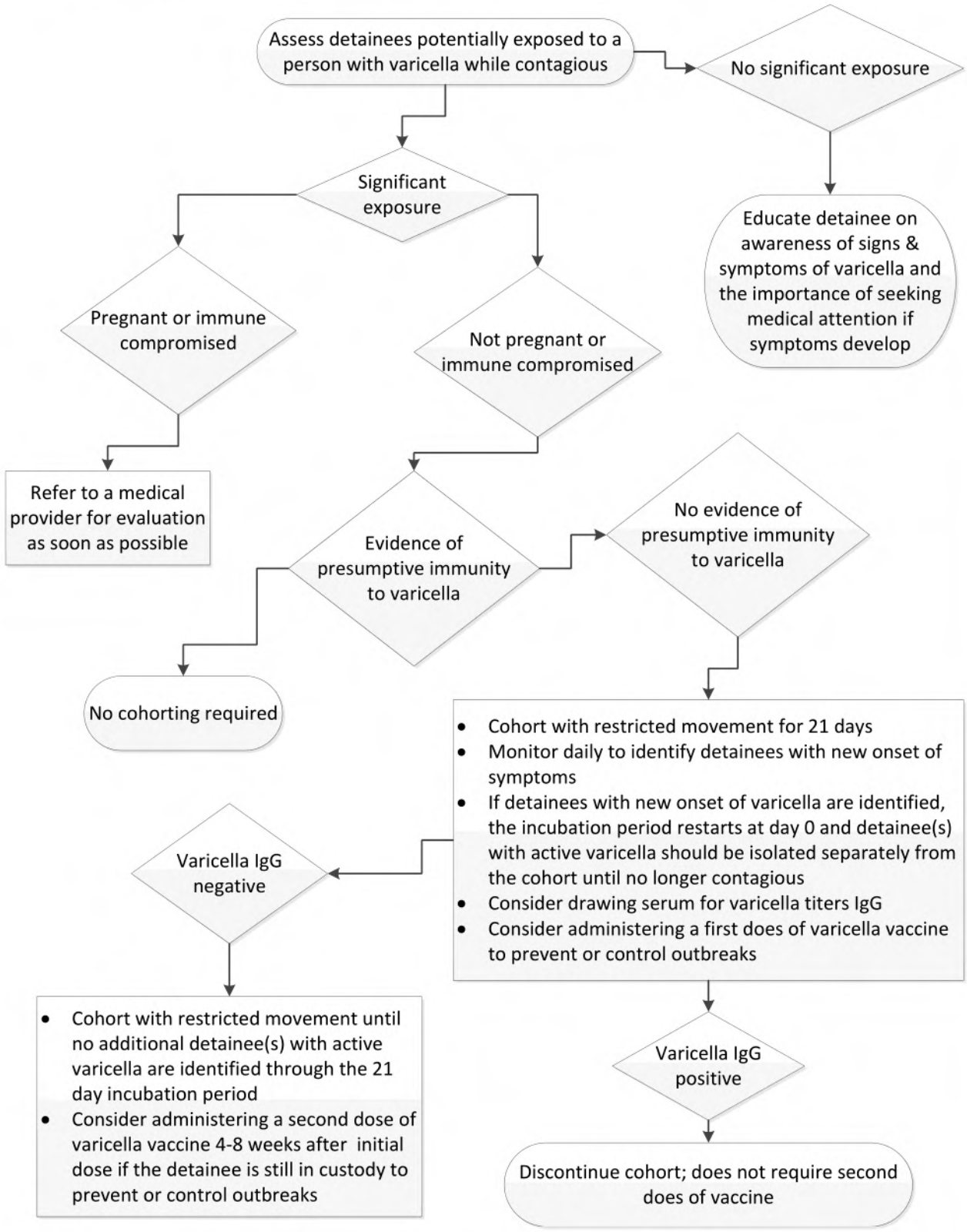
Figure 4. Varicella Exposure Management in Adult Detention Facilities



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V. Varicella Contact Investigations

A varicella contact investigation involves identifying, evaluating, and managing all persons (contacts) who have sustained a significant exposure to a person with varicella. A contact investigation may be required to help control transmission of varicella within the facility and between facilities. Contact investigations are not usually required for exposures to uncomplicated, localized herpes zoster; contact investigations may be recommended for exposures to disseminated herpes zoster or exposures to localized herpes zoster among immunocompromised detainees. Health staff should report contact investigations to the PHSP Unit staff.

For more information refer to 05-06-G-01 *IHSC Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations* and Strategies for the Control and Investigation of Varicella Outbreaks Manual, 2008.

A. Purpose

Contact investigations are performed to:

- Halt transmission
- Identify additional people with varicella disease
- Initiate appropriate medical intervention
- Prevent the development of varicella disease among recently infected contacts

B. Initiating Contact Investigations

Health staff should initiate a contact investigation as soon as a detainee is diagnosed with varicella. This allows for prompt identification of significant close contacts to prevent transmission. Health staff should document relevant laboratory, treatment, and risk factor information for exposed detainees using a contact investigation tracking tool and as appropriate, in the health record.

C. Education

Health care personnel should educate exposed contacts about varicella and herpes zoster, and inform them of the voluntary and confidential nature of a contact investigation.

Health care personnel educate staff about the potential for an outbreak or the current outbreak and encourage everyone to maintain a high index of suspicion for varicella when providing medical care and evaluation.

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D. Collaborations

Health staff should collaborate with local or state health departments to conduct contact investigations, if needed. Health departments have expertise in conducting contact investigations and may be used as a resource for determining the scope of the contact investigation and management of exposed contacts.

Obtain information from the ill detainee(s) regarding places where they stayed during the infectious period prior to arrival at the facility so that the health department or other entities can investigate those potential exposures.

E. Surveillance

Health staff should maintain a high index of suspicion for varicella in the facility to identify additional people with varicella, detect an outbreak, and implement control measures in a timely manner. Health staff must notify the PHSP Unit of known or suspected transmission within the facility. Health staff must also notify the health department in accordance with local and state regulations.

VI. Varicella Outbreak Investigation

Prompt identification, investigation, and control of varicella outbreaks is important. See 05-06-G-01 *IHSC Infectious Disease Public Health Actions Guide: Contact and Outbreak Investigations* and Strategies for the Control and Investigation of Varicella Outbreaks Manual, 2008 for additional guidance.

A. Steps for management of varicella outbreaks

Steps for managing possible varicella outbreaks might occur simultaneously or in a different order than listed below.

1. Confirm the occurrence of an outbreak

    - The occurrence of ≥5 people with varicella with an epidemiologic link defines an outbreak. The following guidance is used to establish epidemiologic links:

        - A known epidemiologic link is established as follows:

            – One of the ill detainees named the other as a contact during one of the ill detainee's infectious period, or

            – The two detainees were at the same place at the same time during one of the ill detainee's infectious periods.

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- A possible epidemiologic link is established as follows:
  - The two ill detainees spent time at the same place around the same time, but the timing was not definite enough to meet the criteria for a known epidemiologic link, or
  - The two ill detainees were in the same geographic area around the same time and shared social or behavioral traits that increased the chances of transmission.

- Health staff must notify the PHSP Unit staff.
- Health staff must report to health departments in accordance with local, state, and federal laws.

2. Identify people with varicella

- Laboratory confirmation is recommended for at least three people with varicella disease to confirm an outbreak.

3. Enhance control measures

- Health staff must implement control measures for case management, exposure management, and contact investigations.
- Health staff should consider enhancing control measures if there is an increase in the number of detainees with varicella in the facility in the absence of an epidemiologic link.
- Health staff might consider enhanced screening for varicella at intake.
- A medical provider might consider vaccination to prevent or control outbreaks.
  - A medical provider should consider vaccinating persons without evidence of immunity to varicella if they do not have a contraindication to vaccination, if vaccine is available, and in consultation with the Clinical Director, Regional Clinical Director, or Deputy Medical Director.
  - Medical providers refer to CDC guidelines regarding the safe administration of the vaccine, Varicella Vaccination Information for Healthcare Professionals.
  - Medical providers must be familiar with potential side effects and adverse reactions associated with the varicella vaccine.

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- Health care personnel must provide the Vaccine Information Statement (VIS) and appropriate detainee education regarding the vaccine schedule and the vaccine's associated benefits and risks.
  - VISs in multiple languages are available at Vaccine Information Statements (VIS)
- For more information on varicella vaccination and recommendations for use, health care personnel should refer to the Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices
- The CDC recommends VariZIG, the only varicella zoster immune globulin preparation available in the United States for postexposure prophylaxis of varicella, for high risk, susceptible contacts within 10 days of exposure. When VariZIG is administered, the incubation period extends to 28 days. Facilities may procure VariZIG directly from the manufacturer: http://www.fffenterprises.com/. See also FDA Approval of an Extended Period for Administering VariZIG for Postexposure Prophylaxis of Varicella.
- Health care personnel offer a first dose of varicella vaccine to eligible, non-high risk, susceptible contacts within five days of exposure if available or as recommended by the health department. For adult detainees, health care personnel offer second dose of vaccine 4 weeks after the first dose.

4. Enhance surveillance

- Health staff should implement surveillance for two incubation periods (42 days) after rash onset of the last identified person with varicella.

5. Documentation and reporting

- Health staff should use a tracking tool to document detainees identified with varicella associated with an outbreak.
- Health staff must notify the PHSP Unit of known or suspected transmission within the facility.
- Health staff must also notify the health department in accordance with local and state regulations.
- Health staff document and summarize outbreak findings to inform efforts to prevent and control future outbreaks.
- The HSA or designee should evaluate the outbreak management process and develop plan to prevent future outbreaks.

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VII. Workforce Health Considerations

Health staff without verified immunity that have had significant, unprotected exposure are recommended to see their personal healthcare provider for evaluation and management; see also *IHSC Directive 05-02, Occupational Health*, and the *05-02-G-04 Occupational Health Guide: Workforce Health* located in the IHSC policy library.

VIII. Program Monitoring

PHSP Unit staff monitor diagnoses of varicella and herpes zoster using the electronic health record reporting tools. PHSP Unit staff will periodically request information from health staff at IHSC-staffed medical clinics for program monitoring.

IX. Training and Education

A. Health Staff

The HSA or designee must ensure that orientation and annual training that includes the public health actions for the management of varicella and herpes zoster is implemented and documented in accordance with IHSC Directive 01-04 Medical Education and Development.

B. Detainees

Health care personnel must educate detainees diagnosed with varicella or herpes zoster about transmission, risk factors, infection prevention and control, and continuity of care.

X. Privacy and Recordkeeping

Health staff should refer to IHSC Directive 05-06, *Infectious Disease Public Health Actions* for guidance on complying with privacy and recordkeeping procedures.

XI. References and Resources

1. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. Lopez AS, Marin M. Strategies for the Control and Investigation of Varicella Outbreaks, 2008.

2. Centers for Disease Control and Prevention. The Pink Book: Course Textbook – 13th Edition, Chapter 21 (Varicella). Atkinson W, Wolfe S, Hamborsky J, eds. Epidemiology and Prevention of Vaccine-Preventable Diseases: Varicella. 2015.

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3. Centers for Disease Control and Prevention. Preventing Varicella Zoster Virus (VZV) Transmission from Zoster in Healthcare Settings.

4. Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

5. Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.

6. Review of the Use of Segregation for ICE Detainees, Policy No. 11065.1, September 4, 2013.

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Surveillance and Reporting

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO AD - IHSC

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Surveillance and Reporting* supplements the following IHSC directive:

- IHSC directive: 05-06, *Infectious Disease Public Health Actions.*

This guide explains concepts, assigns responsibilities, and details procedures for infectious disease surveillance and reporting in IHSC-staffed medical clinics.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

The purpose of this guide is to provide guidance for infectious disease surveillance and reporting in IHSC-staffed medical clinics.

B. Surveillance Definition

Public health surveillance is the timely, continuous, systematic collection, analysis, and interpretation of health-related data for informing urgent and routine public health activities, including public health interventions; contact and outbreak investigations; evidence-based decision making; and planning, implementation, and evaluation of public health practices. Agency-wide surveillance information is used to monitor disease trends and inform infection prevention and control activities that mitigate transmission and protect the health and safety of detainees and staff.

C. Responsibilities

Health Services Administrator (HSA), Field Health Care Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Ensure official guidance related to infectious disease surveillance and reporting are routinely implemented.
- Ensure infectious diseases are reported to the health department in accordance with state and local laws.
- Ensure relevant health staff are informed of appropriate point(s) of contact at the local or state health department for reporting urgent public health issues, and ensure that they have contact information and easy access to reporting guidelines and forms.
- Ensure availability of the FHPM, IPO, or designee on weekday shifts during health department operating hours, for communications with local or state health departments for routine and urgent issues.
- Facilitate completion of information requests for surveillance and reporting.

Medical Providers

- Report infectious diseases to the local or state health department in accordance with state and local laws.

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Public Health, Safety, and Preparedness (PHSP) Unit Staff

- Monitor infectious disease surveillance information from IHSC-staffed medical clinics and maintain awareness of significant infectious disease information disseminated through domestic and international sources.

Field Medical Coordinators

- Responsible for reporting of detainees with suspected, probable, and confirmed highly significant infectious diseases (e.g., mumps, measles).

- Responsible for reporting on facilities in respective areas of responsibilities with housing units cohorted for detainee exposures to significant infectious diseases.

D. Acronyms

CDC – United States Centers for Disease Control and Prevention

DHS – U.S. Department of Homeland Security

eHR – Electronic health record

EpiX – Epidemic Information Exchange

HAN – Health Alert Network

HSIN – Homeland Security Information Network

ICD – International Classification of Diseases

MMWR – Morbidity and Mortality Weekly Reports

NAAT – Nucleic Acid Amplification Test

NBIC – DHS National Biosurveillance Integration Center

PAHO – Pan American Health Organization

ProMED – Program for Monitoring Emerging Diseases

WHO – World Health Organization

E. Definitions with Expanded Information

Epidemic – The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a particular period of time.

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Incidence – The number of new cases of a disease in a specific area during a specific time.

Outbreak – The occurrence of more cases of disease, injury, or other health condition than expected in a given area or among a specific group of persons during a specific period.

Pandemic – An epidemic occurring over a widespread area and usually affecting a substantial proportion of the population.

Reportable Disease – A disease that, by law, must be reported to public health authorities upon diagnosis.

Surveillance – The timely, continuous, systematic collection, analysis and interpretation of health-related data for informing urgent and routine public health activities, including public health interventions; contact and outbreak investigations; evidence-based decision making; and planning, implementation, and evaluation of public health practices.

II. IHSC Infectious Disease Reporting

A. Reporting to the Health Department

Medical providers are required by law to report specific, reportable infectious diseases, to the local or state health department. Each state has its own laws and regulations defining reportable conditions, so medical providers must be knowledgeable of reporting requirements for their jurisdiction.

For tuberculosis (TB) reporting, the FHPM, IPO, or other designated health staff must enter case reporting information in the TB Case Management (TB-CM) template in the electronic health record (eHR) for patients who meet the following criteria. Report TB patients to the PHSP Unit and to the local health department as described in the *IHSC eCW User Guide: TB Case Management*.

1. All patients with confirmed TB disease (culture or NAAT confirmed *M.TB* complex or meeting the clinical definition of active TB disease).

2. Detainees with suspected TB disease that have at least one of the following:
   a. Started or continued treatment.
   b. Smear positive for *acid-fast bacilli (AFB).*
   c. Cavitary lesions on chest x-ray.
   d. Symptoms consistent with pulmonary TB.

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An abnormal chest x-ray alone should not be reported unless any of the above criteria are met. IHSC health staff should report all detainees with confirmed or suspected TB disease to the local or state TB control programs in accordance with local and state regulations. Most states require TB reporting within one working day after meeting the reporting criteria. The PHSP Unit requires reports within one working day of meeting the criteria. *See* 05-11-G-1*, Public Health Actions for TB Care Guide: IHSC-Staffed Medical Clinics.*

IHSC health staff should continue reporting updated TB information in eCW until final culture, drug sensitivity results, and classification are available, regardless of whether the detainee is still in custody at the time final results are received. For each update, a new TB-CM encounter must be generated. At no time should an encounter be left unlocked.

The TB-CM template should only be used for TB case management and reporting; it should not be used for documenting any other encounters, transfer summaries, or templates. Health staff should merge the TB-CM templates into a single progress note and print it for reporting to the local or state health department, if the health department agrees to accept the case report in this format.

See also *IHSC eCW User Guide: TB Case Management*; IHSC directive 05-11, *Public Health Actions for Tuberculosis Care;* and 05-11-G-01, *Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Detention Facilities*.

B. IHSC Reporting

FHPMs, IPOs or designees, and Field Medical Coordinators (FMCs) should report outbreaks and any real or potential significant public health threat to PHSP Unit staff.

At least weekly, FHPMs, IPOs, or designees, and FMCs should report initial and updated status of housing units cohorted for detainee exposures to significant infectious diseases on the PHSP Unit SharePoint page.

FHPMs, IPOs, or designees and FMCs should maintain contact and outbreak investigation line lists of detainees with suspected, probable, or confirmed highly significant infectious diseases (e.g., mumps, measles); these should be updated as new information becomes available. Contact investigation line templates are available on the PHSP Unit SharePoint page. FHPMs, IPOs, or designees and FMCs should upload updated contact investigation line lists to designated folders on the PHSP Unit SharePoint page.

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For TB reporting, FHPMs, IPOs or other designated health care providers should assign the TB-CM progress note to the PHSP Unit staff with lead responsibilities for infection prevention and control. See *IHSC eCW User Guide: TB Case Management* for detailed instructions.

III. IHSC Infectious Disease Surveillance

The eHR is used to conduct monitoring and periodic surveillance of infectious diseases. PHSP Unit staff monitor counts of infectious diseases observed at IHSC-staffed facilities using eHR reporting tools. The medical provider's correct assignment of the ICD code in the eHR is essential for accurate infectious disease surveillance.

IV. Pandemic or Infectious Disease of Public Health Significance

Surveillance activities and reporting requirements might change during a pandemic or emerging infectious disease threat. PHSP Unit staff will provide updated guidance during a pandemic or detection of an emerging infectious disease of public health significance.

V. Domestic and Global Public Health Awareness

PHSP Unit staff monitor information disseminated from domestic and international health organizations for announcements and advisories regarding emerging or established public health threats. This information informs health decisions at IHSC-staffed medical clinics. Sources of information include, but are not limited to the following:

- Epi-X: The Epidemic Information Exchange. Epi-X is a secure, web-based communications network for public health professionals, managed by the Centers for Disease Control and Prevention (CDC). It facilitates public health information exchange between CDC, state and local health departments, poison control centers, and other public health professionals.

- Health Alert Network (HAN). HAN is CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

- Morbidity and Mortality Weekly Report (MMWR). MMWR is a scientific publication and CDC's primary way of providing timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations.

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- National Biosurveillance Integration Center (NBIC) . NBIC integrates, analyzes, and shares the nation's biosurveillance information among Department of Homeland Security (DHS) components. This information enables early warning and shared situational awareness of biological events so that critical decisions directing response and recovery efforts are well-informed and, ultimately, save lives.

- Homeland Security Information Network (HSIN). HSIN is a user-driven, web-based unclassified information sharing platform that connects all homeland security mission partners. The HSIN web-portal makes it possible for all levels of government to share sensitive but unclassified information, in support of the homeland security mission. The HSIN portal brings together homeland security partners across the spectrum from law enforcement, critical infrastructure, emergency management, and fire and emergency services to public health, intelligence, and defense.

- The Program for Monitoring Emerging Infectious Diseases (ProMED)-mail. ProMed-mail is an internet-based reporting system, sponsored by the International Society for Infectious Diseases, dedicated to rapid global dissemination of information on outbreaks of infectious diseases and acute exposures to toxins that affect human health, including those in animals and in plants grown for food or animal feed. Electronic communications enable ProMED-mail to provide up-to-date and reliable news about threats to human, animal, and food plant health around the world.

- WHO Disease Outbreak News (DONs). The World Health Organization (WHO) disseminates DONs to provide public information about officially confirmed outbreaks of international importance.

- WHO Weekly Epidemiological Record (WER). The WER serves as an essential instrument for the rapid and accurate dissemination of epidemiological information on cases and outbreaks of diseases under the International Health Regulations and on other communicable diseases of public health importance, including emerging or re-emerging infections.

- Pan American Health Organization (PAHO) Epidemiological Alerts and Updates. PAHO's epidemiological alerts and updates are released to provide information about the occurrence of international public health events confirmed by member states, as well as share recommendations issued by PAHO. Updates are released as new information becomes available regarding events previously shared through epidemiological alerts. These releases complement the WHO DONs.

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- Pan American Health Organization (PAHO) Situation Reports. Situation Reports are issued by PAHO to provide updates on international public health responses.

VI. Program Monitoring

PHSP Unit staff periodically request information from health staff to monitor surveillance and reporting activities, and obtain information required for reporting and notification with public health entities. The HSA, FHPM, and IPO should facilitate prompt completion of information requests.

VII. Training and Education

The HSA, FHPM, IPO, or designee should ensure that orientation and annual training include surveillance and reporting procedures is implemented and documented in accordance with IHSC directive 01-04*, Medical Education and Development.*

VIII. Privacy and Recordkeeping

Please refer to IHSC directive 05-06, *Infectious Disease Public Health Actions* for guidance on complying with privacy and recordkeeping procedures.

IX. References and Resources

1. IHSC eCW User Guide: TB Case Management.
2. IHSC directive 05-11, Public Health Actions for Tuberculosis Care.
3. IHSC 05-11-G-01, Public Health Actions for Tuberculosis Care Guide: IHSC-Staffed Detention Facilities.
4. Arizona Department of Health Services - Communicable Disease Reporting.
5. California Department of Public Health - Reportable Diseases and Conditions.
6. Florida Department of Health - Disease Reporting Information for Health Care Providers and Laboratories.
7. Georgia Department of Public Health - Disease Reporting.
8. Louisiana Department of Health and Hospitals - Infectious Disease Epidemiology Program.
9. New Jersey Department of Health - Infectious and Zoonotic Disease Program.
10. New York State Department of Health - Communicable Disease Reporting.
11. Pennsylvania Department of Health - List of Reportable Diseases.
12. Texas Department of State Health Services - Notifiable Conditions.

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13. Virginia Department of Health - Surveillance and Investigation.
14. Washington State Department of Health - Notifiable Conditions.

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U.S. Immigration and Customs Enforcement

ICE Health Service Corps (IHSC)
Enforcement and Removal Operations
U.S. Immigration and Customs Enforcement

Infectious Disease Public Health Actions Guide: Zika Virus

Approved by: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) **DHSc**

Title: ERO IHSC AD

Effective Date: June 7, 2019

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Foreword

This *Infectious Disease Public Health Actions Guide: Zika Virus* supplements the following IHSC Directive:

- IHSC Directive: 05-06, *Infectious Disease Public Health Actions.*

This Guide explains concepts, assigns responsibilities and details procedures for public health actions for prevention of and screening for Zika virus.

The intended audience is IHSC-staffed medical clinics supporting health care operations in ICE-owned or contracted detention facilities.

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I. Overview

A. Purpose

This Guide explains concepts, assigns responsibilities and details procedures for public health actions for prevention of and screening for Zika virus.

B. Responsibilities

Health Services Administrator (HSA), Field Healthcare Program Manager (FHPM), and Infection Prevention Officer (IPO)

- Responsible for ensuring implementation, accountability, and oversight of Public Health, Safety, and Preparedness (PHSP) activities in the medical and dental clinics, including public health actions for the prevention of and screening for Zika virus.
- Serves as a key liaison with PHSP Unit staff.
- Report Zika virus to the health department in accordance with applicable local and state laws.

Medical Providers

- Oversee and implement screening and testing of detainees with risk factors for Zika virus exposure and signs or symptoms of Zika.
- Report Zika to the health department in accordance with applicable local and state laws.

Health Staff

- Implement infection prevention and control measures for IHSC staff to prevent mosquito bites in accordance with applicable guidelines.
- Maintain knowledge about infection prevention and control measures applicable to work duties.

Public Health, Safety, and Preparedness Unit Staff

- Provide technical guidance on activities related to public health actions for Zika virus.

IHSC Infectious Disease Consultant

- Provide technical guidance related to clinical management and public health actions for Zika virus.

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C. Epidemiology of Zika Virus

- Zika is spread mostly by the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*). These mosquitoes bite during the day and night.
- Zika can be passed through sexual intercourse from a person with Zika to his or her partners.
- Zika can be passed from a pregnant woman to her fetus. Infection during pregnancy can cause certain birth defects.
- There is no vaccine or medicine for Zika.
- Local mosquito-borne Zika virus transmission has been reported in multiple countries and territories, and in the continental United States.
- Health staff must maintain awareness of the most current listing of areas with active Zika virus transmission; see Areas with Risk of Zika virus | CDC.
- See Zika Virus | CDC for the most current information.

D. Expanded Definitions

Exposure – The condition of being subjected to something (noise, dust, chemicals, radiation, infectious agents) that could have an adverse health effect.

Infection – Invasion and growth of an infectious microorganism, such as a bacterium or virus, in the body. Infection can also refer to the disease caused by the infectious microorganism.

Infection control – Institutional procedures and policies for monitoring and attempting to control the transmission of communicable diseases.

Infectious disease public health actions – a broad range of public health activities and interventions to promote and protect health, and prevent or mitigate infectious disease transmission.

Personal protective equipment (PPE) – Equipment that protects a person from hazardous exposures such as chemicals, dust, noise, radiation, infectious diseases and includes respirators, gloves, mask, goggles, gowns, face shields, ear plugs, hard hats, and steel toe boots.

Standard precautions – Infection prevention practices, including hand hygiene, that apply to all patients regardless of infectious status. Standard precautions are a

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combination and expansion of Universal Precautions and Body Substance Isolation, based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes contain transmissible infectious agents. Standard precautions include hand hygiene, and depending on the anticipated exposure, use of gloves, gown, mask, eye protection, or face shield. Equipment or items in the patient environment likely to have been contaminated with infectious fluids must be handled in a manner to prevent transmission of infectious agents, (e.g., wear gloves for handling, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).

Surveillance – The timely, continuous, systematic collection, analysis and interpretation of health-related data for informing urgent and routine public health activities, including public health interventions; contact and outbreak investigations; evidence-based decision making; and planning, implementation, and evaluation of public health practices.

Transmission – Any mode or mechanism by which an infectious agent is spread to a susceptible host.

II. Procedures

A. Screening, Testing, and Clinical Care

- Health staff must follow usual protocols to screen for pregnancy among all females aged 10 to 56 years.

- Medical providers must screen pregnant women for travel from or through a country or area with Zika virus during their pregnancy as part of the Physical Exam-Complex (PE-C); see Areas with Risk of Zika virus | CDC. If pertinent travel history is obtained, the provider must also screen them for symptoms consistent with Zika virus infection in the past two weeks or any time during the pregnancy (not currently ill, but had symptoms previously); see Appendix A: Zika Virus Disease Screening Algorithm.

- Health staff must ensure that all pregnant women, including those from countries, territories, and areas with active Zika virus transmission, continue to receive standard prenatal care, including ultrasonography, during the time they are in custody. Health staff must document relevant travel risk in the consult request.

- The medical provider must utilize the eClinicalWorks (eCW) template with specific Zika questions in the PE-C for pregnant detainees/residents for the duration of this epidemic.

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- The medical provider should promptly test for Zika virus in pregnant detainees/residents with symptoms consistent with Zika and travel from or through countries, territories, or areas with active Zika virus transmission at any time during her pregnancy. See Testing Guidance | Zika Virus | CDC.

- Medical providers should reference Pan American Health Organization (PAHO)/ World Health Organization (WHO) PAHO/WHO | Provisional considerations for the care of pregnant women in settings with high Zika virus circulation: document for health care professionals, including the following recommendations:

  - All pregnant women should have regular prenatal care and be asked about symptoms consistent with Zika at the initial physical exam (PE-C) and any subsequent visits.

  - Those with suspected current Zika virus infection should have doppler tones from 14 weeks on (or ask about fetal monitoring 20 weeks and on), an ultrasound to measure uterine size, amniotic fluid, fetal anatomy including head circumference as soon as "Zika virus infection is suspected," which should trigger a referral to an obstetrician that occurs at the time of the PE-C.

    - Refer to an obstetrician for counseling and ultrasonography, preferably within 7 days of entering custody and Zika virus testing. If anatomically normal, or if negative, continue scheduling ultrasounds per routine schedules. If testing is positive, perform ultrasound at 18-20 weeks and 28-30 weeks; if there are any abnormalities found, the mother should be sent to complicated obstetrics for additional testing and counseling.

  - Those who are asymptomatic at the time of PE-C yet give a history of Zika-like illness at an earlier time during the pregnancy should be referred to Obstetrics for urgent ultrasonography (ideally within 7 days of PE-C). If anatomical abnormalities are found, a referral to Complicated Obstetrics should follow promptly.

  - Those without suspected Zika virus infection (i.e., no history of symptoms) should have a morphological ultrasound at 18–22 weeks; if normal, the next ultrasound should be scheduled at 28–30 weeks; if normal, follow national standards; if abnormalities are found, further guidance and testing as dictated by Complicated Obstetrics.

- A medical provider should consider submitting testing for Zika virus for non-pregnant detainees and residents (female or male) presenting with clinical illness consistent with Zika and history of relevant travel or possible sexual exposure with a partner who has a relevant travel history, including one or

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more of the following signs or symptoms: acute onset of fever, rash, arthralgia, myalgia, headache, or conjunctivitis. Testing method and timing is dependent on symptom onset; see Testing Guidance | Zika Virus | CDC.

- Medical providers should contact the Clinical Director, Regional Clinical Director, or National Infectious Disease Consultant for advice on further clinical evaluation to exclude other pertinent infections; see also Testing Guidance | Zika Virus | CDC.

B. Patient Education

- A medical provider or nurse should educate all pregnant females on Zika virus and prevention methods; see available Fact Sheets and Posters | Zika virus | CDC and WHO | Zika Virus Fact Sheets in multiple languages.

- Prior to release from custody, health staff must provide pregnant women with contact information for obstetrical health care resources in the community she will be released to as potential options to facilitate ongoing prenatal care.

- In accordance with CDC Clinical Guidance (Exposure, Testing & Risks | Zika and Pregnancy | CDC and Reproductive Planning | Zika and Pregnancy | CDC).

- IHSC health care staff should educate women detained in areas at risk for Zika virus transmission or who will reside in such areas following release regarding the risks of Zika-affected pregnancy. The women will be advised that contraception may be initiated while detained to prevent an unintended pregnancy that may be affected by the Zika virus.

C. Prevention and Control Measures

- IHSC staff must maintain attentiveness to practicing standard precautions with all detainees/residents, including frequent hand hygiene. No additional personal protective equipment (PPE) or transmission-based precautions are required when examining detainees/residents with suspected Zika.

- For spaces occupied during intake screening medical evaluations, IHSC staff must ensure routine cleaning and disinfection protocols are implemented.

- Health staff must maintain awareness of measures to prevent occupational exposure to Zika virus, including minimizing unprotected outdoor exposure in areas experiencing mosquito-borne Zika virus transmission, using Environmental Protection Agency (EPA)-registered insect repellents, and adhering with occupational health and safety protocols to prevent bloodborne pathogen exposures and sharps injuries; see also PHSP Unit SharePoint | Occupational Health | Official Guidance and PHSP Unit SharePoint | Safety

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& Security | Official Guidance. IHSC authorizes procurement of Environmental Protection Agency (EPA)-registered insect repellents for IHSC staff occupational use during the Zika virus epidemic.

III. Surveillance and Reporting

A. Surveillance

The Public Health, Safety, and Preparedness (PHSP) Unit staff monitor the number of detainees diagnosed with Zika at IHSC-staffed medical clinics using the electronic health record reporting tools. To ensure the accuracy of information, it is important that medical providers use the appropriate ICD codes. For more information refer to 05-06-G-03 *Infectious Disease Public Health Actions Guide: Surveillance and Reporting* located in the IHSC policy library.

B. Reporting

All medical providers must maintain awareness of the most current Zika Virus Disease and Zika Virus, Congenital Infection | 2016 Case Definition for reporting and documentation.

A medical provider or designated health staff must report verified cases of Zika to the local health department in accordance with health department-established protocols. For more information refer to 05-06-G-03 *Infectious Disease Public Health Actions Guide: Surveillance and Reporting*.

IV. Program Monitoring

PHSP Unit staff monitor Zika virus information using the electronic health record reporting tools. PHSP Unit staff periodically request information from health staff to monitor public health actions for the management of Zika virus at IHSC-staffed medical clinics.

V. Training

The HSA or designee should ensure that orientation and annual training that includes infection prevention and control in accordance with *01-04 Medical Education and Development* located in the IHSC policy library.

VI. Privacy and Recordkeeping

Please refer to 05-06, *Infectious Disease Public Health Actions* for guidance on complying with privacy and recordkeeping procedures.

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VII. References and Resources

1. Areas with Risk of Zika virus | CDC
2. PAHO/WHO | Provisional considerations for the care of pregnant women in settings with high Zika virus circulation: document for health care professionals
3. For Health Care Providers | Zika virus | CDC
4. Resources & Publications | Zika virus | CDC
5. CDC MMWR | Zika Reports
6. Zika Travel Information | Travelers' Health | CDC
7. IHSC Zika Virus Tools and Resources
8. Clinical Guidance for Healthcare Providers Caring for Pregnant Women | CDC
9. Reproductive Planning | Zika and Pregnancy | CDC
10. Zika Virus Disease and Zika Virus, Congenital Infection | 2016 Case Definition
11. Exposure, Testing & Risks | Zika and Pregnancy | CDC
12. Patient Counseling | Couples Trying to Conceive | Zika and Pregnancy | NCBDDD | CDC
13. PHSP Unit SharePoint | Occupational Health | Official Guidance
14. PHSP Unit SharePoint | Safety & Security | Official Guidance
15. Insect Repellents: Reducing Insect Bites | US EPA
16. Prevent Mosquito Bites | Zika virus | CDC
17. WHO | Zika

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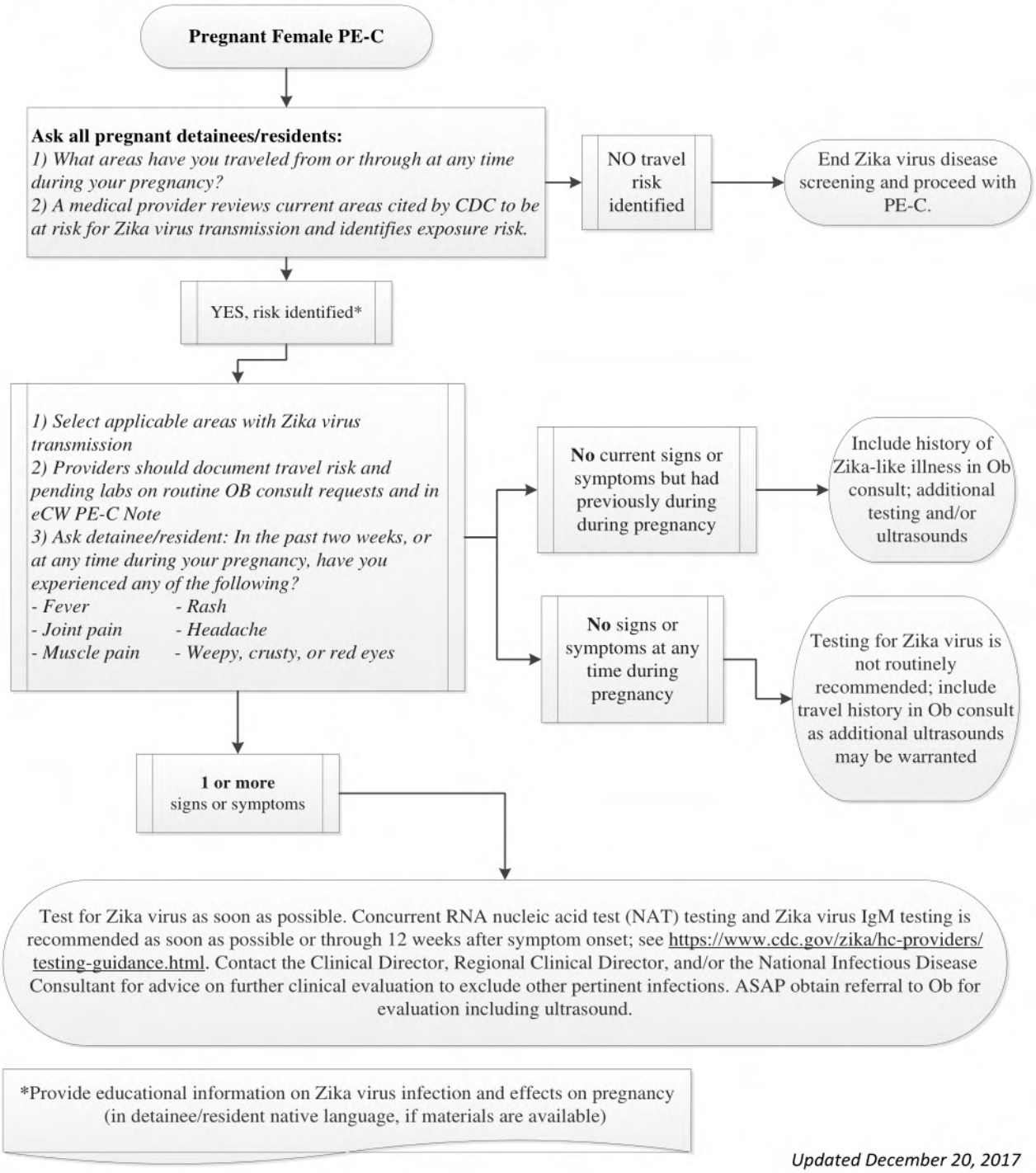
Appendix A: IHSC Zika Virus Disease Screening Algorithm

IHSC Zika Virus Disease Screening Algorithm

Health staff must ensure that all pregnant women, including those traveling from or through areas with active Zika virus transmission, receive standard prenatal care including ultrasonography, during the time they are in custody. Health staff must provide contact information for appropriate local obstetrical services for all pregnant detainees/residents released with instructions to schedule an appointment with a provider in the next 2 weeks.



Updated December 20, 2017

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Immigration and Customs Enforcement
Washington, DC 20536

ICE
ICE Health Service Corps

Mumps Reference Sheet

Last updated July 16, 2019

Highlights

- IHSC recommends that if one or more detainee is identified with RT-PCR or viral culture-confirmed mumps, all exposed detainees be promptly offered MMR vaccination unless contraindicated.
- Vaccination of non-exposed detainees should be considered if resources allow.
- MMR vaccines administered should be documented in the immunization and therapeutic injection section of the health record AND on medical transfer summaries.
- IHSC recommends a second MMR dose after 28 days if possible.
- IHSC recommends that detainees be released from cohorting after receiving two documented doses of MMR (at least 28 days apart) while in custody and completion of a 25-day cohorting period following initial exposure.
- If a detainee has medical documentation of two doses of MMR in the U.S., or in the country of nationality after 1998, he or she may be released from cohorting after one dose of MMR while in custody.
- Detainees that receive two doses of MMR while in custody, or an MMR booster with documentation of two doses of MMR as specified above, should not be cohorted following subsequent exposures.
- IHSC does not recommend any restrictions or precautions for detainees exposed to an asymptomatic detainee who was exposed to a person with confirmed, probable, or suspected mumps, i.e., exposed to exposed do not require housing or transport restrictions.
- Health staff and Field Medical Coordinators (FMCs) should track information for detainees with confirmed, probable, or suspected mumps using the IHSC Mumps Tracking Tool available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page.
- Health staff and FMCs should document cohorting using the IHSC Cohort Tracking Tool available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page for weekly reporting of new cohorted housing units and updating information on existing cohorted housing units.

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What is mumps?
Mumps is a virus that often causes pain, tenderness, and swelling in one or both parotid salivary glands (parotitis) and/or reproductive organs (testes, ovaries). See case definition on page three.‡

Symptoms
Symptoms include swelling in front of or right below the ear, orchitis, and/or oophoritis; prodromal symptoms include fever, malaise, loss of appetite, headache, myalgia in about 66 percent of patients. Approximately 33 percent of those with mumps may have no signs of infection or only mild upper respiratory infection symptoms such as cough and runny nose.

How long does it last?
Prodromal symptoms usually occur for three to four days before onset of parotitis; the swelling usually peaks one to three days and, in some cases, the parotitis lasts longer than ten days.

Incubation period
The incubation period (time between exposure to and appearance of symptoms) ranges from 12 to 25 days with the average incubation period being 16 to 18 days.

Communicability
Mumps is generally considered contagious from two days before the onset of parotitis or swelling to five days after the onset of parotitis. However, if health histories are unreliable, detainees with mumps could be considered contagious for five days prior to the onset of parotitis to between five and nine days following. The mumps virus is spread by contact with infected respiratory secretions.

Precautions
Droplet precautions should be implemented. Those who are suspected of having mumps should wear a mask while sitting in waiting rooms and wait times should be minimized. Airborne infection isolation is not required.

Cleaning and disinfection
Routine procedures for cleaning and disinfecting exam rooms and equipment are recommended.

Potential complications
Orchitis (i.e., inflammation of the testes) occurs in 3 to 10 percent of post pubertal males. Oophoritis (i.e., inflammation of the ovary), meningitis, mastitis (i.e., inflammation of the mammary gland), encephalopathy, pancreatitis, permanent deafness, sterility, and death are rare but can occur.

Pregnancy and mumps
There is a theoretical risk that mumps during early pregnancy (first trimester) may cause complications or miscarriage, but current data are inconclusive.

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Management of detainees with confirmed, probable, or suspected mumps

- Symptoms of mumps include the following:
  - Facial and, or, neck/jaw lymph node swelling, and, or, pain
  - Runny nose
  - Cough
  - Headache
  - Loss of appetite
  - Testicular pain, or swelling in males
  - Lower abdominal pain in females
  - Feeling feverish
- A detainee with symptoms of mumps should be isolated—alone if possible—for at least nine days after the onset of symptoms or until infection is ruled out.
- Droplet precautions should be implemented including appropriate signage.
- Health staff should promptly notify the local or state health department at the earliest identification of a detainee with suspected mumps.
- Detainees with symptoms of mumps should immediately be tested by collecting salivary specimens for reverse transcription polymerase chain reaction (RT-PCR); viral culture is acceptable if PCR is not available. Urine specimens may also be useful if the patient has orchitis/oophoritis, mastitis, pancreatitis, hearing loss, meningitis, or encephalitis.
  - This short video demonstrates how to correctly collect and transport a buccal swab (the preferred sample) for the detection of mumps virus RNA. Staff should wear gloves when massaging and swabbing the parotid gland.
  - Specimen labels must include first AND last names as well as the time and date of collection.
- Health staff should coordinate sending buccal fluid (salivary) specimens to the state public health lab to expedite processing and public health interventions. LabCorp does not have mumps RT-PCR testing available but does have the capability to perform mumps virus culture as an alternative to confirmatory PCR.
- Centers for Disease Control and Prevention (CDC) recommendations on mumps laboratory testing are available at:
  - Illustration of parotid gland and instructions for collection of buccal fluid, and
  - Specimen collection, storage, and shipment.
- If an outbreak (defined as 3 or more cases linked by time and place) is established at the facility among detainees with laboratory-confirmed mumps, if detainees with classic symptoms of mumps (i.e., parotitis or orchitis) have known exposure associated with transmission at the facility, confirmatory testing may be deferred and the patient should be classified as "probable mumps (epi-linked)."
  - Known exposure associated with transmission at the facility includes detainees that develop symptoms and their entire calculated exposure period occurred after the period of known contact with person identified at the facility with confirmed or probable mumps.
  - Detainees with less convincing symptoms (e.g., upper respiratory and/or constitutional symptoms) should have confirmatory testing.
- Detainees with suspected or confirmed mumps should be tested for Human Immunodeficiency Virus (HIV) if status is not already known.
- Health staff and Field Medical Coordinators (FMCs) should track information for detainees with confirmed, probable, or suspected mumps using the IHSC Mumps Tracking Tool available on

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the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page. See also the public health investigation calculator tool.

Movement of detainees with confirmed, probable or suspected mumps during the contagious period

- Symptomatic detainees can be transferred to other facilities only if:
  - the receiving facility is notified in advance,
  - has capability to maintain droplet precautions,
  - a surgical mask is placed on the ill detainee when in close contact with others, and
  - staff promptly notify the local or state health department of the transfer and destination if known.

Release of detainees with confirmed, probable or suspected mumps during the contagious period

- If symptomatic detainees must be released from custody (e.g., if ICE no longer has authority to detain the individual) during the contagious period, health staff should:
  - ascertain the anticipated address, telephone numbers, and mode of transport to the intended destination;
  - notify the local or state health department prior to the anticipated release date of the scheduled release, anticipated completion date of the contagious period, address, telephone numbers, and mode of transport to the intended destination;
  - accommodate health department requests to interview the patient;
  - educate the patient to:
    - not share food, drinks, utensils, or toothbrushes;
    - cover their mouths and nose when sneezing or coughing; and
    - wash hands frequently
- Health staff should recommend to ERO that symptomatic detainees are not safe for transport on public or charter air transport until after the end of the contagious period.

Management of ASYMPTOMATIC detainees who were directly exposed to a person with confirmed, probable, or suspected mumps:

- Health staff should promptly notify the local or state health department at the earliest awareness of detainees having been exposed to suspected, probable, or confirmed mumps at any location in the prior 25 days.
- Exposed detainees should be cohorted with restricted movement until 25 days have passed after most recent exposure to a patient with confirmed mumps infection.
- Health staff should track demographic and exposure management information for detainees exposed to confirmed, probable, or suspected mumps using the mumps contact investigation tracking sheet (exposed cohort tabs) available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page. Contact investigation tracking sheets may be maintained locally See also the public health investigation calculator tool.
- Health staff and FMCs should document cohorting using the IHSC Cohort Tracking Tool available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page for weekly reporting of new cohorted housing units and updating information on existing cohorted housing units.

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- Exposed detainees should be monitored daily for new onset of symptoms; if symptoms are reported or observed, the detainee should be promptly referred to a medical provider for evaluation.
- The CDC does not recommend post exposure mumps serology (IgG or IgM) as it does not necessarily predict the presence of neutralizing antibodies or protection from mumps disease.
- Exposed detainees that are pregnant or immunocompromised should be housed individually, separately from the cohorted unit if possible.
- If there is known exposure to at least one patient with RT-PCR or viral culture-confirmed mumps at the facility the Clinical Director or designee should order the measles, mumps, and rubella (MMR) vaccination for exposed detainees without contraindications. A second dose of MMR vaccine is recommended to be administered 28 days after the first dose, if possible.
  - MMR vaccine is contraindicated for pregnant females
  - MMR vaccine is contraindicated for individuals known or suspected to be HIV positive with CD4 counts and percentage below 200 and 15 percent, respectively.
    - For detainees known or suspected to be HIV positive defer immunization until HIV infection can be confirmed or excluded and if HIV positive, until their CD4 count and percent can be enumerated.
    - HIV infected persons can be immunized with MMR following established immunization guidelines (eligible if their absolute CD4 counts are above 200 and percent above 15).
  - Vaccination does not shorten the incubation period and is not effective as post-exposure prophylaxis.
- Vaccination of non-exposed detainees should be considered if resources allow.
- MMR vaccines administered should be documented in the immunization and therapeutic injection section of the health record AND on medical transfer summaries.
- IHSC recommends that detainees be released from cohorting after receiving two documented doses of MMR (at least 28 days apart) while in custody and completion of a 25 day cohorting period following exposure.
  - If a detainee has medical documentation of two doses of MMR in the U.S., or in the country of nationality after 1998, he or she may be released from cohorting after one dose of MMR while in custody.
  - Detainees that receive two doses of MMR while in custody, or an MMR booster with documentation of two doses of MMR as specified above, should not be cohorted following subsequent exposures.
- Exposed detainees should be educated to do the following during the incubation period:
  - not share food, drinks, utensils, or toothbrushes;
  - cover their mouths and nose when sneezing or coughing;
  - wash hands frequently; and
  - seek medical care if they develop symptoms related to mumps.
- Given the ongoing epidemic of mumps in Central America, and the great likelihood of new infected patients entering detention facilities for an unknown period of time, consider providing educational messaging to all detainees in the facility (not only those in cohorted units) via signage and/or town hall announcements.

Movement of asymptomatic, directly exposed detainees during the incubation and cohort periods:

- Exposed, asymptomatic detainees may be transported or transferred if they do not have symptoms and the receiving facility agrees to continue to cohort in separate housing for the remainder of the incubation period.

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- Exposed, asymptomatic detainees may be cleared for visitation, medical appointments, and/or court.
- Co-mingling with non-exposed detainees in situations where contact with respiratory secretions is likely should be discouraged (e.g., recreation, dining).
- Exposed, asymptomatic detainees that are cohorted may be released or removed by any mode of transport with no other restrictions and should be educated to do the following for the remainder of the incubation period:
  - not share food, drinks, utensils, or toothbrushes;
  - cover their mouths and nose when sneezing or coughing;
  - wash hands frequently; and
  - seek medical care if they develop symptoms related to mumps.
- Health staff should notify the local or state health department of exposed detainees that are transferred, released, or removed and of the destination if known.

Considerations for detainees exposed to an exposed person

- For detainees that are exposed to an asymptomatic detainee who was exposed to a person with confirmed, probable, or suspected mumps:
  - no restrictions on housing or movement are recommended
  - no transmission-based precautions are recommended

Staff considerations

- Staff should consult with their employer's occupational health and safety program for guidance and messaging.
- Staff with visible or observed symptoms should be advised to seek health care services immediately through their personal health care provider or employer's occupational health program.
- Symptomatic staff should stay out of workplace for at least nine days or until mumps infection is ruled out.
  - Supervisors should use available administrative protocols to facilitate excluding staff with symptoms of mumps from the workplace, including use of leave and/or telework as permissible per employer personnel policies.
- Staff should consider having their presumptive immunity (pre-exposure)§ verified through their personal MMR vaccination and medical records and discuss with their personal medical provider whether a booster MMR dose is indicated.
- Staff without documented presumptive immunity (pre-exposure) who work in proximity with cohorted, or isolated detainees, should consider MMR vaccination through their personal health care provider or employer's occupational health program, or limit contact to cohorted areas.
- Staff with partial immunity (i.e., the staff did not receive two doses of MMR vaccine), should consider receiving a booster dose of the vaccine. For outbreak management, three MMR doses are recommended.

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‡Mumps Case Definition (CDC, National Notifiable Diseases Surveillance System)

Suspected

- Parotitis, acute salivary gland swelling, orchitis, or oophoritis unexplained by another more likely diagnosis, or
- A positive lab result with no mumps symptoms (i.e., with or without epidemiological-linkage to a confirmed or probable case).

Probable

Acute parotitis or other salivary gland swelling lasting at least two days, orchitis, or oophoritis unexplained by another more likely diagnosis in:

- A person with a positive test for serum anti-mumps immunoglobulin M (IgM) antibody, or
- A person with epidemiologic linkage to another probable, confirmed case, or linkage to a group/community defined by public health during an outbreak of mumps.

Confirmed

- A positive mumps laboratory confirmation for mumps virus with reverse transcription polymerase chain reaction (RT-PCR) or culture in a patient with an acute illness characterized by any of the following:
- Acute parotitis or other salivary gland swelling, lasting at least two days;
- Aseptic meningitis;
- Encephalitis;
- Hearing loss;
- Orchitis;
- Oophoritis;
- Mastitis; or
- Pancreatitis.

§ Presumptive Immunity

Staff are considered presumptively immune if they have any of the following:

- Written documentation of vaccination with two doses of live mumps or MMR vaccine administered at least 28 days apart,
- Laboratory evidence of immunity (prior to exposure),
- Laboratory confirmation of mumps disease (RT-PCR or culture), or
- Birth before 1957.

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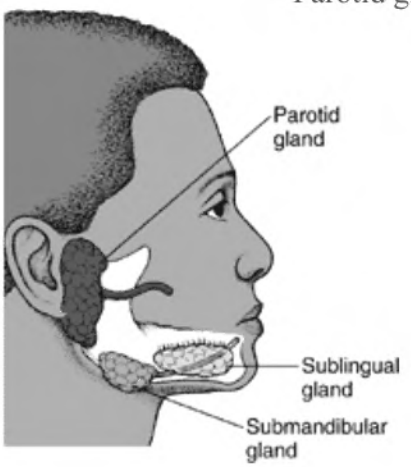
Parotid gland location



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Appendix A: Checklist
for Management of Detainees with Confirmed, Suspected, or Probable Mumps

Management of detainees with confirmed, probable, or suspected mumps	
☐	Notify local or state health department
☐	Detainee is isolated on droplet precautions for 9 days AFTER onset of symptoms (i.e., until the end of the contagious period) or until infection is ruled out
☐	Collect buccal swab and urine for RT-PCR (preferred) or viral culture (if RT-PCR is not available) or document if known to be epidemiologically-linked to transmission at the facility among detainees with laboratory-confirmed mumps
☐	Test for HIV if status is not known
☐	Test females for pregnancy if status is not known
☐	Health staff and Field Medical Coordinators (FMCs) should track information for detainees with confirmed, probable, or suspected mumps using the IHSC Mumps Tracking Tool available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page. See also the public health investigation calculator tool.
Movement of detainees with confirmed, probable, or suspected mumps during the contagious period	
☐	Notify the receiving facility of the detainee with confirmed, probable, or suspected mumps
☐	Affirm that the receiving facility has the ability to maintain droplet precautions for the remainder of the contagious period
☐	Recommend that detainee should be transported wearing a surgical mask
☐	Notify the local or state health department if the detainee transfers and of the destination if known

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Appendix B: Checklist
for Management of Detainees Exposed to Confirmed, Suspected, or Probable Mumps

Management of asymptomatic detainees exposed to confirmed, probable, or suspected mumps	
☐	Notify the local or state health department
☐	Recommend to facility administrators that the exposed detainees be cohorted with restricted movement for 25 days after LAST exposure
☐	Enter an initial encounter in the medical record noting the exposure to mumps, lack of symptoms, that daily monitoring will be done, and the duration of the cohorting period.
☐	Obtain HIV test for individual detainees if HIV infection is suspected.
☐	If detainee is HIV positive, enumerate CD4 count and percent
☐	If there is known exposure to one or more persons with RT-PCR or viral culture-confirmed mumps, the Clinical Director or designee should order MMR vaccine for detainees if not contraindicated (MMR vaccine is contraindicated in pregnant females and HIV positive individuals with CD4 <200 and/or CD4% <15). A second MMR dose should be administered 28 days after the first dose.
☐	Implement daily monitoring for symptoms of mumps
☐	If symptoms are reported or observed; refer the detainee to a medical provider for evaluation
☐	Detainees may be released from cohorting after receiving two documented doses of MMR (at least 28 days apart) while in custody and completion of a 25 day cohorting period following exposure.
☐	At the end of the cohorting period, enter an encounter in the medical record noting the end of the cohorting period and absence of symptoms in the individual for the duration of observation (or other outcome).
☐	Health staff and FMCs should document cohorting using the IHSC Cohort Tracking Tool available on the Public Health, Safety, and Preparedness (PHSP) Unit SharePoint page for weekly reporting of new cohorted housing units and updating information on existing cohorted housing units.
Movement of asymptomatic detainees exposed to confirmed, probable, or suspected mumps during the incubation and cohorting periods	
☐	Notify the receiving facility of the need for cohorting with restricted movement and will continue the cohorting for the remainder of the incubation and cohorting periods
☐	Affirm that the receiving facility will continue the cohorting for the remainder of the incubation and cohorting periods
☐	Educate the detainee on prevention methods
☐	Educate detainees scheduled for release or removal to recognize symptoms
☐	Educate detainees to seek medical care if they notice symptoms
☐	Notify the local or state health department if exposed detainees are transferred, released, or removed and of the destination if known

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Appendix C: Specimen collection job aid



Suspect MUMPS?

Wait! This patient might not need to be tested if they are linked to another mumps patient or outbreak. Refer to outbreak guidance from *Health Department Name*

See short video demonstrating how to correctly collect and transport a buccal swab (the preferred sample) for the detection of mumps virus RNA.

Does patient have parotitis or other salivary gland swelling?

YES
Has it been ≤3 days since symptom onset?

NO
Does the patient have:
- orchitis/oophoritis,
- mastitis,
- pancreatitis,
- hearing loss,
- meningitis, or
- encephalitis?

YES
Collect a buccal specimen for RT-qPCR

NO
Collect a buccal specimen for RT-qPCR and serum specimen for IgM

YES
Collect a buccal and urine specimen for RT-qPCR and serum specimen for IgM

NO
Is patient part of a group at increased risk for mumps as defined by public health authorities?

(If applicable, include description of groups at increased risk here)

Labels MUST include FIRST AND LAST names

Is testing available at your facility?

YES — *Contact or shipping instructions*

NO — *Contact or shipping instructions*

Per your local or state health department

YES — Give MMR

NO — Make sure patient is up to date on MMR and educate on signs and symptoms

Health Department Contact information

CS296024-A

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Appendix D: Signage for facility entry

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Warning

- Some areas of this facility have had recent exposure to mumps.
- People entering this facility should consider having their presumptive immunity verified or measles, mumps, and rubella (MMR) vaccination and medical records confirmed through their personal health care provider, and discuss whether a booster MMR dose is indicated.
- There is a theoretical risk that mumps during early pregnancy may cause complications or miscarriage, but current data are inconclusive.
- Mumps is transmitted by moist respiratory droplets from a contagious person, such as a sneeze in the face, kissing, or sharing drinking containers or utensils.

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Atención

- Algunas areas de este centro han sido expuestas a paperas (parotitis).
- Las personas que entran a este centro deben considerar verificar su imunidad presuntiva o historial de vacunas contra sarampión, paperas, y rubella (MMR) con su proveedor médico y documentos medicos y discutir con su médico la necesidad de una tercera dosis de refuerzo de MMR.
- Theoricamente hay un riesgo que tener paperas durante la etapa temprana del embarazo puede causar complicaciones o aborto espontáneo, pero los datos no son concluyentes.
- Paperas se puede transmitir a través de la saliva o la mucosidad de la boca, nariz o garganta de una persona infectada cuando realiza lo siguiente:
  - besa, tose, estornuda o habla de cerca;
  - comparte artículos, como tazas o cubiertos, con los demás;
  - toca objetos o superficies con las manos sin lavar, que luego son tocadas por otras personas.

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Appendix E: Resources for detainees in English, Spanish, and Hindi

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PROTECT YOURSELF AGAINST MUMPS



MMR VACCINATION IS THE BEST WAY TO PREVENT MUMPS!

THERE IS NO TREATMENT FOR MUMPS IF YOU GET IT

KEEP FROM SPREADING MUMPS



Don't share things that have saliva on them



Cover your coughs and sneezes



Stay home when you are sick



Wash your hands often with soap and water



Clean and disinfect surfaces

SIGNS AND SYMPTOMS OF MUMPS



Mumps is best known for the puffy cheeks and swollen jaw that it causes.



Fever



Headache



Loss of appetite



Muscle aches



Tiredness

VACCINATION ALSO HELPS PREVENT MUMPS COMPLICATIONS



Complications can include swelling of the:

- testicles
- ovaries
- breasts
- pancreas
- brain
- spinal cord tissue

Distributed by:

U.S. Immigration and Customs Enforcement

If you feel sick, ask to go to medical

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CDC

DHS-ICE-19-1276-A-000764

CS302940 2019

PROTÉJASE CONTRA LAS PAPERAS



¡LA VACUNACIÓN CON LA MMR ES LA MEJOR MANERA DE PREVENIR LAS PAPERAS!

NO HAY TRATAMIENTO SI CONTRAE ESTA ENFERMEDAD

EVITE PROPAGAR LAS PAPERAS



No comparta cosas que tengan saliva.



Cúbrase la nariz y la boca al toser y estornudar.



Quédese en casa si está enfermo.



Lávese las manos con agua y jabón frecuentemente.



Limpie y desinfecte las superficies.

SIGNOS Y SÍNTOMAS DE LAS PAPERAS



El signo más conocido de las paperas es hinchazón de las mejillas y alrededor de la mandíbula.



Fiebre



Dolor de cabeza



Pérdida del apetito



Dolores musculares



Cansancio

LA VACUNACIÓN TAMBIÉN AYUDA A PREVENIR LAS COMPLICACIONES DE LAS PAPERAS



Las **complicaciones** pueden incluir inflamación de lo siguiente:

- testículos
- ovarios
- mamas (senos)
- páncreas
- cerebro
- tejido de la médula espinal

Distribuido por:

U.S. Immigration and Customs Enforcement

Si se siente enfermo, pide ir a la clínica médica

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अपने आपको गलगण्ड से सुरक्षित रखें



MMR टीकाकरण गलगण्ड की रोकथाम के लिए सबसे अच्छा तरीका है!

अगर आपको गलगण्ड होता है तो उसके लिए कोई उपचार नहीं है

गलगण्ड को फैलने से रोकें



उन चीजों को साझा न करें जिन पर लार है



अपनी खांसी और छींक को कवर करें



बीमार होने पर घर पर रहें



अपने हाथों को अक्सर साबुन और पानी से धोएँ

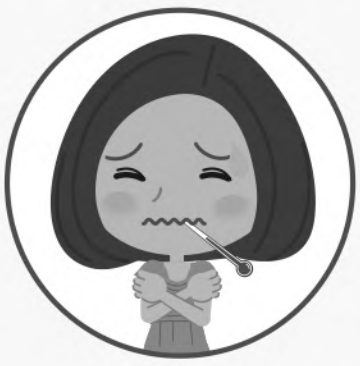


साफ और कीटाणुरहित सतहें

गलगण्ड के संकेत और लक्षण



फूले हुए गाल और सूजे हुए जबड़े से गलगण्ड को पहचाना जाता है जिसके कारण ये है



बुखार



सरदर्द



भूख की कमी



मांसपेशियों में दर्द



थकान

टीकाकरण गलगण्ड के कारण होने वाली जटिलताओं को रोकने में भी मदद करता है



जटिलताओं में इनकी सूजन शामिल हो सकती है:

- अंडकोष
- अंडाशय
- स्तन
- अग्न्याशय
- मस्तिष्क
- रीढ़ की हड्डी का ऊतक

यदि आपको लक्षण दिखाई देते हैं, तो घर में रहे और दूसरों से दूर रहें. अपने संस्थान के अपने डॉक्टर या स्वास्थ्य सेवाओं से संपर्क करें.

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U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT
ENFORCEMENT AND REMOVAL OPERATIONS
ICE HEALTH SERVICE CORPS

OCCUPATIONAL HEALTH

IHSC Directive: 05-02
ERO Directive Number: 11777.1
Federal Enterprise Architecture Number: 306-112-002b
Effective Date: April 25, 2018

By Order of the Assistant Director
(b)(6); (b)(7)(C) **DHSc, MPH**

(b)(6); (b)(7)(C)

1. **PURPOSE:** The purpose of this issuance is to set forth the policies for U.S. Immigration and Customs Enforcement (ICE) Health Service Corps (IHSC) concerning occupational health.

2. **APPLICABILITY:** This directive applies to all IHSC personnel, including, but not limited to, Public Health Service (PHS) officers, civil service employees, and contract personnel supporting health care operations in ICE-owned or contracted detention facilities, and to IHSC Headquarters (HQ) staff. Federal contractors are responsible for the management and discipline of their employees supporting IHSC.

3. **AUTHORITIES AND REFERENCES:**

   3-1. Title 8, Code of Federal Regulations, Section 235.3 (8 CFR § 235.3), Inadmissible Aliens and Expedited Removal.

   3-2. Section 232 of the Immigration and Nationality Act, as amended, Title 8, U.S. Code Section 1222 (8 U.S.C. § 1222), Detention of Aliens for Physical and Mental Examination.

   3-3. Title 8, Code of Federal Regulations, Part 232 (8 CFR 232), Detention of Aliens for Physical and Mental Examination.

   3-4. Section 322 of the Public Health Service Act, as amended, Title 42 U.S. Code, Section 249(a) (42 U.S.C. § 249(a)), Medical Care and Treatment of Quarantined and Detained Persons.

   3-5. Title 42, U.S. Code, Section 252 (42 U.S.C. § 252), Medical Examination of Aliens.

   3-6. The Privacy Act of 1974, Title 5, U.S. Code, Section 552 (a) (5 U.S.C. § 552(a)), as applied in the Department of Homeland Security (DHS)/ICE-

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013 Alien Health Records System of Records Notice, 80 Federal Register 239 (January 5, 2015).

3-7. Title 29, Code of Federal Regulations, Part 1960 (29 CFR 1960), Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters.

3-8. Title 29, Code of Federal Regulations, Section 1910.1030 (29 CFR § 1910.1030), Bloodborne Pathogens.

3-9. Executive Order 12196, Occupational Safety and Health Programs for Federal Employees.

3-10. Public Law 91-596, Occupational Safety and Health Act (OSH Act) of 1970.

3-11. DHS Directive: 066-01, Safety and Health Programs.

3-12. ICE, Occupational Safety and Health (OSH) Program Requirements Handbook.

3-13. DHS | Handbook for Safeguarding Sensitive Personally Identifiable Information.

4. POLICY: IHSC maintains an occupational health program that promotes workforce health, identifies job hazards, implements controls, and trains staff to promote their safety and well-being while at work. IHSC documents, monitors and evaluates workforce injuries and illnesses, and develops preventive and corrective actions. Health staff must adhere to federal occupational health regulations, as mandated by the Occupational Safety and Health Administration (OSHA), and all applicable DHS and ICE policies. IHSC collaborates with ICE field office collateral duty safety officers, and facility administrators, to promote a safe environment for all employees.

4-1. Workforce Health Program.

4-1.1 The health services administrator (HSA), with the assistance of the compliance officer (CO), must oversee workforce health activities within the medical clinic to include the following:

4-1.1.a Initial, annual, and periodic, tuberculosis (TB) infection screenings;

4-1.1.b Initial and ongoing monitoring of vaccination status;

4-1.1.c Monitoring workforce radiation exposure of health staff working with, or in areas where, radiation-emitting equipment is used;

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4-1.1.d Maintaining workforce health files, which must be kept separate from personnel files.

4-1.2 The HSA must perform an annual review of workforce health program requirements.

4-1.3 Health staff must accomplish workforce health program requirements through their usual source of medical care.

4-1.4 The HSA must ensure health staff awareness of workplace reproductive hazards and must provide information to health staff to share with their personal health care provider, if necessary.

4-1.5 The CO, HSA, assistant health services administrator (AHSA), and other designees, should facilitate completion of information requests for monitoring and following up on workforce health-related reports, interventions, and process improvements.

4-2. Bloodborne Pathogen Program.

4-2.1 Program requirements. The HSA, with the assistance of the CO, must oversee the bloodborne pathogens program (BBP), and must implement a medical clinic exposure control plan (ECP) that describes how occupational exposures to BBP and other potentially infectious material (OPIM) are controlled as mandated by the federal OSHA BBP standard.

4-2.2 Exposure control plan. The ECP includes, at a minimum, the following:

4-2.2.a A job hazard analysis (JHA);

4-2.2.b The communication of hazards to health staff; and

4-2.2.c Exposure control methods, which include:

- Standard precautions;
- Transmission-based precautions;
- Administrative controls;
- Engineering controls;
- Work practice controls;
- Personal protective equipment;

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- Housekeeping;
- Regulated waste;
- Cleaning and disinfection; and
- Blood and bodily fluid spill cleanup.

4-2.2.d Hepatitis B vaccination compliance;

4-2.2.e Post-exposure reporting, evaluation, and follow up; and

4-2.2.f Recordkeeping.

4-2.3 The HSA must ensure the ECP is accessible to all staff.

4-2.4 The HSA, or designee, must review and update the ECP annually and more frequently if deemed necessary.

4-3. Personal Protective Equipment Program.

4-3.1 The HSA, with the assistance of the CO, must oversee the personal protective equipment (PPE) program for the medical clinic to include:

4-3.1.a JHA;

4-3.1.b The selection, purchase, use, care, and disposal of PPE; and

4-3.1.c The training and documentation of the PPE program.

4-3.2 Health staff must adhere to the PPE program when performing assigned medical clinic duties as mandated by OSHA regulations.

4-4. Respiratory Protection Program.

4-4.1 The HSA, with the assistance of the CO, must oversee the respiratory protection program (RPP) for the medical clinic to include:

4-4.1.a Medical clearance for respirator use;

4-4.1.b Fit testing of respirators;

4-4.1.c The purchase, use, care, and replacement of respirators; and

4-4.1.d The training and documentation of the RPP.

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4-4.2 Health staff must adhere to RPP requirements when performing assigned clinic duties as mandated by OSHA regulations.

4-5. Occupational Injury and BBP Post-Exposure Management.

4-5.1 The HSA, with the assistance of the CO, must ensure that appropriate recommendations are provided to health staff for occupational injuries and post-exposure management, following exposure to HIV, hepatitis B, and hepatitis C.

4-5.2 Injury and post exposure reporting requirements. The HSA, CO, or designee must use the Public Health, Safety, and Preparedness (PHSP) Unit's workforce injury tool to report the occurrence of staff TB test conversions within seven working days, and must ensure the anonymity of the employee.

4-5.3 Investigative requirements. The HSA, CO, or designee, must investigate and track occupational injuries and BBP exposures across time to determine causes and uncontrolled hazards, and must develop preventive measures and corrective action plans.

4-5.4 Privacy requirement. The HSA must ensure that the injured staff's confidentiality is maintained during investigations of occupational injuries and illnesses.

4-5.5 Medical/injury referral. Health staff must be referred to their usual source of health care for any care other than lifesaving care.

4-6. Recording and Reporting Requirements for Employee Injuries, Illnesses, or Deaths.

4-6.1 Occupational illness and injury recording and reporting oversight. The HSA, with the assistance of the CO, must oversee all OSHA recording and reporting requirements for any occupational injury and illness occurring in the medical clinic.

4-6.2 Persons/entities responsible for recording and reporting. Consistent with OSHA regulations, the entity that provides day-to-day oversight of the work performed at a worksite is required to comply with OSHA recording and reporting requirements for all workers at the worksite. Therefore, the HSA, or CO, must record and report occupational injuries and illnesses for federal employees, and contract staff, in accordance with the specifications outlined in this directive, unless the contract employer supervisor works on-site. If the contract employer supervisor works on-site, the HSA should refer contract staff to their contract supervisor for recording and reporting of occupational injuries or illnesses.

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4-6.3 Privacy requirements. The HSA, and CO, must ensure employee confidentiality and must protect personally identifiable information (PII) when documenting health staff injuries and illnesses.

4-6.4 Reporting requirements for work-related deaths.

4-6.4.a The HSA must immediately notify the supervisor, who should continue immediate notifications through the supervisory chain to the IHSC assistant director (AD), via telephone, of all work-related deaths or deaths occurring within 30 days of a work-related injury.

4-6.4.b The HSA must notify the OSHA Area Office within 8 hours of a death that results from a work-related incident. The initial report to OSHA can be made verbally over the telephone, or in person, to the OSHA Area Office nearest to the site of the incident. If the OSHA Area Office is closed, the initial report to OSHA can also be made using their toll-free central telephone number at 1-800-321-6742. Only fatalities occurring within 30 days of the work-related incident must be reported to OSHA.

4-6.4.c If the incident resulting in death is entirely caused by non-work factors, then it is not work-related and is not required to be recorded in the OSHA records. If work contributed to the illness in some way, then it is work-related and must be evaluated for its recordability. When questionable, the incident must be reported to the local OSHA Area Office director who will decide whether or not to investigate the incident.

4-6.4.d The AD, or designee, must rapidly notify the ICE Safety and Sustainability division chief of a death that results from a work-related incident.

4-6.5 Reporting requirements for work-related injuries that result in inpatient hospitalizations, amputations, or the loss of an eye.

4-6.5.a The HSA must immediately notify the supervisor, who should continue immediate notifications through the supervisory chain to the AD, of all work-related injuries resulting in inpatient hospitalizations, amputations, or the loss of an eye within 24 hours.

4-6.5.b The HSA must notify the OSHA Area Office within 24 hours of an incident resulting in inpatient hospitalizations, amputations, or the loss of an eye.

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4-6.5.c The AD, or designee, must promptly notify the ICE Safety and Sustainability division chief of all work-related injuries or illnesses that result in inpatient hospitalizations, amputations, or the loss of an eye.

4-6.6 Recording requirements for occupational injuries, illnesses, or deaths.

4-6.6.a The HSA must document all work-related deaths, or work-related injuries, or illnesses that result in days away from work, restricted work or job transfer, loss of consciousness, medical treatment beyond first aid, or medical diagnosis resulting from a work-related exposure, illness, or injury on the Illnesses Incident Report (OSHA Form 301) as soon as possible, but no later than seven days after notification.

4-6.6.b The HSA, or CO, must document all recordable work-related deaths, or work-related injuries or illnesses, (per OSHA regulations) that result in days away from work, restricted work, job transfers, loss of consciousness, or medical treatment beyond first aid—or medical diagnosis resulting from a work-related exposure, illness, or injury—on the Workforce Injury Reporting Tool on the PHSP Unit's SharePoint page within seven working days of notification.

- The HSA, or CO, must mark records documenting illnesses or injuries meeting the above criteria as OSHA-recordable or OSHA-reportable.

- The Workforce Injury Reporting Tool can filter records marked as OSHA-recordable, or OSHA-reportable, to function on the Log of Work-Related Injuries and Illnesses form (OSHA Form 300).

4-6.7 Requirements for Annual Summary of Work-Related Injuries and Illnesses.

4-6.7.a The HSA, or CO, must compile all recordable work-related injuries, illnesses, and deaths into the Summary of Work-Related Injuries and Illnesses form (OSHA Form 300A) by December 31st of each year.

4-6.7.b The HSA, or CO, must post the OSHA Form 300A in a visible location in the medical clinic from February 1st until April 30th each year.

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4-6.7.c The HSA must send a copy of the OSHA Form 300A received from the medical clinic to PHSP Unit staff by January 15th each year.

4-6.8 OSHA record retention requirements. The HSA must keep the OSHA Forms 300, 301 and 301A in the IHSC-staffed medical clinic for five years.

4-7. PHSP Unit Oversight and Monitoring.

4-7.1 The PHSP Unit oversees and offers guidance on occupational health requirements.

4-7.2 In addition to routine information requests, the PHSP Unit periodically collects information from the medical clinics to monitor implementation of local occupational health requirements.

4-8. Orientation and Training.

4-8.1 The HSA, or designee, must ensure that orientation and annual training that includes occupational health is implemented and documented in accordance with IHSC Directive *01-04 Medical Education and Development*.

5. **PROCEDURES:** Detailed procedures, related to this directive, are found in the four guides listed below:

5-1. 05-02-G-01 Occupational Health Guide: Bloodborne Pathogens and Other Potentially Infectious Materials;

5-2. 05-02-G-02 Occupational Health Guide: Personal Protective Equipment;

5-3. 05-02-G-03 Occupational Health Guide: Respiratory Protection Program; and

5-4. 05-02-G-04 Occupational Health Guide: Workforce Health Program.

6. **HISTORICAL NOTES:** This directive supersedes all previous versions of IHSC Directive 05-02, Occupational Health.

7. **DEFINITIONS:** See definitions for this policy at IHSC Glossary and the Occupational Health Guides.

8. **APPLICABLE STANDARDS:**

8-1. Performance-Based National Detention Standards (PBNDS):

8-1.1 PBNDS 2011 (updated 2016 version):

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8-1.1.a 1.2: Environmental Health and Safety.

8-1.1.b 7.3: Staff Training.

8-2. ICE Family Residential Standards:

8-2.1 1.2: Environmental Health and Safety.

8-3. American Correctional Association (ACA):

8-3.1 Performance-Based Standards for Adult Local Detention Facilities, 4th edition:

8-3.1.a 14-ALDF-4C-14: Communicable Disease and Infection Control Program.

8-3.1.b 4ALDF- 4D-07: Employee Health.

8-4. National Commission on Correctional Health Care (NCCHC):

8-4.1 Standards for Health Services in Jails, 2008: J-B-01: Infection Control Program.

8-4.1.a J-B-03: Staff Safety.

8-4.1.b J-C-09: Orientation for Health Staff.

9. PRIVACY AND RECORDKEEPING. Records generated pursuant to this policy are maintained in the following offices: The Office of Personnel Management, Employee Medical Records System of Records, 75 Federal Register 35099 (June 21, 2010) at the Department of Labor, Office of Workers' Compensation Programs, Federal Employees' Compensation Act File System of Records, 77 Federal Register 1738, (January 11, 2012); and any other applicable system.

9-1. Protection of Medical Records and Sensitive Personal Identifiable Information (PII).

9-1.1 Medical records must only be disclosed to those officers and employees of the agency who maintain the record, and who have a need for the record, in the performance of their duties. Staff must secure paper records at all times within a locked cabinet or room when not in use or not otherwise under the direct control of an officer or employee with a need to know.

9-1.2 Staff must be trained at orientation and annually on the protection of patient medical information and sensitive PII.

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9-1.3 Staff must reference the Department of Homeland Security *Handbook for Safeguarding Sensitive PII* for guidance on safeguarding sensitive PII.

9-2. OSHA Workforce Health Records Requirements.

9-2.1 OSHA regulations require that staff health records must be maintained for the duration of employment plus 30 years.

9-2.2 Staff departure from IHSC. Electronic copies of staff health records should be available for retrieval, following the subsequent series of accreditation and standards reviews, and following each staff members departure from IHSC.

9-2.3 PHS employees transferring within IHSC. The HSA must retain PHS officer staff health records securely for duration of employment plus 30 years. Upon transferring within IHSC, the HSA of the facility, and the officer departing, must send the health records to the HSA at the new duty station. If a site closes, the HSA must send or upload files electronically to IHSC HQ to the Health Operations Unit for secure storage for the duration of the retention period. Electronic records will go in the "Records Archiving" section of SharePoint.

9-2.4 Civil service staff departing from IHSC. The HSA must maintain civil service staff health records securely for the period of the employee's service with IHSC, after which they must be transferred to the National Personnel Records Center, or as appropriate, to the next employing federal agency in accordance with 5 CFR 293 Subpart E, in the Office of Personnel Management, Employee Medical Records System of Records, 75 Federal Register 35099 (June 21, 2010), at the Department of Labor, Office of Workers' Compensation Programs, Federal Employees' Compensation Act File System of Records, 77 Federal Register 1738, (January 11, 2012), and any other applicable system.

9-2.5 Contract staff departing from IHSC. The HSA must retain contract staff health records securely for the duration of assignment to the duty station. Upon termination of assignment or contract, or for a facility that is closing, the HSA must arrange, through a contract officer representative, to send the original file of the contractor records to the employer. Paper records should be archived and sent to the appropriate Federal Records Center for storage. Electronic records will go in the "Records Archiving" section of SharePoint.

9-2.6 OSHA Forms 300, 300A, and 301, and sharps injury logs. OSHA forms, logs, and sharps injury logs must be retained for five years following the year to which the form or log pertains.

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9-2.7 The HSA must retain OSHA Forms 300, 300A, and 301, and sharps injury logs securely on-site for the duration of the retention period. If the site closes, the forms and logs must be sent to IHSC HQ and uploaded in the "Records Archiving" section of SharePoint for the duration of the retention period.

9-2.8 Sharps injury logs should be retained separately from OSHA forms, but co-located with OSHA forms and logs.

10. **NO PRIVATE RIGHT STATEMENT.** This directive is an internal policy statement of IHSC. It is not intended to, and does not create any rights, privileges, or benefits, substantive or procedural, enforceable against the United States; its departments, agencies, or other entities; its officers or employees; or any other person.

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