# COMMONWEALTH OF VIRGINIA
# Meeting of the Board of Pharmacy

**Perimeter Center, 9960 Mayland Drive, Second Floor** **(804) 367-4456 (Tel)**
**Henrico, Virginia 23233** **(804) 527-4472(Fax)**


## Tentative Agenda of Statewide Protocol Work Group Meeting

***August 9, 2021 In-person Meeting (no virtual component)***

**9AM**

| TOPIC | PAGES |
|---|---|
| **Call to Order:** Dale St.Clair, PharmD, Work Group Chairman | |
| • Welcome & Introductions | |
| • Approval of Agenda | 1 |
| **Call for Public Comment:** The work group will receive public comment at this time. The work group will not receive comment on any board regulation process for which a public comment period has closed or any pending disciplinary matters. | |
| **Agenda Items** | |
| • Review charge of work group as described in the second and third enactment clauses of HB 2079 | 2-4 |
| • Recommend statewide protocols for Board of Pharmacy review and implementation for pharmacists to initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older: | |
| ○ Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment; | 5-7 |
| ○ Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration; | 8-24 |
| ○ Tuberculin purified protein derivative for tuberculosis testing; and | 25-66 |
| ○ Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention. | 67-102 |
| • Adopt recommended emergency regulations for Board of Pharmacy consideration to implement provisions | 103-108 |
| **Adjourn** | |

****The work group will have a working lunch at approximately 12pm.****

Workgroup Members

1. Dale St.Clair, PharmD, Workgroup Chairman, Board of Pharmacy Vice-Chairman
2. Patricia Richards-Spruill, RPh, Board of Pharmacy Member
3. Jacob Miller, D.O., Board of Medicine Member
4. Brenda Stokes, MD, FAAFP, CMD, HMDC, Board of Medicine Member
5. Kristin Collins, MPH, VDH, Office of Epidemiology, Policy Analyst
6. Christy Gray, MPH, CHES, CHTS-CP, VDH, Division of Immunology
7. Jasie Hearn, MPH, MA, VDH, Tuberculosis Controller/TB Program Manager
8. Diana Jordan, VDH, Office of Epidemiology

history | pdf

**CHAPTER 214**

*An Act to amend and reenact §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment; certain drugs and devices.*

[H 2079]
Approved March 18, 2021

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

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"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, *devices, or controlled paraphernalia* in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs ~~and~~, devices, *controlled paraphernalia, and other supplies and equipment* to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; ~~and~~

6. ~~Medications~~ *Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter,* covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, *device, controlled paraphernalia, or other supplies or equipment;*

*7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;*

*8. Tuberculin purified protein derivative for tuberculosis testing; and*

*9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.*

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall



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counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

*C. A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.*

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2021. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to recommend protocols to the Board of Pharmacy for review and implementation. No pharmacist shall initiate treatment with or dispense or administer such drug, device, controlled paraphernalia, or supply or equipment until such protocols have been adopted. Such protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia, as amended by this act.

3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.

4. That the Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine as well as representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board of Pharmacy may deem appropriate to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety and report its recommendations to the Governor and the Chairmen of the Joint Commission on Health Care, the House Committee on Health, Welfare and Institutions, and the Senate Committee on Education and Health by November 1, 2021.

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**Legislative Information System**

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**Agenda Topic:**

Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment

**Included in Agenda Packet:**

Draft amendments to current Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses

**Action Needed:**

Recommend amended protocol as presented or amended for Board of Pharmacy consideration and implementation.

**Adopted: ~~9/9/2020~~**
**Effective Date: ~~1/3/2021~~**

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following ~~drugs~~ to persons 18 years of age or older:

- ~~Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.~~
- Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering ~~medications~~ drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

### PATIENT INCLUSION CRITERIA

Patients eligible for ~~medications~~ drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol:

- An individual, 18 years of age or older, whose over-the-counter ~~medication~~ drug, device, controlled paraphernalia, and other supply or equipment is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed ~~drug~~ item is lower than the out-of-pocket cost to purchase the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter ~~medication~~ drug would cost more out-of-pocket than a prescribed prescription-only ~~medication~~ drug that is a therapeutically equivalent drug product[1], as defined in § 54.1-3401, as the over-the-counter ~~medication~~ drug.

### EXAMPLES OF INCLUDED DEVICES AND CONTROLLED PARAPHERNALIA

Examples of devices and controlled paraphernalia for which a pharmacist may issue a prescription to initiate treatment under the qualifying conditions of this protocol include:

- Diabetic blood sugar testing supplies,
- Injection supplies;
- Hypodermic needles and syringes;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;

- Ostomy products and supplies

## RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

## NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Drug Control Act, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

[1]"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book.", § 54.1-3401.

**Agenda Topic:**

Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration

**Included in Agenda Packet:**

Draft Pharmacist Vaccine Statewide Protocol

CDC 2021 Immunization Schedule for ages 18 years or younger

CDC 2021 Immunization Schedule for ages 19 years or older

**Action Needed:**

Recommend ~~amended~~ DRAFT protocol as presented or amended for persons 18 years of age or older for Board of Pharmacy consideration and implementation.

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Vaccine Statewide Protocol

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the vaccines to persons 18 years of age or older.

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions.

### PATIENT INCLUSION CRITERIA

Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC;
- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

### PATIENT EXCLUSION CRITERIA

Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC; or
- An individual who is fully vaccinated.

### COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

### RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

**NOTIFICATION OF PRIMARY CARE PROVIDER**

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

# Recommended Child and Adolescent Immunization Schedule
## for ages 18 years or younger

UNITED STATES
2021

## Vaccines in the Child and Adolescent Immunization Schedule*

| Vaccines | Abbreviations | Trade names |
|---|---|---|
| Diphtheria, tetanus, and acellular pertussis vaccine | **DTaP** | Daptacel® Infanrix® |
| Diphtheria, tetanus vaccine | **DT** | No trade name |
| *Haemophilus influenzae* type b vaccine | **Hib (PRP-T)** | ActHIB® Hiberix® |
| | **Hib (PRP-OMP)** | PedvaxHIB® |
| Hepatitis A vaccine | **HepA** | Havrix® Vaqta® |
| Hepatitis B vaccine | **HepB** | Engerix-B® Recombivax HB® |
| Human papillomavirus vaccine | **HPV** | Gardasil 9® |
| Influenza vaccine (inactivated) | **IIV** | Multiple |
| Influenza vaccine (live, attenuated) | **LAIV4** | FluMist® Quadrivalent |
| Measles, mumps, and rubella vaccine | **MMR** | M-M-R II® |
| Meningococcal serogroups A, C, W, Y vaccine | **MenACWY-D** | Menactra® |
| | **MenACWY-CRM** | Menveo® |
| | **MenACWY-TT** | MenQuadfi® |
| Meningococcal serogroup B vaccine | **MenB-4C** | Bexsero® |
| | **MenB-FHbp** | Trumenba® |
| Pneumococcal 13-valent conjugate vaccine | **PCV13** | Prevnar 13® |
| Pneumococcal 23-valent polysaccharide vaccine | **PPSV23** | Pneumovax 23® |
| Poliovirus vaccine (inactivated) | **IPV** | IPOL® |
| Rotavirus vaccine | **RV1** | Rotarix® |
| | **RV5** | RotaTeq® |
| Tetanus, diphtheria, and acellular pertussis vaccine | **Tdap** | Adacel® Boostrix® |
| Tetanus and diphtheria vaccine | **Td** | Tenivac® Tdvax™ |
| Varicella vaccine | **VAR** | Varivax® |
| **Combination vaccines** *(use combination vaccines instead of separate injections when appropriate)* | | |
| DTaP, hepatitis B, and inactivated poliovirus vaccine | **DTaP-HepB-IPV** | Pediarix® |
| DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine | **DTaP-IPV/Hib** | Pentacel® |
| DTaP and inactivated poliovirus vaccine | **DTaP-IPV** | Kinrix® Quadracel® |
| DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine | **DTaP-IPV-Hib-HepB** | Vaxelis® |
| Measles, mumps, rubella, and varicella vaccine | **MMRV** | ProQuad® |

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

## How to use the child/adolescent immunization schedule

**1** Determine recommended vaccine by age **(Table 1)**

**2** Determine recommended interval for catch-up vaccination **(Table 2)**

**3** Assess need for additional recommended vaccines by medical condition and other indications **(Table 3)**

**4** Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Assistants (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

## Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Download the CDC Vaccine Schedules App for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

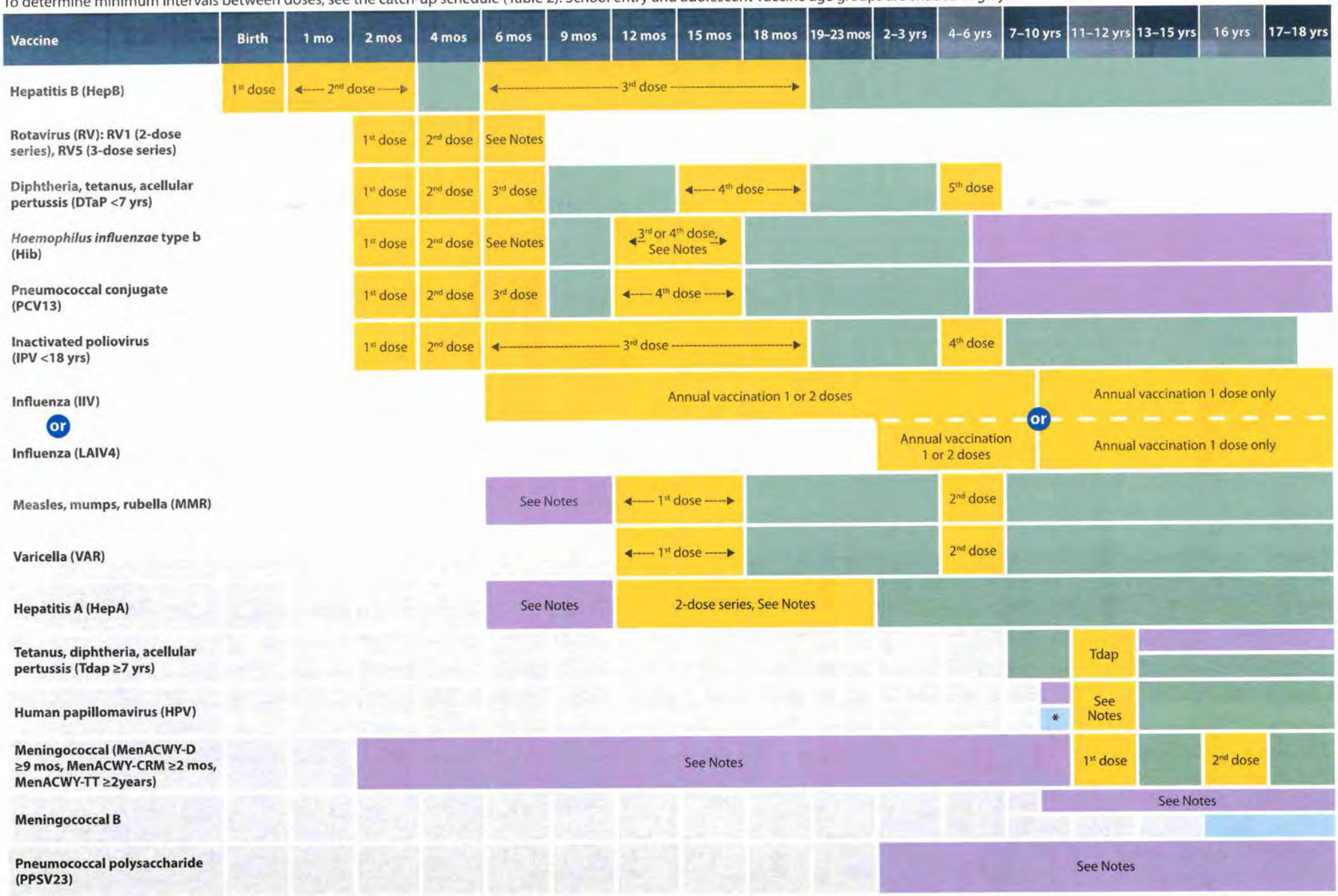
## Helpful information

- Complete ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization*: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Outbreak information (including case identification and outbreak response), see Manual for the Surveillance of Vaccine-Preventable Diseases: www.cdc.gov/vaccines/pubs/surv-manual
- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

**U.S. Department of Health and Human Services**
Centers for Disease Control and Prevention

# Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

**These recommendations must be read with the notes that follow.** For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.



# Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 month Behind, United States, 2021

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the notes that follow.**

## Children age 4 months through 6 years

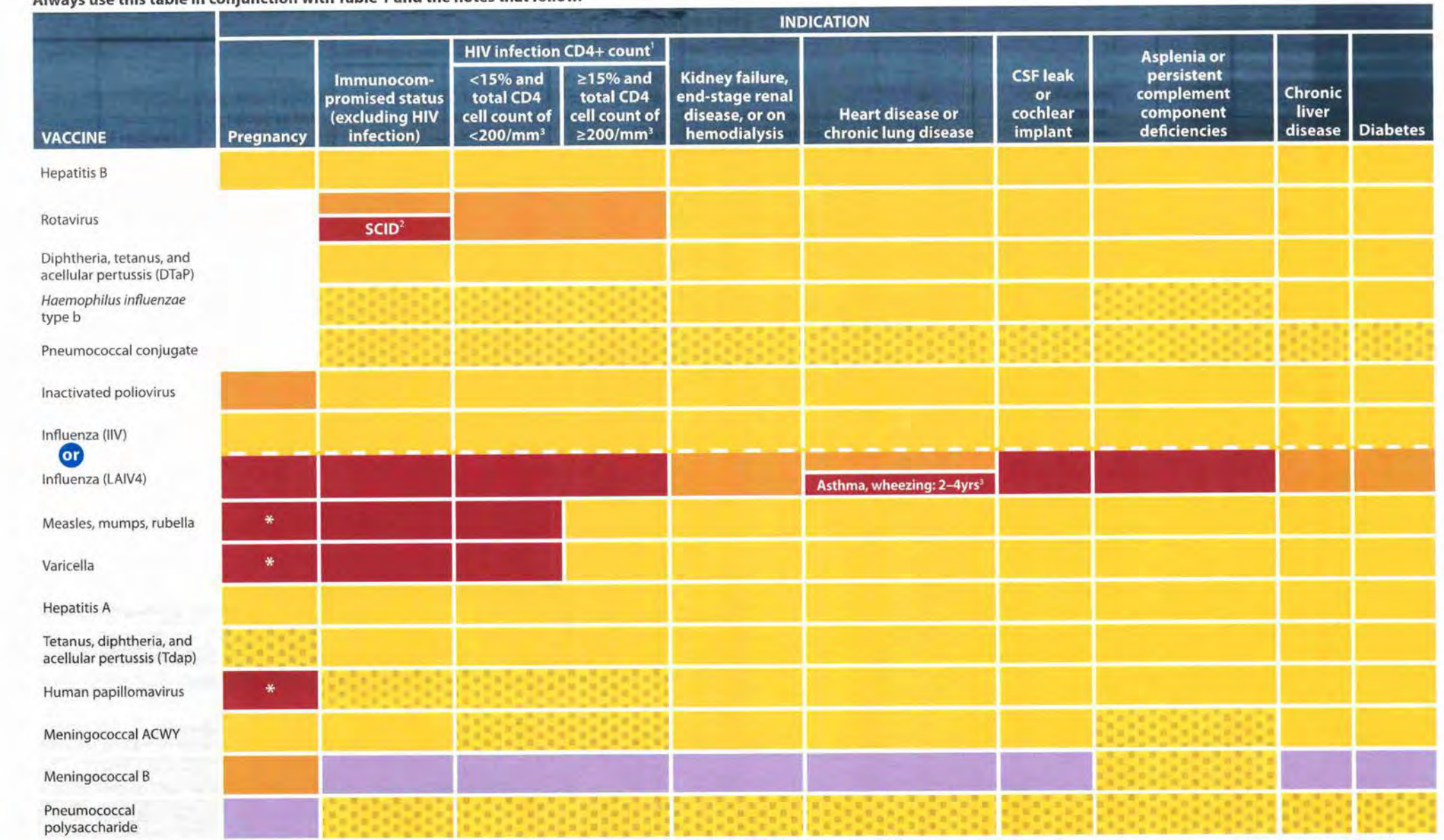
| Vaccine | Minimum Age for Dose 1 | Minimum Interval Between Doses: Dose 1 to Dose 2 | Dose 2 to Dose 3 | Dose 3 to Dose 4 | Dose 4 to Dose 5 |
|---|---|---|---|---|---|
| Hepatitis B | Birth | 4 weeks | 8 weeks *and* at least 16 **weeks after first dose.**<br>Minimum age for the final dose is 24 weeks. | | |
| Rotavirus | 6 weeks<br>Maximum age for first dose is 14 weeks, 6 days. | **4 weeks** | **4 weeks**<br>Maximum age for final dose is 8 months, 0 days. | | |
| Diphtheria, tetanus, and acellular pertussis | 6 weeks | **4 weeks** | **4 weeks** | **6 months** | **6 months** |
| *Haemophilus influenzae* type b | 6 weeks | **No further doses needed** if first dose was administered at age 15 months or older.<br>**4 weeks**<br>if first dose was administered before the 1st birthday.<br>**8 weeks (as final dose)**<br>if first dose was administered at age 12 through 14 months. | **No further doses needed** if previous dose was administered at age 15 months or older.<br>**4 weeks**<br>if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix) or unknown.<br>8 weeks ***and*** **age 12 through 59 months (as final dose)**<br>if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months;<br>OR<br>if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months;<br>OR<br>if both doses were PRP-OMP (PedvaxHIB, Comvax) ***and*** were administered before the 1st birthday. | **8 weeks (as final dose)**<br>This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday. | |
| Pneumococcal conjugate | 6 weeks | **No further doses needed** for healthy children if first dose was administered at age 24 months or older.<br>**4 weeks**<br>if first dose was administered before the 1st birthday.<br>**8 weeks (as final dose for healthy children)**<br>if first dose was administered at the 1st birthday or after. | **No further doses needed** for healthy children if previous dose was administered at age 24 months or older.<br>**4 weeks**<br>if current age is younger than 12 months and previous dose was administered at <7 months old.<br>**8 weeks (as final dose for healthy children)**<br>if previous dose was administered between 7–11 months (wait until at least 12 months old);<br>OR<br>if current age is 12 months or older and at least 1 dose was administered before age 12 months. | **8 weeks (as final dose)**<br>This dose only necessary for children age 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age. | |
| Inactivated poliovirus | 6 weeks | **4 weeks** | **4 weeks** if current age is <4 years.<br>**6 months (as final dose)** if current age is 4 years or older. | **6 months** (minimum age 4 years for final dose). | |
| Measles, mumps, rubella | 12 months | **4 weeks** | | | |
| Varicella | 12 months | **3 months** | | | |
| Hepatitis A | 12 months | **6 months** | | | |
| Meningococcal ACWY | 2 months MenACWY-CRM<br>9 months MenACWY-D<br>2 years MenACWY-TT | **8 weeks** | See Notes | See Notes | |

## Children and adolescents age 7 through 18 years

| | | | | | |
|---|---|---|---|---|---|
| Meningococcal ACWY | Not applicable (N/A) | **8 weeks** | | | |
| Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis | 7 years | **4 weeks** | **4 weeks**<br>if first dose of DTaP/DT was administered before the 1st birthday.<br>**6 months (as final dose)**<br>if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday. | **6 months** if first dose of DTaP/DT was administered before the 1st birthday. | |
| Human papillomavirus | 9 years | **Routine dosing intervals are recommended.** | | | |
| Hepatitis A | N/A | **6 months** | | | |
| Hepatitis B | N/A | **4 weeks** | **8 weeks *and* at least 16 weeks after first dose.** | | |
| Inactivated poliovirus | N/A | **4 weeks** | **6 months**<br>A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose. | A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose. | |
| Measles, mumps, rubella | N/A | **4 weeks** | | | |
| Varicella | N/A | **3 months** if younger than age 13 years.<br>**4 weeks** if age 13 years or older | | | |

# Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2021

**Always use this table in conjunction with Table 1 and the notes that follow.**




1 For additional information regarding HIV laboratory parameters and use of live vaccines, see the *General Best Practice Guidelines for Immunization*, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote D) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

2 Severe Combined Immunodeficiency

3 LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

# Notes

# Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2021.

## Additional information

**COVID-19 Vaccination**

ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/.

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For information on contraindications and precautions for the use of a vaccine, consult the *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html and relevant ACIP statements at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-1, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:67–111).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All routine child and adolescent vaccines are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information, see www.hrsa.gov/vaccinecompensation/index.html.

## Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

### Routine vaccination

- 5-dose series at 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

### Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

### Special situations

- Wound management in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

## *Haemophilus influenzae* type b vaccination (minimum age: 6 weeks)

### Routine vaccination

- **ActHIB, Hiberix, or Pentacel:** 4-dose series at 2, 4, 6, 12–15 months
- **PedvaxHIB:** 3-dose series at 2, 4, 12–15 months

### Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age 12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at 12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Do not require catch-up vaccination
- For other catch-up guidance, see Table 2.

### Special situations

- **Chemotherapy or radiation treatment:**
  12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  *Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.*
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  *Unvaccinated* persons age 5 years or older*
  - 1 dose
- **Elective splenectomy:**
  *Unvaccinated* persons age 15 months or older*
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  *Unvaccinated* persons age 5–18 years*
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency:**
  12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

**Unvaccinated* = Less than routine series (through age 14 months) OR no doses (age 15 months or older)*

# Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

## Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

### Routine vaccination
- 2-dose series (minimum interval: 6 months) beginning at age 12 months

### Catch-up vaccination
- Unvaccinated persons through age 18 years should complete a 2-dose series (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix®**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

### International travel
- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses, separated by at least 6 months, between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

## Hepatitis B vaccination
(minimum age: birth)

### Birth dose (monovalent HepB vaccine only)
- **Mother is HBsAg-negative:** 1 dose within 24 hours of birth for **all** medically stable infants ≥2,000 grams. Infants <2,000 grams: Administer 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams).
- **Mother is HBsAg-positive:**
  - Administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** (in separate limbs) within 12 hours of birth, regardless of birth weight. For infants <2,000 grams, administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose.
- **Mother's HBsAg status is unknown:**
  - Administer **HepB vaccine** within 12 hours of birth, regardless of birth weight.
  - For infants <2,000 grams, administer **HBIG** in addition to HepB vaccine (in separate limbs) within 12 hours of birth. Administer 3 additional doses of vaccine (total of 4 doses) beginning at age 1 month.
  - Determine mother's HBsAg status as soon as possible. If mother is HBsAg-positive, administer **HBIG** to infants ≥2,000 grams as soon as possible, but no later than 7 days of age.

### Routine series
- 3-dose series at 0, 1–2, 6–18 months (use monovalent HepB vaccine for doses administered before age 6 weeks)
- Infants who did not receive a birth dose should begin the series as soon as feasible (see Table 2).
- Administration of **4 doses** is permitted when a combination vaccine containing HepB is used after the birth dose.
- **Minimum age** for the final (3rd or 4th) dose: 24 weeks
- **Minimum intervals:** dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks (when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations)

### Catch-up vaccination
- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents age 18 years or older may receive a 2-dose series of HepB **(Heplisav-B®)** at least 4 weeks apart.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).
- For other catch-up guidance, see Table 2.

### Special situations
- Revaccination is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Revaccination** may be recommended for certain populations, including:
  - **Infants born to HBsAg-positive mothers**
  - **Hemodialysis patients**
  - **Other immunocompromised persons**
- For detailed revaccination recommendations, see www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.

## Human papillomavirus vaccination
(minimum age: 9 years)

### Routine and catch-up vaccination
- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted.
- No additional dose recommended after completing series with recommended dosing intervals using any HPV vaccine.

### Special situations
- **Immunocompromising conditions, including HIV infection:** 3-dose series as above
- **History of sexual abuse or assault:** Start at age 9 years.
- **Pregnancy:** HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination

## Influenza vaccination
(minimum age: 6 months [IIV], 2 years [LAIV4], 18 years [recombinant influenza vaccine, RIV4])

### Routine vaccination
- Use any influenza vaccine appropriate for age and health status annually:
  - 2 doses, separated by at least 4 weeks, for **children age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2020, or whose influenza vaccination history is unknown (administer dose 2 even if the child turns 9 between receipt of dose 1 and dose 2)
  - 1 dose for **children age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2020
  - 1 dose for **all persons age 9 years or older**
- For the 2021–22 season, see the 2021–22 ACIP influenza vaccine recommendations.

### Special situations
- **Egg allergy, hives only**: Any influenza vaccine appropriate for age and health status annually
- **Egg allergy with symptoms other than hives** (e.g., angioedema, respiratory distress, need for emergency medical services or epinephrine): Any influenza vaccine appropriate for age and health status annually. If using an influenza vaccine other than Flublok or Flucelvax, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
- Severe allergic reactions to vaccines can occur even in the absence of a history of previous allergic reaction. All vaccination providers should be familiar with the office emergency plan and certified in cardiopulmonary resuscitation.
- A previous severe allergic reaction to influenza vaccine is a contraindication to future receipt of any influenza vaccine.
- **LAIV4 should not be used** in persons with the following conditions or situations:
  - History of severe allergic reaction to a previous dose of any influenza vaccine or to any vaccine component (excluding egg, see details above)
  - Receiving aspirin or salicylate-containing medications
  - Age 2–4 years with history of asthma or wheezing
  - Immunocompromised due to any cause (including medications and HIV infection)
  - Anatomic or functional asplenia
  - Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
  - Pregnancy
  - Cochlear implant
  - Cerebrospinal fluid-oropharyngeal communication
  - Children less than age 2 years
  - Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours,. peramivir within the previous 5 days, or baloxavir within the previous 17 days

# Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

## Measles, mumps, and rubella vaccination (minimum age: 12 months for routine vaccination)

### Routine vaccination
- 2-dose series at 12–15 months, 4–6 years
- Dose 2 may be administered as early as 4 weeks after dose 1.

### Catch-up vaccination
- Unvaccinated children and adolescents: 2-dose series at least 4 weeks apart
- The maximum age for use of MMRV is 12 years.

### Special situations
**International travel**
- **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
- **Unvaccinated children age 12 months or older:** 2-dose series at least 4 weeks apart before departure

## Meningococcal serogroup A,C,W,Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra], 2 years [MenACWY-TT, MenQuadfi])

### Routine vaccination
- 2-dose series at 11–12 years, 16 years

### Catch-up vaccination
- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

### Special situations
**Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:**
- **Menveo**
  - Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
  - Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **Menactra**
  - **Persistent complement component deficiency or complement inhibitor use:**
    - Age 9–23 months: 2-dose series at least 12 weeks apart
    - Age 24 months or older: 2-dose series at least 8 weeks apart
  - **Anatomic or functional asplenia, sickle cell disease, or HIV infection:**
    - Age 9–23 months: Not recommended
    - Age 24 months or older: 2-dose series at least 8 weeks apart
    - **Menactra** must be administered at least 4 weeks after completion of PCV13 series.
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

**Travel in countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj** (www.cdc.gov/travel/):
- Children less than age 24 months:
  - **Menveo (age 2–23 months)**
    - Dose 1 at age 8 weeks: 4-dose series at 2, 4, 6, 12 months
    - Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - **Menactra (age 9–23 months)**
    - 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose Menveo, Menactra, or MenQuadfi

**First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:**
- 1 dose **Menveo, Menactra,** or **MenQuadfi**

**Adolescent vaccination of children who received MenACWY prior to age 10 years:**
- **Children for whom boosters are recommended** because of an ongoing increased risk of meningococcal disease (e.g., those with complement deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Note: Menactra** should be administered either before or at the same time as DTaP. For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

## Meningococcal serogroup B vaccination (minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba])

### Shared clinical decision-making
- **Adolescents not at increased risk** age 16–23 years (preferred age 16–18 years) based on shared clinical decision-making:
  - **Bexsero:** 2-dose series at least 1 month apart
  - **Trumenba:** 2-dose series at least 6 months apart; if dose 2 is administered earlier than 6 months, administer a 3rd dose at least 4 months after dose 2.

### Special situations
**Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:**
- **Bexsero:** 2-dose series at least 1 month apart
- **Trumenba:** 3-dose series at 0, 1–2, 6 months

**Bexsero** and **Trumenba** are not interchangeable; the same product should be used for all doses in a series.
For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

## Pneumococcal vaccination (minimum age: 6 weeks [PCV13], 2 years [PPSV23])

### Routine vaccination with PCV13
- 4-dose series at 2, 4, 6, 12–15 months

### Catch-up vaccination with PCV13
- 1 dose for healthy children age 24–59 months with any incomplete* PCV13 series
- For other catch-up guidance, see Table 2.

### Special situations
**Underlying conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during same visit.**

**Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:**

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

Age 6–18 years
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

**Cerebrospinal fluid leak, cochlear implant:**

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years
- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23

# Notes

## Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2021

**Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:**

Age 2–5 years

- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a 2nd dose of PPSV23 5 years later

Age 6–18 years

- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2nd dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

**Chronic liver disease, alcoholism:**

Age 6–18 years

- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series See Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations (www.cdc.gov/mmwr/pdf/rr/rr5911.pdf) for complete schedule details.

## Poliovirus vaccination
(minimum age: 6 weeks)

### Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

### Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- IPV is not routinely recommended for U.S. residents age 18 years or older.

Series containing **oral polio vaccine (OPV)**, either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

## Rotavirus vaccination
(minimum age: 6 weeks)

### Routine vaccination

- **Rotarix:** 2-dose series at 2 and 4 months
- **RotaTeq:** 3-dose series at 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

### Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

## Tetanus, diphtheria, and pertussis (Tdap) vaccination
(minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

### Routine vaccination

- **Adolescents age 11–12 years:** 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

### Catch-up vaccination

- **Adolescents age 13–18 years who have not received Tdap:** 1 dose Tdap, then Td or Tdap booster every 10 years
- **Persons age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Children age 7–9 years** who receive Tdap should receive the routine Tdap dose at age 11–12 years.
  - **Children age 10 years** who receive Tdap do not need the routine Tdap dose at age 11–12 years.
- **DTaP inadvertently administered on or after age 7 years:**
  - **Children age 7–9 years**: DTaP may count as part of catch-up series. Administer routine Tdap dose at age 11–12 years.
  - **Children age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.

### Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

## Varicella vaccination
(minimum age: 12 months)

### Routine vaccination

- 2-dose series at 12–15 months, 4–6 years
- Dose 2 may be administered as early as 3 months after dose 1 (a dose administered after a 4-week interval may be counted).

### Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: routine interval: 3 months (a dose administered after a 4-week interval may be counted)
  - **Age 13 years and older**: routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of MMRV is 12 years.

# Recommended Adult Immunization Schedule
## for ages 19 years or older

UNITED STATES
2021

## How to use the adult immunization schedule

**1** Determine recommended vaccinations by age **(Table 1)**

**2** Assess need for additional recommended vaccinations by medical condition and other indications **(Table 2)**

**3** Review vaccine types, frequencies, and intervals and considerations for special situations **(Notes)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American College of Physicians (www.acponline.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), and American Academy of Physician Assistants (www.aapa.org).

### Vaccines in the Adult Immunization Schedule*

| Vaccines | Abbreviations | Trade names |
|---|---|---|
| *Haemophilus influenzae* type b vaccine | Hib | ActHIB®<br>Hiberix®<br>PedvaxHIB® |
| Hepatitis A vaccine | HepA | Havrix®<br>Vaqta® |
| Hepatitis A and hepatitis B vaccine | HepA-HepB | Twinrix® |
| Hepatitis B vaccine | HepB | Engerix-B®<br>Recombivax HB®<br>Heplisav-B® |
| Human papillomavirus vaccine | HPV | Gardasil 9® |
| Influenza vaccine (inactivated) | IIV | Many brands |
| Influenza vaccine (live, attenuated) | LAIV4 | FluMist® Quadrivalent |
| Influenza vaccine (recombinant) | RIV4 | Flublok® Quadrivalent |
| Measles, mumps, and rubella vaccine | MMR | M-M-R II® |
| Meningococcal serogroups A, C, W, Y vaccine | MenACWY-D<br>MenACWY-CRM<br>MenACWY-TT | Menactra®<br>Menveo®<br>MenQuadfi® |
| Meningococcal serogroup B vaccine | MenB-4C<br>MenB-FHbp | Bexsero®<br>Trumenba® |
| Pneumococcal 13-valent conjugate vaccine | PCV13 | Prevnar 13® |
| Pneumococcal 23-valent polysaccharide vaccine | PPSV23 | Pneumovax 23® |
| Tetanus and diphtheria toxoids | Td | Tenivac®<br>Tdvax™ |
| Tetanus and diphtheria toxoids and acellular pertussis vaccine | Tdap | Adacel®<br>Boostrix® |
| Varicella vaccine | VAR | Varivax® |
| Zoster vaccine, recombinant | RZV | Shingrix |

*Administer recommended vaccines if vaccination history is incomplete or unknown. Do not restart or add doses to vaccine series if there are extended intervals between doses. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

### Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to the local or state health department
- Clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

### Injury claims

All vaccines included in the adult immunization schedule except pneumococcal 23-valent polysaccharide (PPSV23) and zoster (RZV) vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation.

### Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.

### Helpful information

- Complete ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- Travel vaccine recommendations: www.cdc.gov/travel
- Recommended Child and Adolescent Immunization Schedule, United States, 2021: www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

**U.S. Department of Health and Human Services**
Centers for Disease Control and Prevention

# Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2021

| Vaccine | 19–26 years | 27–49 years | 50–64 years | ≥65 years |
|---|---|---|---|---|
| **Influenza inactivated** (IIV) or **Influenza recombinant** (RIV4) | 1 dose annually | | | |
| or | or | | | |
| **Influenza live, attenuated** (LAIV4) | 1 dose annually | | | |
| **Tetanus, diphtheria, pertussis** (Tdap or Td) | 1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (see notes) | | | |
| | 1 dose Tdap, then Td or Tdap booster every 10 years | | | |
| **Measles, mumps, rubella** (MMR) | 1 or 2 doses depending on indication (if born in 1957 or later) | | | |
| **Varicella** (VAR) | 2 doses (if born in 1980 or later) | | 2 doses | |
| **Zoster recombinant** (RZV) | | | 2 doses | |
| **Human papillomavirus** (HPV) | 2 or 3 doses depending on age at initial vaccination or condition | 27 through 45 years | | |
| **Pneumococcal conjugate** (PCV13) | 1 dose | | | 1 dose |
| **Pneumococcal polysaccharide** (PPSV23) | 1 or 2 doses depending on indication | | | 1 dose |
| **Hepatitis A** (HepA) | 2 or 3 doses depending on vaccine | | | |
| **Hepatitis B** (HepB) | 2 or 3 doses depending on vaccine | | | |
| **Meningococcal A, C, W, Y** (MenACWY) | 1 or 2 doses depending on indication, see notes for booster recommendations | | | |
| **Meningococcal B** (MenB) | 2 or 3 doses depending on vaccine and indication, see notes for booster recommendations | | | |
| | 19 through 23 years | | | |
| ***Haemophilus influenzae* type b** (Hib) | 1 or 3 doses depending on indication | | | |

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

# Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2021

| Vaccine | Pregnancy | Immuno-compromised (excluding HIV infection) | HIV infection CD4 count | | Asplenia, complement deficiencies | End-stage renal disease; or on hemodialysis | Heart or lung disease, alcoholism[1] | Chronic liver disease | Diabetes | Health care personnel[2] | Men who have sex with men |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | <200 mm³ | ≥200 mm³ | | | | | | | |
| IIV or RIV4 | 1 dose annually | | | | | | | | | | |
| or | | | | | | | | | | or | |
| LAIV4 | Not Recommended | | | | | | Precaution | | | 1 dose annually | |
| Tdap or Td | 1 dose Tdap each pregnancy | 1 dose Tdap, then Td or Tdap booster every 10 years | | | | | | | | | |
| MMR | Not Recommended* | Not Recommended | 1 or 2 doses depending on indication | | | | | | | | |
| VAR | Not Recommended* | Not Recommended | | 2 doses | | | | | | | |
| RZV | | | 2 doses at age ≥50 years | | | | | | | | |
| HPV | Not Recommended* | 3 doses through age 26 years | 2 or 3 doses through age 26 years depending on age at initial vaccination or condition | | | | | | | | |
| PCV13 | | 1 dose | | | | | | | | | |
| PPSV23 | | 1, 2, or 3 doses depending on age and indication | | | | | | | | | |
| HepA | | | 2 or 3 doses depending on vaccine | | | | | | | | |
| HepB | | | 2, 3, or 4 doses depending on vaccine or condition | | | | | | | <60 years | |
| | | | | | | | | | | ≥60 years | |
| MenACWY | 1 or 2 doses depending on indication, see notes for booster recommendations | | | | | | | | | | |
| MenB | Precaution | 2 or 3 doses depending on vaccine and indication, see notes for booster recommendations | | | | | | | | | |
| Hib | | 3 doses HSCT[3] recipients only | 1 dose | | | | | | | | |

- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Recommended vaccination based on shared clinical decision-making
- Not recommended/ contraindicated—vaccine should not be administered.
- No recommendation/ Not applicable

*Vaccinate after pregnancy.

**1.** Precaution for LAIV4 does not apply to alcoholism. **2.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **3.** Hematopoietic stem cell transplant.

# Notes

# Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2021



For vaccine recommendations for persons 18 years of age or younger, see the Recommended Child/Adolescent Immunization Schedule.

## Additional Information

### COVID-19 Vaccination

ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for the use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

## *Haemophilus influenzae* type b vaccination

### Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib; if elective splenectomy, 1 dose, preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

## Hepatitis A vaccination

### Routine vaccination

- **Not at risk but want protection from hepatitis A** (identification of risk factor not required): 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])

### Special situations

- **At risk for hepatitis A virus infection:** 2-dose series HepA or 3-dose series HepA-HepB as above
  - **Chronic liver disease** (e.g., persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A** (HepA-HepB [Twinrix] may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months)
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A (administer dose 1 as soon as adoption is planned, at least 2 weeks before adoptee's arrival)
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure, including** health care settings targeting services to injection or noninjection drug users or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

## Hepatitis B vaccination

### Routine vaccination

- **Not at risk but want protection from hepatitis B** (identification of risk factor not required): 2- or 3-dose series (2-dose series Heplisav-B at least 4 weeks apart [2-dose series HepB only applies when 2 doses of Heplisav-B are used at least 4 weeks apart] or 3-dose series Engerix-B or Recombivax HB at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks]) or 3-dose series HepA-HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 5 months])

### Special situations

- **At risk for hepatitis B virus infection:** 2-dose (Heplisav-B) or 3-dose (Engerix-B, Recombivax HB) series or 3-dose series HepA-HepB (Twinrix) as above
  - **Chronic liver disease** (e.g., persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice upper limit of normal)
  - **HIV infection**
  - **Sexual exposure risk** (e.g., sex partners of hepatitis B surface antigen [HBsAg]-positive persons; sexually active persons not in mutually monogamous relationships; persons seeking evaluation or treatment for a sexually transmitted infection; men who have sex with men)
  - **Current or recent injection drug use**
  - **Percutaneous or mucosal risk for exposure to blood** (e.g., household contacts of HBsAg-positive persons; residents and staff of facilities for developmentally disabled persons; health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids; hemodialysis, peritoneal dialysis, home dialysis, and predialysis patients; persons with diabetes mellitus age younger than 60 years, shared clinical decision-making for persons age 60 years or older)
  - **Incarcerated persons**
  - **Travel in countries with high or intermediate endemic hepatitis B**
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy (Heplisav-B not currently recommended due to lack of safety data in pregnant women)

## Human papillomavirus vaccination

### Routine vaccination

- **HPV vaccination recommended for all persons through age 26 years:** 2- or 3-dose series depending on age at initial vaccination or condition:
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted
- **No additional dose recommended after completing series with recommended dosing intervals using any HPV vaccine**

### Shared clinical decision-making

- **Some adults age 27–45 years: Based on shared clinical decision-making,** 2- or 3-dose series as above

### Special situations

- **Age ranges recommended above for routine and catch-up vaccination or shared clinical decision-making also apply in special situations**

- **Immunocompromising conditions, including HIV infection**: 3-dose series as above, regardless of age at initial vaccination
- **Pregnancy**: HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination

## Influenza vaccination

### Routine vaccination

- **Persons age 6 months or older:** 1 dose any influenza vaccine appropriate for age and health status annually
- For additional guidance, see www.cdc.gov/flu/professionals/index.htm

### Special situations

- **Egg allergy, hives only:** 1 dose any influenza vaccine appropriate for age and health status annually
- **Egg allergy–any symptom other than hives** (e.g., angioedema, respiratory distress): 1 dose any influenza vaccine appropriate for age and health status annually. If using an influenza vaccine other than RIV4 or ccIIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
- Severe allergic reactions to any vaccine can occur even in the absence of a history of previous allergic reaction. Therefore, all vaccine providers should be familiar with the office emergency plan and certified in cardiopulmonary resuscitation.
- A previous severe allergic reaction to any influenza vaccine is a contraindication to future receipt of the vaccine.
- **LAIV4 should not be used** in persons with the following conditions or situations:
  - History of severe allergic reaction to any vaccine component (excluding egg) or to a previous dose of any influenza vaccine
  - Immunocompromised due to any cause (including medications and HIV infection)
  - Anatomic or functional asplenia
  - Close contacts or caregivers of severely immunosuppressed persons who require a protected environment
  - Pregnancy
  - Cranial CSF/oropharyngeal communications
  - Cochlear implant
  - Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days
  - Adults 50 years or older
- **History of Guillain-Barré syndrome within 6 weeks after previous dose of influenza vaccine:** Generally, should not be vaccinated unless vaccination benefits outweigh risks for those at higher risk for severe complications from influenza

## Measles, mumps, and rubella vaccination

### Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

### Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 count ≥200 cells/mm$^3$ for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 count <200 cells/mm$^3$
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **Health care personnel:**
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** 2-dose series at least 4 weeks apart for measles or mumps or at least 1 dose for rubella
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for measles or mumps or 1 dose for rubella

## Meningococcal vaccination

### Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose series MenACWY-D (Menactra, Menveo or MenQuadfi) at least 8 weeks apart and revaccinate every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose MenACWY (Menactra, Menveo or MenQuadfi) and revaccinate every 5 years if risk remains
- **First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) and military recruits:** 1 dose MenACWY (Menactra, Menveo or MenQuadfi)
- For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting (e.g., in community or organizational settings and among men who have sex with men) and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

### Shared clinical decision-making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred) not at increased risk for meningococcal disease:** Based on shared clinical decision-making, 2-dose series MenB-4C (Bexsero) at least 1 month apart or 2-dose series MenB-FHbp (Trumenba) at 0, 6 months (if dose 2 was administered less than 6 months after dose 1, administer dose 3 at least 4 months after dose 2); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series)

### Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, microbiologists routinely exposed to *Neisseria meningitidis*:** 2-dose primary series MenB-4C (Bexsero) at least one month apart or

- MenB-4C (Bexsero) at least 1 month apart or 3-dose primary series MenB-FHbp (Trumenba) at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed); MenB-4C and MenB-FHbp are not interchangeable (use same product for all doses in series); 1 dose MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks
- For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting (e.g., in community or organizational settings and among men who have sex with men) and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

## Pneumococcal vaccination

### Routine vaccination

- **Age 65 years or older** (immunocompetent—see www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm?s_cid=mm6846a5_w): 1 dose PPSV23
  - If PPSV23 was administered prior to age 65 years, administer 1 dose PPSV23 at least 5 years after previous dose

### Shared clinical decision-making

- **Age 65 years or older** (immunocompetent): 1 dose PCV13 based on **shared clinical decision-making** if previously not administered.
  - PCV13 and PPSV23 should not be administered during the same visit
  - If both PCV13 and PPSV23 are to be administered, PCV13 should be administered first
  - PCV13 and PPSV23 should be administered at least 1 year apart

### Special situations

(www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm)

- **Age 19–64 years with chronic medical conditions (chronic heart [excluding hypertension], lung, or liver disease, diabetes), alcoholism, or cigarette smoking:** 1 dose PPSV23
- **Age 19 years or older with immunocompromising conditions (congenital or acquired immunodeficiency [including B- and T-lymphocyte deficiency, complement deficiencies, phagocytic disorders, HIV infection], chronic renal failure, nephrotic syndrome, leukemia, lymphoma, Hodgkin disease, generalized malignancy, iatrogenic immunosuppression [e.g., drug or radiation therapy], solid organ transplant, multiple myeloma) or anatomical or functional asplenia (including sickle cell disease and other hemoglobinopathies):** 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later, then another dose PPSV23 at least 5 years after previous PPSV23; at age 65 years or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)
- **Age 19 years or older with cerebrospinal fluid leak or cochlear implant:** 1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later; at age 65 years or older, administer another dose PPSV23 at least 5 years after PPSV23 (note: only 1 dose PPSV23 recommended at age 65 years or older)

## Tetanus, diphtheria, and pertussis vaccination

### Routine vaccination

- **Previously did not receive Tdap at or after age 11 years:** 1 dose Tdap, then Td or Tdap every 10 years

### Special situations

- **Previously did not receive primary vaccination series for tetanus, diphtheria, or pertussis:** At least 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks after Tdap and another dose Td or Tdap 6–12 months after last Td or Tdap (Tdap can be substituted for any Td dose, but preferred as first dose), Td or Tdap every 10 years thereafter
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

## Varicella vaccination

### Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella-containing vaccine (VAR or MMRV [measles-mumps-rubella-varicella vaccine] for children); if previously received 1 dose varicella-containing vaccine, 1 dose at least 4 weeks after first dose
  - Evidence of immunity: U.S.-born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella-containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease

### Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella-containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella-containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella-containing vaccine, regardless of whether U.S.-born before 1980
- **HIV infection with CD4 count ≥200 cells/mm³ with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 count <200 cells/mm³
- **Severe immunocompromising conditions:** VAR contraindicated

## Zoster vaccination

### Routine vaccination

- **Age 50 years or older:** 2-dose series RZV (Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination (administer RZV at least 2 months after ZVL)

### Special situations

- **Pregnancy:** Consider delaying RZV until after pregnancy if RZV is otherwise indicated.
- **Severe immunocompromising conditions (including HIV infection with CD4 count <200 cells/mm³):** Recommended use of RZV under review

**Agenda Topic:**

Tuberculin purified protein derivative for tuberculosis testing

**Resource Documents Included in Agenda Packet:**

Kentucky Tuberculin Skin Testing One-Step Protocol, Approved 12/11/2019

Article from the Journal of Emergency Medical Services *New CDC Guidelines Recommend Against Annual Tuberculosis Testing*, Published 5/6/2021

CDC *Core Curriculum on Tuberculosis: What the Clinician Should Know*

CDC Mantoux Tuberculin Skin Test One-Page Resource

CDC Tuberculin Skin Testing Document, Published 9/2020

Resources located on VDH Website:

- Tuberculosis Screening and Testing for Occupational Purposes
- Who Should be Screened for Tuberculosis?
- Health Care Personnel Baseline Individual TB Risk Assessment
- Virginia TB Risk Assessment (6 years and older)
- Types of TB Screening
- High Burden TB Country List 2021
- Report of TB Screening
- Webinar Questions and Answers

**Action Needed:**

Review information included in agenda packet, discuss, and recommend to the Board of Pharmacy elements which should be included in a statewide protocol for TB skin testing protocols.

# TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL
## v2

## Approved 12/11/2019

**PURPOSE**

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration and interpretation of the Mantoux Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

**PHARMACIST EDUCATION AND TRAINING**

Prior to initiating the dispensing, administration and interpretation of TST under this protocol, the pharmacist(s) must successfully complete training and follow procedures as specified by the US Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education, completion of Module 3 of the CDC Core Curriculum on Tuberculosis: Targeted testing and the diagnosis of latent tuberculosis infection and tuberculosis disease[2], or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date of Training: _____

**Inclusion Criteria**

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration and interpretation of TST to adults ages ≥ 18 years of age who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance or insurance purposes

**Exclusion Criteria**

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last 28 days
- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

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[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm**.

[2] CDC Core Curriculum on Tuberculosis. Available at https://www.cdc.gov/tb/education/corecurr/pdf/chapter3.pdf.



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**MEDICATIONS**

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The Mantoux tuberculin skin test (TST) is the standard method of determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

| Product | Mfr. / Dist. | NDCs* |
|---|---|---|
| **Tubersol** | Sanofi Pasteur | 1mL (10 tests) = 49281-752-21<br>5mL (50 tests) = 49281-752-22 |
| **Aplisol** | Parkdale | 1 mL (10 tests) = 42023-104-05<br>5mL (50 tests) = 42023-104-05 |

**or any other FDA-approved tuberculin skin test antigen*

**PROCEDURES FOR INITIATION OF TB SCREENING**

Decision to conduct TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined below and in the ATS/CDC Guideline.[1]

Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of TST and reactions to TST

Contraindications and Precautions (Refer to Exclusion Criteria)

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last 28 days
- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix A for detailed procedures).

## PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix B). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred toa healthcare provider for treatment and further advised regarding isolation precautions.

## EDUCATION REQUIREMENTS

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- Result of the TST
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred to a health care provider for treatment and further advised regarding isolation precautions.

## DOCUMENTATION

Pharmacists will document via prescription record with each person who receives a TST under this protocol including:

1. Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and Documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of test and result must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as requirement of employment.

## NOTIFICATION AND REFERRAL

Pharmacist shall ask all persons receiving TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

Guidance provided by 902 KAR 20:205 indicates **all positive results** must be sent to the local health department within one (1) business day and, if available, the individual's primary care provider for follow-up.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving TST under this protocol within 7 days of initiating dispensing.]

**TERMS**

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

## SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

# Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[3]



## Appendix F. Quality control (QC) procedural observation checklists

### Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

*Date* _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

*Scoring:* ✓ or Y = Yes X or N = No NA = Not Applicable

**1. Preliminary**

- ____ Uses appropriate hand hygiene methods before starting.
- ____ Screens patient for contraindications (severe adverse reactions to previous TST).*
- ____ Uses well-lit area.

**2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§**

- ____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
- ____ Checks label and expiration date on vial.
- ____ Marks opening date on multidose vial.
- ____ Fills immediately after vial removed from refrigeration.
- ____ Cleans vial stopper with antiseptic swab.
- ____ Twists needle onto syringe to ensure tight fit.
- ____ Removes needle guard.
- ____ Inserts needle into the vial.
- ____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
- ____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
- ____ Removes needle from vial.
- ____ Returns antigen vial to the refrigerator immediately after filling.

**3. TST administration site selected and cleaned**

- ____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
- ____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
- ____ Cleans the site with antiseptic swab using circular motion from center to outside.
- ____ Allows site to dry thoroughly before administering antigen.

**4. Needle inserted properly to administer antigen**

- ____ Rests arm on firm, well-lit surface.
- ____ Stretches skin slightly.††
- ____ Holds needle bevel-up and tip at 5°–15° angle to skin.
- ____ Inserts needle in first layer of skin with tip visible beneath skin.
- ____ Advances needle until entire bevel is under the first layer of skin.
- ____ Releases stretched skin.
- ____ Injects entire dose slowly.
- ____ Forms wheal, as liquid is injected.
- ____ Removes needle without pressing area.
- ____ Activates safety feature of device per manufacturer's recommendations, if applicable.
- ____ Places used needle and syringe immediately in puncture resistant container without recapping needle.
- ____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
- ____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
- ____ Discards used gauze or cotton ball according to local standard precautions.

If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.

- ____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
- ____ Uses appropriate hand hygiene methods after placing TST.

**5. Explanation to the client regarding care instructions for the injection site**

- ____ The wheal (bump) is normal and will remain about 10 minutes.
- ____ Do not touch wheal; avoid scratching.
- ____ Avoid pressure or bandage on injection site.
- ____ Rare local discomfort and irritation does not require treatment.
- ____ May wash with soap and water (without pressure) after 1 hour.
- ____ No lotions or liquids on site, except for light washing, as above.
- ____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ⅝–½ inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:682–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.
**SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

[3] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.



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## Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

### Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

**Date** _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

**Scoring:** ✓ or Y = Yes X or N = No NA = Not Applicable

**1. Preliminary**

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

**2. Palpate — finding margin ridges (if any)**

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

**If induration is present, continue with these steps†:**

**3. Placing marks**

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

**4. Placing and reading ruler**

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

**5. Documenting results**

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes_____ No_____

**NOTE:** In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

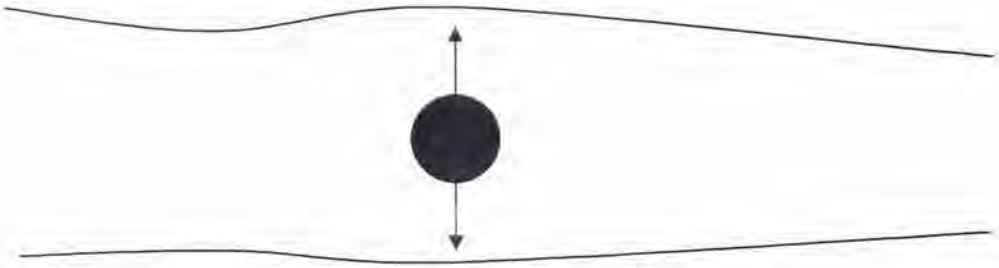
Appendix B: Interpretation of the Tuberculin Skin Test

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction (Table 8: page 1390)

| Induration of >5mm | Induration of >10mm | Induration of >15mm |
|---|---|---|
| Positive if certain factors present:<br>• HIV positive<br>• Recent contact with active TB patient<br>• Individuals with fibrotic changes on chest radiograph consistent with prior TB<br>• Individuals with organ transplants<br>• Individuals who are immunosuppressed for other reasons | Positive if certain factors present:<br>• Recent immigrants (<5years) from high prevalence country<br>• Injection drug users<br>• Residents and employees of high-risk congregant settings<br>• Mycobacteriology lab personnel<br>• Persons with clinical conditions that place them at high risk | • Positive for any individual, including persons with no known risk factors for TB testing<br>• However, targeted skin testing programs should only be conducted among high-risk groups |

A negative TST result does not exclude LTBI or active TB disease.



**Measure TSTs Transversely**

## CDC LTBI: A Guide for Primary Health Care Providers

## Sample Risk Assessment

http://www.cdc.gov/tb/publications/ltbi/appendixa.htm

Appendix C: Kentucky Department for Public Health TB Risk Assessment Forms (Example of TB-4 TB Risk Assessment Form (Rev. July 2018); TB-4a Instructions for TB Risk Assessment; TB-4b Additional Instructions) *Please check the Kentucky Department for Public Health website for updates to TB Risk Assessment forms under Clinical Service Guide Forms and Teaching Sheets: https://chfs.ky.gov/agencies/dph/dpqi/hcab/Pages/ccsguide.aspx*

| INSERT LOGO HERE | **Kentucky Department For Public Health**<br>**Tuberculosis (TB) Risk Assessment** |
|---|---|

Patient name (L,F,M): _____ DOB: _____ Race: ____ Sex: ____ SSN: _____

Address: _____ City, State, Zip: _____

Home/Work #: _____ Cell# _____ Patient Pregnant: ____ No ____ Yes; If Yes, LMP _____

Language: _____ Country of Origin: _____ Year arrived in US: _____ Interpreter needed: ____ No ____ Yes

Allergies: _____ Current Medications: _____

**I. Screen for Active TB Symptoms (Check all that apply)**

___None (Skip to Section II, "Screen for TB Infection Risk")
___Cough for ≥ 3 weeks → Productive: ___YES ___NO
___Hemoptysis
___Fever, unexplained
___Unexplained weight loss
___Poor appetite
___Night sweats
___Fatigue

*Evaluate these symptoms in context*

**Pediatric Patients (≤ 5 years of age):**
___Wheezing
___Failure to thrive
___Decreased activity, playfulness and/or energy
___Lymph node swelling
___Personality changes

**II. Screen for TB Infection Risk *(Check all that apply)***

Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.

**A. Assess Risk for Acquiring LTBI. The Patient:**
___ is a current high risk contact of a person known or suspected to have TB disease.
___ has been in another country for - 3 or more months where TB is common, and has been in the US for ≤ 5 years
___ is a resident or an employee of a high TB risk congregate setting
___ is a healthcare worker who serves high-risk patients
___ is medically underserved
___ has been homeless within the past two years
___ is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories
___ injects illicit drugs or uses crack cocaine
___ is a member of a group identified by the health department to be at an increased risk for TB infection
___ needs baseline/annual screening approved by the health department

**B. Assess Risk for Developing TB Disease if Infected The Patient...**
___ is HIV positive
___ has risk for HIV infection, but HIV status is unknown
___ was recently infected with *Mycobacterium tuberculosis*
___ has certain clinical conditions, placing them at higher risk for TB disease: _____
___ injects illicit drugs (determine HIV status): _____
___ has a history of inadequately treated TB
___ is >10% below ideal body weight
___ is on immunosuppressive therapy (this includes treatment for rheumatoid arthritis with drugs such as REMICADE, HUMIRA, etc.)

**History of BCG / TB Skin Test / BAMT / TB Treatment:**

History of prior BCG: ___NO ___YES → Year: _____
History of prior (+) TST or (+) BAMT: ___NO ___YES
Date (+) TST / (+) BAMT _____ TST: ____mm
CXR Date: _____ CXR result: ___ABN ___WNL
Dx: ___LTBI ___Disease
Tx Start: _____ Tx End: _____
Rx: _____
Completed: ___NO ___YES
Location of Tx: _____

**III. Finding(s) *(Check all that apply)***

___ Previous Treatment for LTBI and/or TB disease
___ No risk factors for TB infection
___ Risk(s) for infection and/or progression to disease
___ Possible TB suspect
___ Previous (+) TST or (+) BAMT, no prior treatment

**IV. Action(s) *(Check all that apply)***

___ Issued screening letter ___ Issued sputum containers
___ Referred for CXR ___ Referred for medical evaluation
___ Administered the Mantoux TB Skin Test
___ Draw BAMT / Interferon-gamma Release Assay ((IGRA)
___ Other: _____

| **TST Brand/Lot #_____** | **TST Brand/Lot#_____** |
|---|---|
| Arm: ___Left ___Right | Arm: ___Left ___Right |
| Date/Time _____ | Date/Time _____ |
| Induration_____mm | Induration_____mm |

**___BAMT ___T-SPOT.*TB*** **___QFT-TB-Gold-Plus**

Date/Time drawn: _____

Result: ___Pos ___Neg ___Borderline/Indeterminate

Screener's signature: _____

Screener's name (print): _____

Screener's title: _____

Date: _____ Phone #: _____

Comments: _____

- I hereby authorize the doctors, nurses, or nurse practitioners of the _____Department for Public Health to administer a Tuberculin Skin Test (TST) or draw blood from me or my child named above for a Blood Assay for *Mycobacterium tuberculosis* (BAMT) test.
- I agree that the results of this test may be shared with other health care providers.
- I understand that: • this information will be used by health care providers for care and for surveillance /statistical purposes only.
  • this information will be kept confidential

X _____ Date: _____

**IMPORTANT: A decision to test is a decision to treat.** Given the high rates of false positive TB skin test results, the Kentucky TB Prevention and Control Program discourages administration of the Mantoux TST to persons who are at a low risk for TB infection.

# Kentucky Department For Public Health
# Instructions for the TB Risk Assessment

**Purpose of Form**
The TB Risk Form is a tool to assess and document a patient's TB symptoms and/or risk factors. Completing this form will also help in determining the need for further medical testing and evaluation.

**Directions for Completing the Form**
Print clearly and complete this form according to the instructions provided below.

## I. Screen for Presence of TB Symptoms

- Screen the patient for symptoms of active TB disease
- All symptomatic individuals who have not had a positive tuberculin skin test (TST) in the past should: (1) receive a TST or a Blood Assay for *Mycobacterium tuberculosis* (BAMT or Interferon Gamma Release Assay [IGRA]); (2) have their sputum collected; and (3) be referred for an immediate chest x-ray and medical evaluation regardless of the TST or BAMT result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- *Symptoms of active TB disease are more subtle in children.* Children with symptoms of active TB disease should receive a TST, CXR and immediate medical evaluation by medical personnel knowledgeable about pediatric TB.

## II. Screen for TB Infection Risk (In subsections A and B, check all the risk factors that apply.)

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III and administer the TST or BAMT.
- If a patient does not have risk factors for LTBI, do not administer the TST or BAMT. Go to Section III and place a check next to "No Risk *Factors for TB Infection.*"
- If the patient's school, employment, etc. requires a TB screening, place a check next "Issued Screening Letter" (Section IV) and provide that document to the patient.

**A. Assess Risk for Acquiring LTBI -- The following are definitions of select categories of persons at risk for LTBI**

- *Person is a current close contact of another individual known or suspected to have TB disease* --
  Person is part of a current TB contact investigation
- *Person is a resident/employee of high TB risk congregate settings*-
  These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill, and persons with AIDS.
- *Person is a health care worker who serves high-risk clients* --
  Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- *Person is medically underserved* –
  Person does not have a regular health care provider, and has not received medical care within the last 2 years.
- *Person is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories* –
  Child has foreign-born parents, or child's parents/caretakers are at high risk for acquiring TB infection.
- *Person is a member of a group identified by a local health department to be at an increased risk for TB infection* --
  Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group
- *Person needs baseline/annual screening approved by health department* –
  Screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI

**B. Assess Risk for Developing TB Disease if Infected - The following are definitions of select categories of persons at risk for TB disease if infected**

- *Person's HIV Status is unknown but has risk for HIV infection*
  Offer HIV test. Proceed with the TB Skin Test or BAMT, even if the patient refuses the HIV test.
- *Person with clinical conditions that place them at high risk* --
  Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, smoker, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- *Person is on immunosuppressive therapy* –
  Person is taking $\geq$ 15 mg/day of prednisone for $\geq$ 1 month; person is receiving treatment for rheumatoid arthritis with medications such as REMICADE, Enbrel, or HUMIRA and/or person needs baseline evaluation prior to start of arthritis treatment with the medications cited here.

## III. Finding(s) (Check all findings that apply.)

In this section, indicate findings from the assessments in all previous sections.

## IV. Action(s) (Check all actions that apply.)

- Indicate the action(s) to take as a result of the findings in Section III
- If administering a TST or BAMT, provide all requested data.
- Write other pertinent patient information next to "Comments"

***Additional Follow-up to the TST or BAMT***

- If the patient's TST reaction or BAMT result is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for a chest x-ray.
- If a person has a history of a positive TST or a positive BAMT and is currently asymptomatic, then refer him/her for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment and 2) patient is willing to adhere to the treatment.

**Additional Guidelines for**
**Tuberculosis (TB) Risk Assessments, Form TB-4**

Since 2007, Local Health Departments (LHDs) have had more activity for "**Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**," http://www.cdc.gov/MMWR/preview/MMWRhtml/rr4906a1.htm. The TB Risk Assessment Form, TB-4, was developed to aid Local Health Departments in conducting TB risk assessments with targeted testing for those Kentuckians with increased risk for latent TB infection (LTBI).

As noted in the CDC guideline, "Targeted tuberculin testing for LTBI is a strategic component of tuberculosis (TB) control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB. Following that principle, targeted tuberculin testing programs should be conducted only among groups at high risk and discouraged in those at low risk. Infected persons who are considered to be at high risk for developing active TB should be offered treatment of LTBI irrespective of age."

The overall goal of these TB risk assessments at LHDs is to increase the percentage of tuberculin skin tests (TSTs) or blood assays for *Mycobacterium tuberculosis* (BAMTs) that are administered to individuals at increased risk for LTBI and to decrease the percentage of TSTs or BAMTs that are administered to individuals who have no risk factors for LTBI.

LHDs should use the TB risk assessment for all patients presenting for TB screenings, including those individuals identified in contact investigations. The TB Risk assessment form is an ideal tool for educating patients about the signs and symptoms of active TB, the risk factors for developing LTBI, and the risk factors for rapid progression of LTBI to active TB.

The TB risk assessment process also more easily enables LHD staff to determine the cut-off values for reading a TST when a TST is used for screening. A "Report of Tuberculosis Screening," Form TB-3, can be completed for those patients who need documentation of the results of TB screening for their employers or other groups.

*The Kentucky TB Program recognizes that the LHD may choose to collaborate with other organizations for the management and treatment of LTBI or other TB-related occupational health services. In these instances, a written agreement should be initiated between the two agencies to clearly identify the roles of each organization and define a payment schedule for any TB-related services provided by the LHD.

# New CDC Guidelines Recommend Against Annual Tuberculosis Testing

By **Bryan Bledsoe, DO, FACEP, FAAEM, EMT-P** - 5.6.2021

*The image shows a medical illustration of drug-resistant, Mycobacterium tuberculosis bacteria. (CDC Image/Medical Illustrators are Alissa Eckert and James Archer)*

On May 7, 2019, the Centers for Disease Control and Prevention (CDC) updated guidelines for Tuberculosis (TB) testing of healthcare workers including EMS personnel. This was updated on March 8, 2021. One of the most significant changes was that annual TB testing of health care personnel is no longer recommended. The new guidelines call for all U.S. health care personnel to be screened for TB upon hire including a risk assessment, TB symptom evaluation and TB testing. Following that, annual TB testing of health care personnel is *not* recommended unless there is a known exposure or ongoing transmission. Instead, employees should receive annual TB education that includes information on TB risk factors, the signs and symptoms of TB disease, and TB infection control policies and procedures.

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## What is Tuberculosis?

Tuberculosis is an infection caused by the bacteria *Mycobacterium tuberculosis*.

## Where is Tuberculosis Found?

TB is found worldwide. While relatively uncommon in the United States, it has been estimated that approximately one-fourth of the world population has TB infection. In excess of 95% of TB cases and deaths occur in developing countries.

**Related:** Strategies for Keeping You and Your Patients Infection-Free

Specifically, 88% of new TB cases worldwide come from 30 countries that have a high TB burden. Eight countries account for two thirds of the total new TB cases:

- India (highest),
- Indonesia,
- China,
- The Philippines,
- Pakistan,
- Nigeria,
- Bangladesh, and
- South Africa.

Fortunately, the incidence of TB worldwide is falling at about 2% per year. In 2019, the United States reported only 8,916 cases new TB cases (2.7 per 100,000 population).

## Who Is At Risk for Tuberculosis?

Tuberculosis is primarily a disease of adults but can affect all age groups. Patients with active HIV infections and those on immunosuppressive therapy (e.g., cancer patients) are significantly more likely to contract TB. Other risk factors include people with tobacco use disorder, alcohol use disorder, diabetes, low body weight and malnutrition. Also, infants and children less than four years of age are at increased risk due to an immature immune system.

## What Are the Signs and Symptoms of TB Infection?

TB is primarily a respiratory disease and is spread through the air. The infected person spreads the bacteria when they cough, speak, or sneeze. People in close proximity may then inhale the TB bacteria and become infected. Interestingly, not everyone infected with TB bacteria become sick. Two TB-related conditions exist:

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- *Latent TB infection (LTBI).* People with LTBI are infected with *M. tuberculosis* but they do not have TB disease. They do not have any of the signs and symptoms of TB disease and they cannot spread *M. tuberculosis* to others. They usually have a positive TB skin test or a positive TB blood test. Only 5-10% of people with LTBI later develop TB disease if they do not receive treatment. However, many people who have latent TB infection never develop TB disease. In these people, the TB bacteria remain inactive for a lifetime without causing disease.
- *TB disease*. TB disease, also called "active TB," is a potentially serious infectious disease caused by infected with *M. tuberculosis* that primarily affects the respiratory tract (lungs). The signs and symptoms of TB disease include:
  - Persistent cough lasting three weeks or longer
  - Chest pain
  - Coughing up sputum or blood (hemoptysis)
  - Weakness or fatigue
  - Weight loss
  - Loss of appetite
  - Chills
  - Fever (often recurrent)Night sweats

In some cases, TB infection can spread outside of the lungs and is called *extrapulmonary TB (EPTB).* EPTB infection can involve the lymph nodes (lymphadenitis), pleura (pleuritis), the meninges (meningitis), abdomen (peritonitis), genitourinary tract, and bone. TB infection of the spine is called Pott's disease. *Miliary TB* occurs when the TB bacteria are spread through the blood affecting both pulmonary and extrapulmonary sites. Approximately 10% of all TB cases have both pulmonary and extrapulmonary TB.

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## How is TB Diagnosed?

There are several ways to diagnose TB. The most common methods are skin testing and blood testing.

- *Skin test*. The skin test, also called a Mantoux tuberculin skin test (TST), is commonly used. For this test, a small amount of fluid called tuberculin or purified protein derivative (PPD) is injected into the skin (intradermal) of the volar forearm. This fluid contains inactivated *purified protein* fraction obtained from human strains of *M. tuberculosis* and is antigenic (will invoke an immune response). The injection site is checked at 72 hours post-injection. If there is an induration (not redness) of 10 millimeters or more at the injection site, the test is deemed positive.

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- *Blood test*. There are two TB blood tests approved for use in the United States: QuantiFERON® and T-Spot®. These tests detect and measure the body's cell-mediated immune response (interferon gamma) following exposure to antigens from *M. tuberculosis*. A positive test means that the person has been infected with TB bacteria and additional tests are needed to determine if the person has LTBI or TB disease. A negative TB blood test means that the person did not react to the test and that latent TB infection or TB disease is not likely.
- *Chest x-ray (CXR)*. Chest x-rays are frequently used to determine whether or not there is pulmonary infection associated with a positive TB test. In some instances, an abnormal chest x-ray may be the first indicator of TB in a patient. A negative chest x-ray does not exclude the presence of TB infection in other parts of the body.
- *Lab testing*. Microscopic examination of expectorated sputum from an infected patient may demonstrate the presence of *M. tuberculosis* bacteria. Specialized blood cultures for *M. tuberculosis* and similar bacteria are also available.

## Is There a Vaccine for TB?

There is a vaccine for TB but it is not used in the United States. The vaccine, called the Bacillus Calmette–Guérin (BCG) vaccine, is primarily used in countries where TB and leprosy are common (primarily in South America and Europe).

**Related:** Infection Control and Liability in EMS

The vaccine is generally effective and safe but can cause pain and scarring at the injection site. Persons who received the BCG vaccine will test positive during subsequent TB testing and require specialized evaluation.

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## What is the Treatment for TB?

LTBI is typically treated with a 3-4 months course of isoniazid (INH), rifapentine (RPT), or rifampin (RIF). TB disease is typically treated using several drugs for 6 to 9 months. The first-line anti-TB agents are isoniazid (INH), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA). There are several strains of the *M. tuberculosis* bacteria that have become resistant to many of these drugs (multi-drug resistant) and specialized treatment strategies are required. Multi-drug resistant TB is most commonly seen in patients with HIV infection or those with immunosuppression.

## References

https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm

https://www.cdc.gov/tb/topic/basics/default.htm



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Tuberculosis (TB)

# Core Curriculum on Tuberculosis: What the Clinician Should Know

## Print-Version

The Core Curriculum on Tuberculosis: What the Clinician Should Know [PDF – 6.8 MB] presents information about TB for health care professionals. This document is intended for use as a reference manual for clinicians caring for persons with or at high risk for TB disease or infection. It is not meant to provide detailed answers to all public health or clinical questions about TB, and it is not meant as a substitute for any specific guidelines. It is anticipated that new guidelines will be published in the future that will supersede information in this document, and these new guidelines will be posted on the DTBE website.

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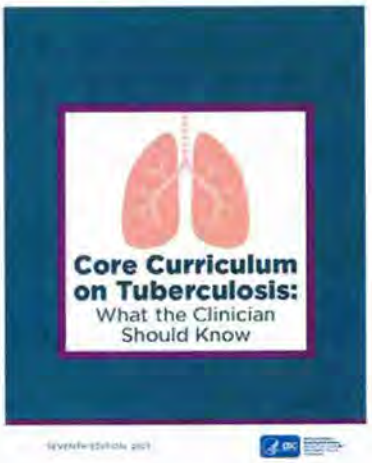


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### Continuing Education Credits

The Centers for Disease Control and Prevention is accredited to provide continuing education (CE) for various professions. CE is offered free of charge.

The Core Curriculum on Tuberculosis: What the Clinician Should Know – Continuing Education

## Interactive


**The Interactive Core Curriculum on Tuberculosis was last updated in 2015. Please refer to the print Core Curriculum for the latest content.**

The *Interactive Core Curriculum on Tuberculosis: What the Clinician Should Know* provides clinicians and other public health professionals with information on diagnosing and treating latent TB infection and TB disease. The target audience of the course is clinicians caring for people with or at high risk for TB disease.

Interactive Core Curriculum

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Content source: Division of Tuberculosis Elimination

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# Mantoux
## tuberculin skin test

## 1 Administration

For each patient, conduct a risk assessment that takes into consideration recent exposure, clinical conditions that increase risk for TB disease if infected, and the program's capacity to deliver treatment for latent TB infection to determine if the skin test should be administered.

### 1 Locate and clean injection site

- 2 to 4 inches below elbow joint
- Place forearm palm side up on a firm, well-lit surface
- Select an area free of barriers (e.g., scars, sores) to placing and reading
- Clean the area with an alcohol swab

### 2 Prepare syringe


- Check expiration date on vial and ensure vial contains tuberculin (5 TU per 0.1 ml)
- Use a single-dose tuberculin syringe with a ¼- to ⅝-inch, 27-gauge needle with a short bevel
- Fill the syringe with 0.1 ml of tuberculin

### 3 Inject tuberculin

- Insert slowly, bevel up, at a 5- to 15-degree angle

- Needle bevel must be seen just below skin surface
- After injection, a tense, pale wheal should appear over the needle

### 4 Check skin test


- Wheal should be 6 to 10 mm in diameter. If not, repeat test at a site at least 2 inches away from original site

### 5 Record information

- Record all the information required for documentation by your institution (e.g., date and time of test administration, injection site location, lot number of tuberculin)

## 2 Reading

The skin test should be read between 48 and 72 hours after administration. A patient who does not return within 72 hours will probably need to be rescheduled for another skin test.

### 1 Inspect site

- Visually inspect site under good light
- Erythema (reddening of the skin) – do not measure
- Induration (hard, dense, raised formation)

### 2 Palpate induration

- Use fingertips to find margins of induration

### 3 Mark induration

- Use fingertip as a guide for marking widest edges of induration across forearm

### 4 Measure induration (not erythema)


- Place "0" ruler line inside left dot edge
- Read ruler line inside right dot edge (use lower measurement if between two gradations on mm scale)

### 5 Record measurement of induration in mm

- If no induration, record as 0 mm
- Do not record as "positive" or "negative"
- Only record measurement in mm

## 3 Interpretation

Skin test interpretation depends on two factors:
- Measurement in millimeters (mm) of the induration
- Person's risk of being infected with TB and progression to disease if infected

The three cut points below should be used to determine whether the skin test reaction is positive. A person with a positive reaction should be referred for a medical evaluation for latent TB infection and appropriate follow-up and treatment if necessary. A measurement of 0 mm or a measurement below the defined cut point for each category is considered negative.

### Induration of ≥ 5 mm is considered positive in

- Human immunodeficiency virus (HIV)-infected persons
- Recent contacts of TB case patients
- Persons with fibrotic changes on chest radiograph consistent with prior TB
- Patients with organ transplants and other immunosuppressed patients (e.g., receiving the equivalent of ≥15 mg/d of prednisone for 1 month or more)

### Induration of ≥ 10 mm is considered positive in

- Recent immigrants (i.e., within the last 5 years) from countries with a high prevalence of TB
- Injection drug users
- Residents and employees* of the following high-risk congregate settings:
  - prisons and jails
  - nursing homes and other long-term facilities for the elderly
  - hospitals and other health care facilities
  - residential facilities for patients with acquired immunodeficiency syndrome (AIDS)
  - homeless shelters
- Mycobacteriology laboratory personnel
- Persons with the following clinical conditions that place them at high risk:
  - silicosis
  - diabetes mellitus
  - chronic renal failure
  - some hematologic disorders (e.g., leukemias and lymphomas)
  - other specific malignancies (e.g., carcinoma of the head, neck, or lung)
  - weight loss of ≥10% of ideal body weight
  - gastrectomy
  - jejunoileal bypass
- Children < 5 years of age
- Infants, children, and adolescents exposed to adults at high risk for developing active TB

### Induration of ≥ 15 mm is considered positive in

- Persons with no known risk factors for TB

* For employees who are otherwise at low risk for TB and who are tested as part of an infection control screening program at the start of employment, a reaction of ≥15 mm is considered positive. Some health care workers participating in an infection control screening program may have had an induration >0 mm that was considered negative at baseline. If these health care workers have an increase in induration size upon subsequent testing, they should be referred for further evaluation.

Note: Reliable administration and reading of the tuberculin skin test involves standardization of procedures, training, supervision, and practice. Always follow your institution's policies and procedures regarding infection control, evaluation, and referral. Also remember to provide culturally appropriate patient education before and after administration, reading, and interpretation of the skin test.

For more information on tuberculosis, visit www.cdc.gov/tb

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CDC
TB Elimination

# Tuberculin Skin Testing

## What is it?

The **Mantoux tuberculin skin test (TST)** is one method of determining whether a person is infected with *Mycobacterium tuberculosis*. Reliable administration and reading of the TST requires standardization of procedures, training, supervision, and practice.

## How is the TST Administered?

The TST is performed by injecting 0.1 ml of tuberculin purified protein derivative (PPD) into the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter.

## How is the TST Read?

The skin test reaction should be read between 48 and 72 hours after administration by a health care worker trained to read TST results. A patient who does not return within 72 hours will need to be rescheduled for another skin test.

The reaction should be measured in millimeters of the induration (firm swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis).

## How Are TST Reactions Interpreted?

Skin test interpretation depends on two factors:

- Measurement in millimeters of the induration
- Person's risk of TB infection or the risk of progression to TB disease if infected

## Classification of the Tuberculin Skin Test Reaction

- An **induration of 5 or more millimeters** is considered positive in
  - » People living with HIV
  - » A recent contact of a person with infectious TB disease
  - » People with chest x-ray findings suggestive of previous TB disease
  - » People with organ transplants
  - » Other immunosuppressed people (e.g., patients on prolonged therapy with corticosteroids equivalent to/greater than 15 mg per day of prednisone or those taking TNF-α antagonists)

- An **induration of 10 or more millimeters** is considered positive in
  - » People born in countries where TB disease is common, including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB
  - » People who abuse drugs
  - » Mycobacteriology laboratory workers
  - » People who live or work in high-risk congregate settings (e.g., nursing homes, homeless shelters, or correctional facilities)
  - » People with certain medical conditions that place them at high risk for TB (e.g., silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions)
  - » People with a low body weight (<90% of ideal body weight)
  - » Children younger than 5 years of age
  - » Infants, children, and adolescents exposed to adults in high-risk categories

- An **induration of 15 or more millimeters** is considered positive in
  - » People with no known risk factors for TB

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## What Are False-Positive Reactions?

Some persons may react to the TST even though they are not infected with *M. tuberculosis*. The causes of these false-positive reactions may include, but are not limited to, the following:

- Previous TB vaccination with the bacille Calmette-Guérin (BCG) vaccine
- Infection with nontuberculosis mycobacteria (mycobacteria other than *M. tuberculosis*)
- Incorrect measurement or interpretation of reaction
- Incorrect antigen used

A TB blood test is the preferred method of testing for people who have received the BCG vaccine in order to prevent false-positive reactions. TB blood tests are also called interferon-gamma release assays or IGRAs.

## What Are False-Negative Reactions?

Some persons may not react to the TST even though they are infected with *M. tuberculosis*. The reasons for these false-negative reactions may include, but are not limited to, the following:

- Anergy
- Recent TB infection (within the past 8 to 10 weeks)
- Very young age (younger than 6 months)
- Recent live-virus measles or smallpox vaccination
- Incorrect method of giving the TST
- Incorrect measuring or interpretation of TST reaction

## Who Can Receive a TST?

Most persons can receive a TST. TST is the recommended method of testing for children younger than 5 years of age. It should be noted that the American Academy of Pediatrics (AAP) recommends that either a TST or TB blood test (interferon-gamma release assay [IGRA]), can be used in children 2 years and older. In children previously vaccinated with BCG, a TB blood test is preferred to avoid a false-positive TST result caused by a previous vaccination with BCG.

TST is contraindicated only for persons who have had a severe reaction (e.g., necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST. It is not contraindicated for any other persons, including infants, children, pregnant women, or persons living with HIV. However, TB blood tests are the preferred method of testing for people who have received the BCG TB vaccine.

## How Often Can TSTs Be Repeated?

In general, there is no risk associated with repeated tuberculin skin test placements. If a person does not return within 48-72 hours for a tuberculin skin test reading, a second test can be placed as soon as possible. There is no contraindication to repeating the TST, unless a previous TST was associated with a severe reaction.

## What is a Boosted Reaction?

A boosted reaction occurs mainly in previously infected, older adults whose ability to react to tuberculin has decreased over time. When given a TST years after infection, these persons may have an initial negative reaction. However, the TST may stimulate the immune system, causing a positive or boosted reaction to subsequent tests. Giving a second TST after an initial negative TST reaction is called two-step testing.

## Why is Two-Step Testing Conducted?

Two-step testing is useful for the initial skin testing of adults who are going to be retested periodically, such as some health care workers. This two-step approach can reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection.

## Can TSTs Be Given To Persons Receiving Vaccinations?

Vaccination with live viruses, including measles, mumps, rubella, oral polio, varicella, yellow fever, BCG, and oral typhoid, may interfere with TST reactions. For persons scheduled to receive a TST, testing should be done as follows:

- Either on the same day as vaccination with live-virus vaccine or
- At least 1 month after the administration of the live-virus vaccine

## Are there alternative tests to the TST?

There are two kinds of tests that are used to determine if a person has been infected with TB bacteria: the TB blood test and the TB skin test. TB blood tests (sometimes called IGRAs) use a blood sample to find TB infection. The tests measure the response of TB proteins when they are mixed with a small amount of blood. Only one visit is required to draw blood for this test. Health care providers are encouraged to use newer TB blood tests to screen for TB infection. In order to prevent false-positive reactions, TB blood tests are also the preferred method of TB testing for people 5 years of age and older who have received the BCG TB vaccine.

## What does a positive TST mean for the diagnosis of latent TB infection and TB disease?

### Diagnosis of Latent TB Infection

A diagnosis of latent TB infection is made if a person has a positive TB test result and a medical evaluation does not indicate TB disease. The decision about treatment for latent TB infection will be based on a person's chances of developing TB disease by considering their risk factors.

### Diagnosis of TB Disease

TB disease is diagnosed by medical history, physical examination, chest x-ray, and other laboratory tests. TB disease is treated by taking several drugs as recommended by a health care provider.

## What are treatment options for latent TB infection?

Treating latent TB infection is effective in preventing TB disease and less costly than treating TB disease. There are several treatment regimens for the treatment of latent TB infection. These regimens use the drugs isoniazid, rifapentine, or rifampin.

CDC and the National Tuberculosis Controllers Association (NTCA) preferentially recommend short-course, rifamycin-based, 3- or 4-month latent TB infection treatment regimens over 6- or 9-month isoniazid monotherapy (6H or 9H, respectively). Short-course regimens include: Three months of once-weekly isoniazid plus rifapentine (3HP), four months of daily rifampin (4R), or three months of daily isoniazid plus rifampin (3HR). Short-course latent TB infection treatments are effective, are safe, and have higher completion rates than longer treatments.

If a short-course treatment regimen is not an option, 6H or 9H is an effective alternative latent TB infection treatment regimen.

## Additional Information


- CDC. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR 2005; 54 (No. RR-17). www.cdc.gov/tb/publications/guidelines/infectioncontrol.html
- CDC. Mantoux Tuberculin Skin Test: Training Materials Kit (2003).
- CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000; 49 (No. RR-6). www.cdc.gov/MMWR/PDF/rr/rr4906.pdf
- Lewinsohn et al., Official American Thoracic Society/Infectious Diseases Society of America/CDC Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, Clinical Infectious Diseases, 2017, Pages e1–e33. www.academic.oup.com/cid/article/64/2/e1/2629583
- Latent TB Infection Testing and Treatment: Summary of U.S. Recommendations www.cdc.gov/tb/publications/ltbi/pdf/CDC-USPSTF-LTBI-Testing-Treatment-Recommendations-508.pdf
- What You Need To Know About the Tuberculosis Skin Test www.cdc.gov/tb/publications/pamphlets/tb_skin_test.pdf
- Patient Education Materials Series www.cdc.gov/tb/education/patient_edmaterials.html


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Tuberculosis Screening and Testing for Occupational Purposes
Virginia Department of Health
Division of Clinical Epidemiology – TB Program

**BACKGROUND**

Many types of occupations and employers require the evaluation of employees for active tuberculosis (TB) disease or the risk of active tuberculosis disease. Typically, tuberculosis evaluation is required for those working in health care settings as well as others working with vulnerable populations. The purpose of screening and testing for TB varies with the occupational group, and ensures that individuals with active tuberculosis disease are not present in the work site, putting others at risk.

Decisions as to whether the evaluation of individual employees is needed is based on many factors including national standards for certain occupations; statutory and regulatory law; and evaluation of work sites for the potential of encountering individuals with active tuberculosis disease. For any given work site, several of these factors may influence the type of evaluation needed by employees as well as the frequency of the evaluation.

**EVALUATION FOR TUBERCULOSIS**

The process of evaluation for tuberculosis will vary for each individual. Evaluation may be as simple as answering questions about past medical history and current health or it may be more extensive, requiring a number of tests. The need for testing and a more extensive evaluation will be based on an individual's personal health factors, the setting in which work occurs, and regulatory/statutory requirements. Employees should not be permitted to work until the full, initial TB evaluation is completed.

**It is extremely important** to remember that any evaluation for tuberculosis does not provide protection against future infection or disease. It only provides information on an individual's current TB status or risk.

**Types of Evaluations:**

**TB Risk Assessment** or "TB Screening"– The TB risk assessment is a series of questions designed to determine an individual's risk for either acquiring the TB bacteria in the body or of becoming ill with the disease, if infected. Questions may include information about current health status and recent illnesses, travel history, exposure to known individuals with TB disease, and selected medical diagnoses. While these questions may be asked by a licensed health care provider (MD, PA, NP, RN, LPN), consistent with Virginia professional practice acts, only physicians, physician's assistants, nurse practitioners, and registered nurses can assess risk for TB infection and/or disease based on the answers. Facilities and employers may design their own screening and clearance forms incorporating the elements found on VDH TB Risk Assessment form. For reference, an adult VDH TB Risk Assessment form can be found at: http://www.vdh.virginia.gov/content/uploads/sites/112/2019/02/VA-TB-Risk-Assessment-and-User-Guide-2019-1.pdf and a pediatric VDH TB Risk Assessment form can be found at: http://www.vdh.virginia.gov/content/uploads/sites/112/2019/02/VA-TB-Risk-Assessment-for-Children-Under-6-and-User-Guide-2019.pdf

Certain occupations and regulations allow and accept the results of the TB risk assessment without further required testing. However, regardless of regulations, individuals with positive findings during the TB risk assessment will require additional evaluation. Consistent with Virginia professional practice acts, only a physician, physician's assistant, nurse practitioner, or registered nurse may determine if employment clearance can be provided based on the answers or if additional testing is required before employment clearance can be given. Employment clearance will not be provided until all additional testing is completed, and it is safe for the individual to be present in the work site.

**Testing for TB Infection** – Testing for the presence of the TB bacteria in the body may be required for some seeking clearance for employment purposes. There are several types of tests available for this purpose. The healthcare provider will determine which test is most appropriate for each individual.

**Blood Tests for TB Infection** – An Interferon Gamma Release Assay (IGRA) is a blood test that can determine if a person has been infected with TB bacteria. An IGRA tests a person's blood in a laboratory to measure how the immune system reacts to the TB bacteria. IGRAs approved by the U.S. Food and Drug Administration (FDA) and available in the United States include QuantiFERON®-TB Gold in-Tube, QuantiFERON®-Plus, and T-SPOT® TB. These tests may be used in place of the tuberculin skin tests and are preferred for persons age 2 and older. Further information on the use of IGRA tests can be found at: https://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf

**Tuberculin Skin Test** – The tuberculin skin test (TST) is performed by the injection of a small amount of TB protein under the skin. If the body has interacted with the TB bacteria in the past, the immune system will produce a reaction at the site of injection.

Some important points to know:

- TB bacteria are NOT injected into the body. Only a small amount of protein from the TB bacteria is injected. You can NOT get TB from the test.
- The TST is NOT an immunization or vaccine. It does not provide any protection against TB for those who are tested. It only shows the immune system responded to the bacteria from an exposure in the past. It is more like allergy testing.
- Individuals need to return 48-72 hours after the injection for the health care provider to observe any reaction present at the injection site. Consistent with professional practice acts, palpation and measurement of any reaction at the site can be performed by many types of health care workers, however, only physicians, physician's assistants, nurse practitioners, and registered nurses can determine the significance of any reaction and the need for additional evaluation. For registered nurses to perform this task, a standing protocol must be signed by a healthcare worker with prescriptive authority and be in place (§ 54.1-3408. Professional use by practitioners, paragraph G).
- Individuals who may be screened and tested on a regular basis for TB exposure, as part of an infection control program, may need to have two tests upon employment. The health care provider will determine if two tests are needed.

**Chest X-rays** – Individuals with symptoms of active pulmonary tuberculosis or those with a new positive test for TB infection will need to obtain a chest x-ray. If abnormal findings are present in the x-ray, further testing will be required before employment clearance can be provided.

**Additional Tests** – Based on the evaluation process and the findings, additional testing, such as the collection of sputum, may be required. The healthcare provider will determine what additional evaluation is needed based on the findings to date. Employment clearance will be deferred until completion of the evaluation process.

In the event that an individual is found to have active TB disease, the health department will determine when an individual can safely enter a work setting and will provide employment clearance.

**EVALUATION REQUIREMENTS OF SPECIFIC EMPLOYERS**

There are differences in the type of evaluations needed by specific groups of employees. Requirements for pre-employment and ongoing TB evaluation are based on national standards for selected occupations as well as statutory and regulatory requirements. Although the health department assists agencies in determining regulatory requirements, it does not mandate specific evaluation requirements for specific settings.

As stated previously, regulations and standards for TB evaluation for occupational groups and settings are developed and implemented for several purposes. Specific groups of employees include:

**Healthcare personnel** – According to recommendations from the Centers for Disease Control and Prevention (CDC) and national standards, all newly employed healthcare personnel are required to have **baseline screening and testing for TB infection** prior to entering the work site. This includes a TB risk assessment, symptom screen and a test for the presence of TB infection (2-step TST or a single IGRA blood test). Based on the results of this testing, additional evaluation may be required prior to the granting of employment clearance using the process described above in the Evaluation for Tuberculosis section. Employees should not be permitted to work until the TB evaluation is completed. Treatment for Latent TB Infection (LTBI) is strongly encouraged for all health care personnel newly diagnosed with LTBI.

Healthcare personnel with a documented prior positive test for TB infection and documented normal chest radiograph performed after the positive test for TB infection do not require repeat TB testing or a repeat radiograph unless they are symptomatic. These individuals need a TB screening upon employment and should be offered and strongly encouraged to complete LTBI treatment, if previously untreated. If they elect to be treated for TB infection, a new chest x-ray will need to be performed prior to the initiation of treatment.

Annual TB testing of health care personnel is **not** recommended unless there is a known exposure or ongoing transmission at a healthcare facility. Health care personnel with untreated LTBI should receive an annual TB symptom screen and risk assessment. Symptoms for TB disease include any of the following: a cough lasting longer than three weeks, unexplained weight loss, night sweats or a fever, and loss of appetite.

Healthcare facilities might consider using annual TB screening for certain groups at increased occupational risk for TB exposure (e.g., pulmonologists or respiratory therapists) or in certain settings if transmission has occurred in the past (e.g., emergency departments). Facilities should work with the local health department to make these decisions.

Facilities should educate all front-line supervisors and managers about symptoms for TB disease so that any symptomatic individuals in the workplace are promptly identified and referred for immediate evaluation regardless of any periodic screening programs in place.

All healthcare personnel should receive TB education annually. TB education should include information on TB risk factors, the signs and symptoms of TB disease, and TB infection control policies and procedures.

**Public School employees** – All Virginia public school employees are required to be screened and if needed, tested prior to employment. (http://law.lis.virginia.gov/vacode/title22.1/chapter15/section22.1-300/). There is no state requirement for ongoing periodic screening or testing. According to statute, an RN can sign the Report of Tuberculosis Screening for school employees. Employees should be aware that testing may be required in the event of exposure to an active case of tuberculosis in a school setting.

**Correctional facilities** - According to recommendations from the Centers for Disease Control and Prevention (CDC) and national standards, all persons working with correctional populations are required to have **2-step TST baseline testing for TB infection or single IGRA blood test** prior to entering the work site. Based on the results of this testing, additional evaluation may be required prior to the granting of employment clearance using the process described above in the Evaluation for Tuberculosis section.

In addition, the CDC recommends that all correctional employees be screened AND tested annually. Correctional facilities should refer to the MMWR, "Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC", for additional information. (https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm).

**Daycare centers, group homes, and other settings/programs** - Based on the vulnerability of served populations, workers in other occupations may require TB evaluation prior to employment. The requirement for this evaluation is generally found in state regulations for each program. Regulations governing the vast majority of these programs accept the results of the TB risk assessment without further testing. However, regardless of regulations, individuals found to have positive findings during the TB risk assessment will require additional evaluation as noted above. A licensed health care provider (MD, PA, NP, RN) will determine if additional testing is required before employment clearance can be given. Employment clearance will not be provided until the additional testing is completed, and it is safe for the individual to be present in the work site.

**Medicaid Waiver Programs** – Individuals providing in-home services to clients under various Medicaid Waiver programs are required to have a TB evaluation prior to employment as well as annually thereafter. The Virginia TB Program recommends exempting follow-up screening for caregivers already residing with a client, or for extended family members/others providing care prior to enrollment in a Medicaid Waiver program. This recommended exemption does not apply to caregivers working for healthcare or other employment agencies.

Employment agencies providing personal care services under Medicaid waiver programs must consider the setting in which services are provided and match the level of screening to the site with the highest level of screening/testing required.

**ADDITIONAL CONSIDERATIONS**

All employers should remain alert for changes to recommendations and regulations concerning the need for TB evaluation by their employees. Employers should also provide copies of the governing regulation to their employees, if requested.

No evaluation for active tuberculosis disease is perfect. With all the tests used in the evaluation of individuals for tuberculosis, while extremely rare, it is possible to have infectious tuberculosis in spite of negative test results. Employers and work settings are cautioned to remain vigilant for employees and

others who appear ill. Such individuals should be referred for evaluation by a health care provider and be excluded from the work setting until the evaluation is complete and clearance is provided.

For questions not addressed in this document, please consult with your with the local/state health department, regulatory agency, or legal counsel.

**EVIDENCE BASE**


Centers for Disease Control Fact Sheet: Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. November 2011. https://www.cdc.gov/tb/publications/factsheets/testing/IGRA.pdf

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Code of Virginia. § 22.1-300. Tuberculosis certificate. https://law.lis.virginia.gov/vacode/title22.1/chapter15/section22.1-300/

Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005. CDC Morbidity and Mortality Weekly Report. https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

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Prevention and Control of Tuberculosis in Correctional and Detention Facilities: Recommendations from CDC. Morbidity and Mortality Weekly Report July 7, 2006. Endorsed by the Advisory Council for the Elimination of Tuberculosis, the National Commission on Correctional Health Care, and the American Correctional Association. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5509a1.htm

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Virginia Tuberculosis (TB) Risk Assessment for Children Under 6 Years Old. February 2019. http://www.vdh.virginia.gov/content/uploads/sites/112/2019/02/VA-TB-Risk-Assessment-for-Children-Under-6-and-User-Guide-2019.pdf

## Who Should Be Screened For Tuberculosis?

Groups that are at high risk of TB infection or progression to TB disease if infected should be screened. Screening of other groups diverts resources from high-priority activities and is not endorsed or supported by the Division of TB and Newcomer Health. High risk groups include:

- Close contacts of persons with known or suspected active tuberculosis disease
- Persons infected with or at risk of being infected with HIV
- Persons who inject illicit drugs or other locally identified high-risk substance users
- Persons who have medical risk factors known to increase the risk for TB disease once infected
- Residents and employees of high-risk congregate settings (e.g. correctional institutions, nursing homes, mental institutions, other long-term residential facilities)Health care workers who serve high-risk groups
- Foreign-born persons, including children, who were born in or lived in countries more than 3 months that have a high TB incidence or prevalence
- Infants, children, and adolescents exposed to adults in high-risk categories

### Persons with HIV infection

In persons with TB infection, co-infection with HIV is the most powerful risk factor for progression to active TB disease. Screening for TB infection and disease among with HIV is a high priority. This screening occurs at the initial diagnosis of HIV infection consists of a TST or IGRA test and a detailed symptom review. All individuals with positive tuberculin skin tests or blood tests with TB-like symptoms must undergo a chest radiograph and/or sputum collection to exclude active TB disease. Those with a positive TST or IGRA, but without symptoms or radiographic abnormalities should receive preventive therapy. There is no indication for preventive therapy in the absence of a positive skin test unless the individual is a close contact of a known case of TB disease.

### Transient Populations (homeless persons, seasonal workers)

Screening among high-risk populations that are mobile or otherwise unlikely to complete a course of preventive therapy (homeless persons, migrant or seasonal workers) should focus on finding disease among all, infection and disease among contacts of active cases, and among the immunosuppressed. Screening for TB infection among asymptomatic, non-immunosuppressed members of these populations should be abandoned unless procedures are in place for assuring completion of therapy. If such procedures can be assured, screening for infection among young children (up to the age of 4 years) should take priority over screening in the population as a whole.

### Students (preschool, daycare, primary/secondary schools, colleges and universities)

Studies have consistently shown the routine testing of all children for TB infection prior to school entry or advancement to be of low yield. This practice should be abandoned. Testing of selected groups of children may be justified if they fall into one of the risk categories outlined above. In addition, we do not advocate pre-matriculation testing of all college and university students for tuberculous infection. In this population, unless measures are in place to ensure and monitor compliance with preventive therapy, screening should focus on the identification of persons with TB disease. If screening for infection is to be done, we suggest risk assessment and symptom evaluation be done in order to identify subgroups of students in whom TST, IGRA or other evaluation is indicated.

### Prenatal clinics

Pregnancy does not confer an added risk of tuberculosis infection. There is therefore no rationale for screening for TB infection in this population unless the individual belongs to one of the risk groups. Although tuberculin skin testing and IGRA blood testing are safe during pregnancy, treatment for TB infection is generally deferred until 3 months after the post-partum period. We therefore recommend that in cases were screening for infection is indicated, it be deferred until after delivery so that the interval between diagnosis of infection and initiation preventive therapy can be minimized. This practice would eliminate the need for multiple radiographic examinations. Screening for disease with a symptom assessment is appropriate and those with TB-like symptoms should undergo further evaluation, including a tuberculin skin test or IGRA blood test, chest radiograph, and sputum collection as indicated. Pregnant women with HIV infection or who are known to be close contacts of persons with TB disease should undergo TB skin testing or IGRA blood testing and, if indicated, receive preventive therapy without delay.

### Occupational risk groups – health care workers, residents of congregate facilities

### Patients with a history of TB infection or disease (treated and cured)

There is no indication for routine follow-up chest radiographs in asymptomatic persons with a history of tuberculous infection or a prior history of tuberculosis disease that has been treated and cured. The practice of performing annual screening chest radiographs in those with a history of disease or prior infection should be abandoned. Persons in these categories who must undergo screening for employment or school entry should undergo a symptom assessment. Those with TB-like symptoms should be evaluated further with a chest radiograph and/or sputum collection. In order to satisfy screening regulations, it is suggested that the HCW performing the symptom assessment provide the employee/employer with a statement such as:

> The above named individual has a history of tuberculous infection (or tuberculous disease which has been treated and cured) and is currently free of symptoms suggestive of active tuberculosis. There is no indication for a chest x-ray at this time. This individual is believed to be free of tuberculosis in a communicable form.

Patients with a history of treated and cured MDR-TB represent important exceptions to this rule and may require a more thorough evaluation, including a chest radiograph, to document the absence of recurrence.

## Health Care Personnel (HCP)
# Baseline Individual TB Risk Assessment

## HCP should be considered at increased risk for TB if any of the following statements are marked "Yes":

**Temporary or permanent residence of ≥1 month in a country with a high TB rate**

Any country other than the United States, Canada, Australia, New Zealand, and those in Northern Europe or Western Europe

YES ☐ NO ☐

**OR**

**Current or planned immunosuppression,**

including human immunodeficiency virus (HIV) infection, organ transplant recipient, treatment with a TNF-alpha antagonist (e.g., infliximab, etanercept, or other), chronic steroids (equivalent of prednisone ≥15 mg/day for ≥1 month) or other immunosuppressive medication

YES ☐ NO ☐

**OR**

**Close contact with someone who has had infectious TB disease since the last TB test**

YES ☐ NO ☐

Abbreviations: HCP, health-care personnel; TB, tuberculosis; TNF, tumor necrosis factor.

Individual risk assessment information can be useful in interpreting TB test results (see Lewinsohn DM, Leonard MK, LoBue PA, et al. Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of tuberculosis in adults and children. Clin Infec Dis 2017;64:111–5).

Adapted from: Risk assessment form developed by the California Department of Health, Tuberculosis Control Branch.

Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal Wkly Rep 2019;68:439–43. https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

TUBERCULOSIS TESTING + TREATMENT OF U.S. HEALTH CARE PERSONNEL

Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

# Virginia Tuberculosis (TB) Risk Assessment

For use in individuals 6 years and older

First screen for TB Symptoms: ☐ None (If no TB symptoms present→Continue with this tool)

☐Cough ☐Hemoptysis ☐Fever ☐Weight Loss ☐Poor Appetite ☐Night Sweats ☐Fatigue

If TB symptoms present→Evaluate for active TB disease

Use this tool to identify asymptomatic **individuals 6 years and older** for latent TB infection (LTBI) testing

- Re-testing should only be done in persons who previously tested negative and have new risk factors since the last assessment
- A negative Tuberculin Skin Test (TST) or Interferon Gamma Release Assay (IGRA) does not rule out active TB disease

Check appropriate risk factor boxes below.

TB infection testing is recommended if any of the risks below are checked.

If TB infection test result is positive and active TB disease is ruled out, TB infection treatment is recommended.

☐ **Birth, travel, or residence in a country with an elevated TB rate ≥ 3 months**

- Includes countries other than the United States (US), Canada, Australia, New Zealand, or Western and North European countries
- IGRA is preferred over TST for non-US-born persons ≥ 2 years old
- Clinicians may make individual decisions based on the information supplied during the evaluation. Individuals who have traveled to TB-endemic countries for the purpose of medical or health tourism < 3 months may be considered for further screening based on the risk estimated during the evaluation.

☐ **Medical conditions increasing risk for progression to TB disease**

Radiographic evidence of prior healed TB, low body weight (10% below ideal), silicosis, diabetes mellitus, chronic renal failure or on hemodialysis, gastrectomy, jejunoileal bypass, solid organ transplant, head and neck cancer

☐ **Immunosuppression, current or planned**

HIV infection, injection drug use, organ transplant recipient, treatment with TNF-alpha antagonist (e.g., infliximab, etanercept, others), steroids (equivalent of prednisone ≥15 mg/day for ≥1 month) or other immunosuppressive medication

☐ **Close contact to someone with infectious TB disease at any time**

☐ **None; no TB testing indicated at this time**

Patient Name _____ Provider Name _____

Date of Birth _____ Assessment Date _____

# Virginia Tuberculosis Risk Assessment User Guide

### Avoid testing persons at low risk

Routine testing of low-risk populations is not recommended and may result in unnecessary evaluations and treatment because of falsely positive test results.

### Prioritize persons with risks for progression

Prioritize patients with at least one of the following medical risks for progression:

- diabetes mellitus
- smoker within past 1 year
- end stage renal disease
- leukemia or lymphoma
- silicosis
- cancer of head or neck
- intestinal bypass/gastrectomy
- chronic malabsorption
- low body weight (10% below ideal)
- history of chest x-ray findings suggestive of previous or inactive TB (no prior treatment). Includes fibrosis or non-calcified nodules, but does not include solitary calcified nodule or isolated pleural thickening. In addition to LTBI testing, evaluate for active TB disease.

### US Preventive Services Task Force recommendations

The USPSTF has recommended testing persons born in, or former residents of, a country with an elevated tuberculosis rate and persons who live in, or have lived in, high-risk congregate settings such as homeless shelters and correctional facilities. Because the increased risk of exposure to TB in congregate settings varies substantially by facility and local health jurisdiction, clinicians are encouraged to follow local recommendations when considering testing among persons from these congregate settings. USPSTF did not review data supporting testing among close contacts to persons with infectious TB or among persons who are immunosuppressed because these persons are recommended to be screened by public health programs or by clinical standard of care.

### Virginia Department of Health recommendations

This risk assessment has been customized according to the Virginia Department of Health's (VDH) TB Program recommendations. Providers should check with local TB control programs, or the VDH TB Program at (804) 864-7906 for local recommendations.

### Mandated testing and other risk factors

Several risk factors for TB that have been used to select patients for TB screening historically or in mandated programs are not included among the components of this risk assessment. This is purposeful in order to focus testing on patients at highest risk. However, certain populations may be mandated for testing by statute, regulation, or policy. This risk assessment does not supersede any mandated testing. Examples of these populations include: healthcare workers, residents or employees of correctional institutions, substance abuse treatment facilities, homeless shelters, and others.

### Age as a factor

Age (among adults) is not considered in this risk assessment. However, younger adults have more years of expected life during which progression from latent infection to active TB disease could develop. Some programs or clinicians may additionally prioritize testing of younger, non-US-born persons when all non-US-born are not tested. An upper age limit for testing has not been established but could be appropriate depending on individual patient TB risks, comorbidities, and life expectancy.

### Young children

This risk assessment tool is intended for individuals ≥ 6 years old. A risk assessment tool created for use in children < 6 years old can be found on the VDH website: http://www.vdh.virginia.gov/tuberculosis-and-newcomer-health/screening-testing/

### Foreign travel

Travel to countries with an elevated TB rate may be a risk for TB exposure in certain circumstances (e.g., extended duration, likely contact with persons with infectious TB, high prevalence of TB in travel location, non-tourist travel). The duration of at least 3 consecutive months to trigger testing is intended to identify travel most likely to involve TB exposure. TB screening tests can be falsely negative within the 8-10 weeks after exposure, so are best obtained 8-10 weeks after return from travel. A list with countries with an elevated TB rate can be found here: http://www.vdh.virginia.gov/tuberculosis-and-newcomer-health/screening-testing/

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# Virginia Tuberculosis Risk Assessment User Guide — *continued*

### When to repeat a test

Re-testing should only be done in persons who previously tested negative, and have new risk factors since the last assessment. In general, this would include new close contact with an infectious TB case or new immunosuppression, but could also include foreign travel in certain circumstances.

### When to repeat a risk assessment

The risk assessment should be administered at least once. Persons can be screened for new risk factors at subsequent preventive health visits.

### IGRA preference in BCG vaccinated

Because IGRA has increased specificity for TB infection in persons vaccinated with BCG, IGRA is preferred over the TST in these persons. Most persons born outside the US have been vaccinated with BCG.

### Previous or inactive tuberculosis

Chest radiograph findings consistent with previous or inactive TB include fibrosis or non-calcified nodules, but do not include a solitary calcified nodule or isolated pleural thickening. Persons with a previous chest radiograph showing findings consistent with previous or inactive TB should be tested for TB infection. In addition to TB infection testing, evaluate for active TB disease.

### Negative test for TB infection does not rule out active TB disease

It is important to remember that a negative TST or IGRA result does not rule out active TB disease. In fact, a negative TST or IGRA in a patient with active TB disease can be a sign of extensive disease and poor outcome.

### Symptoms that should trigger evaluation for active TB disease

Patients with any of the following symptoms that are otherwise unexplained should be evaluated for active TB disease: cough for more than 2-3 weeks, fevers, night sweats, weight loss, hemoptysis.

### How to evaluate for active TB disease

Evaluate for active TB disease with a chest x-ray (CXR), symptom screen, and if indicated, sputum acid-fast bacilli (AFB) smears, cultures and nucleic acid amplification testing. A negative TST or IGRA does not rule out active TB disease.

## Decision to test is a decision to treat

### Emphasis on short course for treatment of TB infection

Shorter regimens for treating TB infection have been shown to be more likely to be completed and the 3-month 12-dose regimen has been shown to be as effective as 9 months of isoniazid. Use of these shorter regimens is preferred in most patients. Drug-drug interactions and contact to drug-resistant TB are typical reasons these regimens cannot be used.

### Shorter duration TB infection treatment regimens

| Medication | Frequency | Duration |
|---|---|---|
| Rifampin | Daily | 4 months |
| Isoniazid + Rifapentine* | Weekly | 12 weeks** |

*VDH recommends Directly Observed Therapy (DOT)

**11-12 doses in 16 weeks required for completion

### Patient refusal of TB infection treatment

Refusal should be documented. Offers of treatment should be made at future encounters with medical services. Annual chest radiographs are not recommended in asymptomatic persons. If treatment is later accepted, TB disease should be excluded and CXR repeated if it has been > 3 months from the initial evaluation.

# TYPES OF SCREENING

## Screening for TB disease

Screening for disease is appropriate in populations where the prevalence of active TB disease is high (e.g. homeless persons, migrant and seasonal workers, the foreign born). Screening for disease should begin with a clinical assessment for symptoms suggestive of tuberculosis. Those with TB-like symptoms should then undergo further evaluation, including sputum examination and/or chest radiography to either confirm or exclude the presence of disease. In some circumstances, screening with chest radiographs alone may be appropriate. However, this practice should be restricted to those settings where the risk of disease and of disease transmission are high and where a symptom evaluation is likely to be ineffective. It is suggested that this office be consulted before any radiographic screening program is initiated. Additionally, all persons with TB-like symptoms and sputum or radiographic examination suggestive of tuberculosis should be started on a standard, four-drug, anti-tuberculous regimen currently recommended by the American Thoracic Society/Centers for Disease Control and Prevention (ATS/CDC), pending final confirmation of the diagnosis.

## Screening for TB infection (Latent TB Infection – LTBI)

There are currently two methods for detecting tuberculosis infection: The Mantoux tuberculin skin test (TST) and an Interferon Gamma Release Assay (IGRA) blood test.

Patients must be carefully assessed for risk factors PRIOR to administration of either test. This assessment may be carried out individually or for a population group (homeless persons, foreign born from high prevalence countries). The evaluation must also include some assessment as to the likelihood that treatment for LTBI will be completed if prescribed. Populations or individuals that will not or cannot complete treatment for LTBI should not, in general, be screened for infection. Patients who are candidates for screening should undergo a clinical assessment, including symptom review. Tuberculous disease must be excluded in patients in high-risk groups with TB-like symptoms, regardless of the results of the skin test or IGRA.

All tuberculin skin testing (TST) performed for the evaluation of tuberculous infection must utilize 5TU (0.1cc) PPD applied intradermally by the Mantoux method. Multiple puncture techniques (e.g. Tine testing) have insufficient sensitivity to be of value and their use, even in newborns and infants, should be abandoned. Current CDC/ATS guidelines for interpretation of the tuberculin skin test must be utilized. Once new tuberculous infection is identified, disease must be excluded with a chest radiograph.

An Interferon Gamma Release Assay (IGRA) is a blood test that can determine if a person has been infected with TB bacteria. An IGRA tests a person's blood in a laboratory to measure how the immune system reacts to the TB bacteria. Two IGRAs

are approved by the U.S. Food and Drug Administration (FDA) and are available in the United States: QuantiFERON®-TB Gold in-Tube test and T-SPOT® TB test.

A positive TST or IGRA only means that TB infection is likely present in the body and additional testing is needed to determine if the person has active TB disease or latent TB infection (LTBI). The IGRA test is the preferred test for persons who have received the BCG vaccine and those who have a difficult time returning for a second appointment to read the TST test.

A recent chest radiograph (within 3 months) showing no evidence suggestive of tuberculosis disease is required before treatment for LTBI is initiated. Depending on clinical and radiographic characteristics, treatment for LTBI may then be offered. Patients on treatment for LTBI must be followed monthly to assess for TB-like symptoms as well as symptoms of drug side effects and toxicity. Additionally, some groups require laboratory monitoring. All screening programs must include defined measures for ensuring and monitoring compliance and completion of the prescribed course of treatment. No specific follow up plan is required after completion of treatment for LTBI, although patients should be instructed to return for evaluation if TB-like symptoms develop. The practice of obtaining routine follow-up chest x-rays, including annual screening radiographs should be abandoned

## High Burden TB Country List 2021

**(Countries with TB incidence rates of ≥ 20/100,000 population)**

**Data obtained from 2020 WHO Global Tuberculosis Report and reflects 2019 data**

| Country | Country | Country | Country |
|---|---|---|---|
| Afghanistan | Ecuador | Malawi | Singapore |
| Algeria | El Salvador | Malaysia | Solomon Islands |
| Angola | Equatorial Guinea | Maldives | Somalia |
| Anguilla | Eritrea | Mali | South Africa |
| Argentina | Eswatini | Marshall Islands | South Sudan |
| Armenia | Ethiopia | Mauritania | Sri Lanka |
| Azerbaijan | Fiji | Mexico | Sudan |
| Bangladesh | French Polynesia | Micronesia (Federated States of) | Suriname |
| Belarus | Gabon | Mongolia | Tajikistan |
| Belize | Gambia | Morocco | Thailand |
| Benin | Georgia | Mozambique | Timor-Leste |
| Bhutan | Ghana | Myanmar | Togo |
| Bolivia | Greenland | Namibia | Tokelau |
| Botswana | Guam | Nauru | Tunisia |
| Brazil | Guatemala | Nepal | Turkmenistan |
| Brunei Darussalam | Guinea | Nicaragua | Tuvalu |
| Bulgaria | Guinea-Bissau | Niger | Uganda |
| Burkina Faso | Guyana | Nigeria | Ukraine |
| Burundi | Haiti | Northern Mariana Islands | United Republic of Tanzania |
| Cabo Verde | Honduras | Pakistan | Uruguay |
| Cambodia | India | Palau | Uzbekistan |
| Cameroon | Indonesia | Panama | Vanuatu |
| Central African Republic | Iraq | Papua New Guinea | Venezuela (Bolivarian Republic of) |
| Chad | Kazakhstan | Paraguay | Viet Nam |
| China | Kenya | Peru | Yemen |
| China, Hong Kong SAR | Kiribati | Philippines | Zambia |
| China, Macao SAR | Kuwait | Qatar | Zimbabwe |
| Colombia | Kyrgyzstan | Republic of Korea (South Korea) | |
| Comoros | Lao People's Democratic Republic | Republic of Moldova | |
| Congo | Latvia | Romania | |
| Cote d'Ivoire | Lesotho | Russian Federation | |
| Democratic People's Republic of Korea | Liberia | Rwanda | |
| Democratic Republic of the Congo | Libya | Sao Tome and Principe | |
| Djibouti | Lithuania | Senegal | |
| Dominican Republic | Madagascar | Sierra Leone | |

**Persons from these countries should be screened for TB and TB infection. Persons from countries not found on this list should only be tested if symptomatic or if they have risk factors.**

**Updated 3/30/2021 VDH TB Program**

VIRGINIA DEPARTMENT OF HEALTH
REPORT OF TUBERCULOSIS SCREENING

Name_____ Date of Birth_____ Date_____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by: _____
(PLEASE PRINT name of health department, facility or clinician)

## TB Screening and/or Testing Conclusions

### I. No Symptoms nor Other Risks Identified on TB Risk Assessment

_____ A tuberculin skin test (TST) or blood test (IGRA) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and has no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need testing.

_____ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If neither applies, go to section II.
If in a health-care setting that *requires* a test for TB infection but no symptoms are present, go to section III.
If one of these two statements applies, select the appropriate statement and skip to Section V and select statement 'A'.

### II. Symptoms Consistent with Potential Tuberculosis are Present

**Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Proceed to Section V and select statement 'B.'**
If there are no symptoms consistent with TB, go to Section III.

### III. Testing for TB Infection – Choose TST or IGRA

Tuberculin Skin Test (TST): (record both tests if a 2-step TST was required)
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive

Interferon Gamma Release Assay (TB infection blood test):
Date drawn: _____ Test done: ____ T-Spot TB ____ Quantiferon TB Gold
Result: ___ negative ___ positive ___ indeterminate ___ borderline ___ invalid

If test above is negative, proceed to Section V and select statement 'A'. If either test for TB infection is positive, proceed to Section IV,

### IV. Chest X-Ray to Evaluate for Potential TB Disease

Date of chest x-ray: _____ Location of chest x-ray: _____
Interpretation:
___ no evidence of active tuberculosis
___ chest x-ray abnormal, active tuberculosis to be ruled out

### V. TB Screening/Testing Conclusion

_____ A. Based on the TB Screening and/or further testing, the individual listed above is free of communicable tuberculosis in a communicable form.

_____ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual has been referred to their physician and the local health department for further evaluation.

Signature _____ Date _____ Phone _____
(Clinician with prescriptive authority or health department official)

Address _____

_____

Webinar: Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel (HCP)
September 16, 2020
Virginia Department of Health

Questions and Answers

**Question:** For confirmed positive testing [related to a new hire HCP]. You retest after a positive result to confirm it is positive if you had a previous negative test? How long do you wait to repeat positive test after the positive?

**Answer:** For a new hire HCP - the only time that you would repeat a positive test for TB infection is if they were low risk, and no reason for exposure could be identified. If any risk was identified, a repeat test is not advised.

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**Question:** It seems that the recommendation is to do a symptom screening for annual clearance. How should it be defined that someone needs testing clearance annually? What about for physicians?

**Answer:** Annual symptom screening is only required for those who have a positive test for TB infection and have not taken treatment. Annual TB testing will be determined by your facility based on the individual's risk. For example, respiratory therapists, and those working in the emergency room may be considered at a high risk for exposure and should receive annual TB testing. Additionally, all HCP should receive annual TB education and should be advised to report any new risk or exposure - as this may warrant TB testing or additional evaluation.

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**Question:** Any idea when regulations will change to reflect the updates?

**Answer:** VDH TB Program is working to reach out to licensing agencies to advocate that changes to regulations be made, but the adoption of these recommendations may unfortunately take time. The Program is also happy to reach out to any contacts that you may have. Please share these via email: tuberculosis@vdh.virginia.gov

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**Question:** I thought that BCG did interfere with QuantiFERON-TB Gold test. Is this correct?

**Answer:** The BCG vaccine does not cross react with the QuantiFERON or the T-SPOT. These are both Interferon Gamma Release Assay (IGRA) tests. These blood tests are a great option for your HCP with a history of BCG vaccination. BCG can interfere with the tuberculin skin test.

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**Question:** Regarding assessing HCP for identified exposure to TB I recall learning there is a portion of time; in close proximity; in an enclosed environment; without adequate PPE to help make determination. Are there specific related guidelines included in the new guidelines?

**Answer:** Table 2 in the companion document addresses factors that may decrease and increase the risk of TB transmission. Additionally, VDH had developed some tools to assist you in making testing decisions during contact investigations. These tools can be found on our website: https://www.vdh.virginia.gov/tuberculosis/tb-disease/ The tools are close to the bottom of this page under the Contact Investigation section. Your local health department can also assist you with the contact investigation and making testing decisions.

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**Question:** Are environmental health specialists considered HCP? They conduct inspections in food establishments.

**Answer:** This would be a decision made by your organization and can be a tough decision. The first step would be determining if they are considered "HCP." If yes, they should at least have screening and testing upon hire. The next step would be determining if they have an occupational risk high enough to warrant annual testing.

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**Question:** Where do I find the sample TB screening form for Healthcare workers annual screening?

**Answer:** Here is the sample HCP risk assessment:
https://www.cdc.gov/tb/topic/infectioncontrol/pdf/healthCareSettings-assessment.pdf

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**Question:** In your presentation today several times it was reviewed that the stay in a high risk area was > 1 month. The current TB 512 form [the risk assessment form used by Virginia health departments] states "3 months". Will that be changed?

**Answer:** VDH TB Program has had multiple discussions about the time period spent in other countries and when TB testing should be triggered. There isn't a significant amount of research surrounding the time period spent in high risk countries and TB testing, which leads to the different time periods when testing might be triggered. For example, the 512 has >3 months; the VDH simplified risk assessment states *"Clinicians may make individual decisions based on the information supplied during the evaluation. Individuals who have traveled to TB-endemic countries for the purpose of medical or health tourism < 3 months may be considered for further screening based on the risk estimated during the evaluation.";* and the CDC risk assessment for healthcare personnel states *"Temporary or permanent residence of ≥1 month in a country with a high TB rate."*

After discussion with TB experts, when developing the simplified VDH risk assessment, the Program felt that the 3 month time period for general population screening was appropriate. However, each case should be considered individually and a conversation should be had about whether the time spent was related to a healthcare setting, healthcare work, or just general travel to the country, as this could change the risk of exposure significantly. If the individual had traveled to the high risk country and worked in a healthcare setting or received healthcare, the trigger for testing should be considered earlier due to a possible increased risk of exposure. This, we believe, is why you see the 1 month timeframe in the CDC document and the recommendations we discussed today. Because HCPs may be at a higher risk for exposure when traveling to high risk countries and performing work in healthcare settings.

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**Agenda Topic:**

Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

**Included in Agenda Packet:**

VDH DRAFT HIV Pre-Exposure and Post-Exposure Prophylaxis Protocol as of 7/28/21

- Staff Note: Content in VDH's draft is based mostly on Colorado's protocol. Areas highlighted in yellow are references that need to change to Virginia. Areas highlighted in gray are details added to Colorado's version.

Colorado Pre-Exposure and Post-Exposure Prophylaxis of HIV

Oregon HIV Pre-Exposure Prophylaxis Protocol

Oregon HIV Post-Exposure Prophylaxis Protocol

**Action Needed:**

Review various protocol models included in agenda packet and recommend Board of Pharmacy consider adopting an HIV Pre-Exposure Prophylaxis Protocol and HIV Post-Exposure Prophylaxis Protocol similar to one included in the agenda packet or as amended.

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

## I. Professional Requirements:

This statewide pharmacy protocol authorizes qualified Virginia-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe HIV pre-exposure and post-exposure prophylaxis (PrEP and PEP, respectively) medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the US Centers for Disease Control and Prevention (CDC)[1] and the United States Preventive Services Task Force (USPSTF)[2]. Note: new guidelines may be finalized prior to our release.

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Virginia.
2. Complete a training program by the Board of Pharmacy or the Accreditation for Pharmacy Education.
3. Agree to follow the rules included in these protocols.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

1. Pursuant to Pharmacy Board Rule (insert VA citation here), a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.
2. Pharmacists shall comply with all aspects of Pharmacy Board Rules (insert VA citation here) with respect to the maintenance of proper records.

## II. Provision of PrEP

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table I according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within 7 days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

A. MSM (men who have sex with men)

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following:

- any anal sex without condoms (receptive or insertive) in the past 6 months
- A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months

B. Heterosexually Active Men and Women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following:

- Is a man who has sex with both women and men (behaviorally bisexual)
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be substantial risk of HIV infection (persons who inject drugs PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

C. Persons Who Inject Drugs (PWID)

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following:

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (see above)

From draft of CDC PrEP Guidelines 2021
PrEP is indicated for:

- Sexually-active adults and adolescents who have had anal or vaginal sex in the past six months **AND** any of the following
  - HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
  - Bacterial STI in past 6 months
  - History of inconsistent or no condom use with sexual partner(s)
- Persons who inject drugs who
  - Have an HIV-positive injecting partner **OR**
  - Share injection equipment

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:

- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
- CrCL < 60 ml/min

**TABLE 1 – MEDICATION OPTIONS**

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Up for Discussion: Should we include two pill options?

| Medication | Frequency | Duration of Therapy | Notes |
|---|---|---|---|
| **FTC/TDF emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg (Truvada® or generic)** | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CrCL <60 ml/min.<br><br>Pharmacist must review drug/drug interaction considerations as per package insert. |
| **FTC/TAF emtricitabine 200mg/ tenofovir alafenamide 25mg (Descovy®)** | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CrCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women.<br><br>Pharmacist must review drug/drug interaction considerations as per package insert. |

## TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

**Labs:**

- PrEP cannot be started without a negative HIV test at baseline.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.
- PrEP refills will not be authorized past the initial 30-day supply if recommended baseline testing is not done by one of the above mechanisms.

| Test | Frequency | CDC Recommendations | Notes |
|---|---|---|---|
| **HIV, 4th generation** | **Baseline + Every 3 months** | **Required** | **If positive, refer to care (*see note 1 )** |
| Syphilis | Baseline + At 3 months if symptomatic. Every 6 months if asymptomatic. | Recommended | If positive, refer to care (*see note 2) |
| Extragenital Gonorrhea/ Chlamydia | Baseline + At 3 months if symptomatic. Every 6 months if asymptomatic. | Recommended | If positive, refer to care (*see note 2) |
| Serum creatinine | Baseline, at 3 months, and thereafter every 6 months | Recommended | If CrCL <60 ml/min, cannot use FTC/TDF If CrCL <30 ml/min cannot use FTC/TAF (*see note 3) |
| Hepatitis B | Baseline | Recommended | If positive, refer to care (*see note 4 ) |
| Hepatitis C | Baseline | Recommended | If positive, refer to care (*see note 5) |
| Pregnancy | Baseline | Recommended | If positive, refer to care (*see note 6) |

From draft of CDC PrEP Guidelines 2021:

| Test | Screening/Baseline Visit | Q 3 months | Q 6 months | Q 12 months | When stopping PrEP |
|---|---|---|---|---|---|
| HIV Test | X* | X | | | X* |
| eCrCl | X | | If age ≥50 or eCrCL <90 ml/min at PrEP initiation | If age <50 and eCrCl ≥90 ml/min at PrEP initiation | X |
| Syphilis | X | MSM /TGW | X | | MSM/TGW |
| Gonorrhea | X | MSM /TGW | X | | MSM /TGW |
| Chlamydia | X | MSM /TGW | X | | MSM /TGW |
| Hep B serology | X | | | | |
| Hep C serology | MSM and PWID only | | | MSM and PWID only | |
| Pregnancy | Persons with childbearing potential | Persons with childbearing potential | | | Persons with childbearing potential |

* Assess for acute HIV infection (see Figure 4)

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Individualized strategies for optimum adherence
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care.
- The importance and requirement of testing for HIV, renal function, hepatitis B, hepatitis C and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

Referrals to primary care provider:

* (note 1) If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care. Insert Virginia link

* (note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

*(note 3) If a patient test has abnormal renal values and/or signs of acute renal injury, refer for urgent evaluation.

*(note 4) If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

*(note 5) If a patient tests positive for Hepatitis C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

*(note 6) If a female patient becomes pregnant while on PrEP, refer for care.

[1] CDC. Pre-exposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

[2] USPTF. Pre-exposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

## III. Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. It must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. This regimen should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. Providers include local health departments. For more information contact the Disease Prevention Hotline at: 800-533-4148.

**If the following criteria are met, antiretroviral agents in Table 1 are recommended:**

- The exposure must have occurred within 72 hours
- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.
- Exposure to a source individual known to be HIV-positive.
- Exposure of:
    - Vagina
    - Rectum
    - Eye
    - Mouth
    - Other mucous membrane
    - Broken skin
    - Percutaneous contact( (e.g. injecting drugs with contaminated needle or needle stick injury)

  WITH
    - Blood
    - Semen
    - Vaginal secretions
    - Rectal secretions
    - Any body fluid visibly contaminated with blood
- Exposure types with highest risk of transmission of HIV are:
    - Needle sharing during injection drug use
    - Percutaneous needle stick
    - Receptive anal intercourse

- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 1 may be prescribed. nPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Virginia Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

**Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:**

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted.

**Other Considerations:**

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff).
- Resources may be found at https://www.ccasa.org/gethelp/health-related-organizations/
- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-844-CO-4-KIDS.

**Table 1 - Medication Options**

Other FDA approved/CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Dose | Duration | Notes |
|---|---|---|---|---|
| **emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)** | ≥ 13 years | Once daily<br>No refills | 28 days | Dosing adjustments with renal dysfunction if CrCL <60 ml/min.<br><br>Dolutegravir should not be used in |

| | | | | |
|---|---|---|---|---|
| **PLUS**<br><br>**raltegravir 400mg**<br><br>**OR**<br><br>**Dolutegravir 50mg** | | Twice daily<br>No refills<br><br>Once daily<br>No refills | | pregnant women<br>If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used. |

**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is.
- Ask the following screening question:
  - Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

    In this event, pharmacist should make arrangements to refer patient for a serum creatinine blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.
- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

| **Test:** | **Frequency:** | **CDC Recommendations:** | **Notes:** |
|---|---|---|---|
| **HIV, 4th generation** | **Baseline + Post exposure at week 4-6, and months 3 and 6** | **Required** | **If positive refer to care (*see note 1)** |
| Syphilis | Baseline | Recommended | If positive refer to care (*see note 2) |

| | | | |
|---|---|---|---|
| Extragenital Gonorrhea/ Chlamydia | Baseline | Recommended | If positive, refer to care (* see note 2) |
| Serum creatinine | Baseline + at 4-6 weeks. | Recommended | If elevated refer to care (*see note 3) |
| ALT/AST | Baseline + at 4-6 weeks. | Recommended | |
| Hep B | Baseline + 6 months | Recommended | If positive, refer to care (*see note 4 ) |
| Hep C | Baseline + 6 months | Recommended | If positive, refer to care (*see note 4) |
| Pregnancy | Baseline + at 4-6 weeks. | Recommended | Pregnancy is not a contraindication to nPEP |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in 17.00

Referrals:

- *(note 1) Patient should have urgent evaluation referral for signs or symptoms of acute HIV infection. If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of

providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.
- *(note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care
- *(note 3) Urgent evaluation referral for symptoms or signs of acute renal injury.
- *(note 4)If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care
- Signs of symptoms of acute drug toxicities or serious side effects
- Usual care for any other issues, stress importance of routine primary care and health maintenance.

Resources and References

CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

National Clinicians Consultation Center

- Pre-Exposure Prophylaxis consultation for clinicians **(855) 448-7737** or **(855) HIV-PrEP** Monday – Friday, 9 a.m. – 8 p.m. ET https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/
- Non-occupational PEP consultation for clinicians **(888) 448-4911** Hours of operation for are 9 a.m. – 8 p.m. ET Monday – Friday, and **11 a.m. – 8 p.m. ET on weekends & holidays** .https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/

USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

Virginia Department of Health Disease Prevention Hotline answers questions and provides crisis intervention, referrals, and written educational materials regarding Sexually Transmitted Diseases (STDs), HIV/AIDS, and Viral Hepatitis. Reach a hotline counselor toll free at (800) 533-4148 or by email at hiv-stdhotline@vdh.virginia.gov. To view or request educational materials, please visit the resources page. Hotline hours are Monday-Friday from 8 am until 5 pm. The hotline is closed for Virginia State Holidays.

**Appendix C**

**Colorado State Board of Pharmacy Statewide Protocol**

**Pre-Exposure and Post-Exposure Prophylaxis of HIV**

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the US Centers for Disease Control and Prevention (CDC)[1, 3] and the United States Preventive Services Task Force (USPSTF)[2].

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Colorado
2. Be engaged in the practice of pharmacy
3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist
4. Carry adequate professional liability insurance as determined by the Board
5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.)
6. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.

B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

**Pre-Exposure Prophylaxis (PrEP) Protocol**

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table I according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within 7 days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

   a. MSM (men who have sex with men)
      - Adult man
      - Without acute or established HIV infection
      - Any male sex partners in past 6 months
      - Not in a monogamous partnership with a recently tested, HIV-negative man

      AND at least one of the following:
      - any anal sex without condoms (receptive or insertive) in the past 6 months
      - A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months

   b. Heterosexually Active Men and Women
      - Adult person
      - Without acute or established HIV infection
      - Any sex with opposite sex partners in past 6 months
      - Not in a monogamous partnership with a recently tested HIV-negative partner

      AND at least one of the following:
      - Is a man who has sex with both women and men (behaviorally bisexual)
      - Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be substantial risk of HIV infection (persons who inject drugs PWID or bisexual male partner)
      - Is in an ongoing sexual relationship with an HIV-positive partner
      - A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

   c. Persons Who Inject Drugs (PWID)
      - Adult person
      - Without acute or established HIV infection
      - Any injection of drugs not prescribed by a clinician in past 6 months

      AND at least one of the following:
      - Any sharing of injection or drug preparation equipment in past 6 months
      - Risk of sexual acquisition (see above)

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:
- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
- CRCL < 60 ml/min

**TABLE 1 – MEDICATION OPTIONS**

Other FDA approved / CDC recommended medications or regimens can be used if they become available.

Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Frequency | Duration of Therapy | Notes |
|---|---|---|---|---|
| **FTC/TDF emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)** | ≥35 kg | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CRCL <60 ml/min. |
| **FTC/TAF emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)** | ≥35 kg | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert Table 5. |

**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**

**Labs:**

- PrEP cannot be started without a negative HIV test at baseline.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.
- PrEP refills will not be authorized past the initial 30 day supply if recommended baseline testing is not done by one of the above mechanisms.

| Test | Frequency | CDC recommendations | Notes |
|---|---|---|---|
| **HIV** | Baseline + Every 3 months | **Required** | If positive, refer |
| **Three site STI screening (syphilis, gonorrhea, chlamydia)** | Baseline + At 3 mo if symptomatic. Every 6 months if asymptomatic | Recommended | If positive – refer for care |
| **Serum creatinine** | Baseline, at 3 months, and thereafter every 6 months | Recommended | If CRCL <60 ml/min, cannot use FTC/TDF If CRCL <30 ml/min cannot use FTC/TAF |
| **Hepatitis B screening** | Baseline | Recommended | If positive – refer for care |
| **Bone health** | | Optional | |
| **Need to continue PrEP** | Annually | Recommended if at continued risk | Discuss with patient |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care



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- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- If a female patient becomes pregnant while on PrEP

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

* What is this for?

[1] CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

2 USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

**Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol**

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. nPEP must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. nPEP should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. PEP providers in Colorado include the STD Clinic at Denver Public Health (303.602.3540) and local emergency departments (CDPHE to comment).

**If the following criteria are met, antiretroviral agents in Table 1 are recommended:**

- The exposure must have occurred within 72 hours

- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.

- Exposure to a source individual known to be HIV-positive. Exposure of:

  - Vagina
  - Rectum
  - Eye



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- Mouth
- Other mucous membranes
- Nonintact skin
- Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

WITH

- Blood
- Semen
- Vaginal secretions
- Rectal secretions
- Breast milk
- Any body fluid visibly contaminated with blood

- Exposure types with the highest risk of transmission of HIV are:
  - Needle sharing during injection drug use
  - Percutaneous needle stick
  - Receptive anal intercourse
- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 1 may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

**Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:**

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services MUST be contacted.



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Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at https://www.ccasa.org/gethelp/health-related-organizations/
- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-844-CO-4-KIDS.

**TABLE 1 – MEDICATION OPTIONS**

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Dose | Duration of Therapy | Notes |
|---|---|---|---|---|
| **PREFERRED REGIMEN** | | | | |
| **emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)** | ≥ 13 years | Once daily #28 no refills | 28 days | Dosing adjustments with renal dysfunction if CrCL <60 ml/min. |
| **PLUS raltegravir 400mg** | | Twice daily #56 no refills | | |
| **OR Dolutegravir 50mg** | | Once daily #28 no refills | | Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used. |

**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**

**Labs:**

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is.
- Ask the following screening question:
  - Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?



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In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.
- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

| Test | Frequency | CDC recommendations | Notes |
|---|---|---|---|
| **HIV** | Baseline + Post-exposure at week 4-6, and months 3 and 6 | **Required** | If positive, refer. |
| **STI screenings (syphilis, gonorrhea, chlamydia)** | Baseline | Recommended | If positive – refer for care |
| **Serum creatinine** | Baseline + @4-6 weeks. | Recommended | |
| **ALT/AST** | Baseline + @4-6 weeks. | Recommended | |
| **Hepatitis B screening** | Baseline + 6 mo | Recommended | If positive – refer. If negative and clinically appropriate, vaccinate |
| **Hepatitis C screening** | Baseline + 6 mo | Recommended | If positive - refer |
| **Pregnancy** | Baseline + @4-6 weeks. | Recommended | Pregnancy is not a contraindication to NPEP |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care



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- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases

- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.

- The pharmacist will also follow all documentation rules in 17.00

Referrals:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- Signs of symptoms of acute drug toxicities or serious side effects

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

[3] CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use or Other Nonoccupational Exposure to HIV – United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856



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## PREVENTIVE CARE

# HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

### STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

**AUTHORITY and PURPOSE:** Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe pre-exposure prophylaxis (PrEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
  - Utilize the standardized PrEP Provider Fax (pg.10)

  **PHARMACIST TRAINING/EDUCATION:**
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

# Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

## (CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Preferred Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____

Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

Any allergies to medications? Yes / No If yes, please list _____

**Background Information:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

**Do you answer yes to any of the following?** □ **yes** □ **no**

| |
|---|
| 1. Do you sexually partner with men, women, transgender, or non-binary people? |
| 2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom.<br>_____% of the time<br>__/__/__ last sex without a condom |
| 3. Do you have oral sex?<br>• Giving- you perform oral sex on someone else<br>• Receiving- someone performs oral sex on you |
| 4. Do you have vaginal sex?<br>• Receptive- you have a vagina and you use it for vaginal sex<br>• Insertive- you have a penis and you use it for vaginal sex |
| 5. Do you have anal sex?<br>• Receptive- someone uses their penis to perform anal sex on you<br>• Insertive- you use your penis to perform anal sex on someone else |
| 6. Do you inject drugs? |
| 7. Are you in a relationship with an HIV-positive partner? |
| 8. Do you exchange sex for money or goods? (includes paying for sex) |
| 9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex? |

**Medical History:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

| | |
|---|---|
| 1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)? | □ yes □ no |
| 2. Do you see a (healthcare provider) for management of Hepatitis B? | □ yes □ no |
| 3. Have you ever received an immunization for Hepatitis B? If yes, when:<br>• If no, would you like a Hepatitis B immunization today? □ yes □ no | □ yes □ no<br>Date of vaccine __/__/__ |
| 4. Do you see a healthcare provider for problems with your kidneys? | □ yes □ no |
| 5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)?<br>• Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen) | □ yes □ no |
| 6. Are you currently or planning to become pregnant or breastfeeding? | □ yes □ no |
| 7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____ | □ yes □ no |

## Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

**Testing and Treatment:**

| | |
|---|---|
| 1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription.<br>• I may be able to have tests performed at the pharmacy.<br>• I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.<br>o I brought my labs in today □ Yes □ No<br>• I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month. | □ Yes □ No |
| 2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV.<br>• I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate. | □ Yes □ No |
| 3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV. | □ Yes □ No |

**Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.**

**Please list any questions you have for the pharmacy staff:**

**Patient Signature:** _____ **Date:** _____

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

## (CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

### Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

| Risk Factor: | Notes and considerations |
|---|---|
| 1. Sexual partners | • MSM activity is highest risk for HIV.<br>• Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present. |
| 2. Estimated condom use _____% of the time __/__/__ last sex without a condom | • Condomless sex greatly increases risk of HIV and STIs.<br>• For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).<br>• Condomless sex within last 14 days, repeat HIV test in one month. |
| 3. Oral sex | • Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals.<br>• STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex. |
| 4. Vaginal sex | • Receptive vaginal sex can be high risk for HIV.<br>• Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present. |
| 5. Anal sex | • Receptive anal sex has the most risk of HIV of any sex act.<br>• Insertive anal sex has high risk for HIV.<br>• STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex. |
| 6. Injection drug use | • Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes. |
| 7. HIV-positive partner | • People living with HIV who have undetectable viral loads will not transmit HIV.<br>• For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP. |
| 8. Exchanging sex for money or goods | • People who buy or sell sex are at high risk for HIV. |
| 9. Popper and/or methamphetamine use | • Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.<br>• Recommend adequate lubrication in persons who use poppers for sex. |

**1. Is one or More Risk Factor Present:** □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

## Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway
## (CONFIDENTIAL- Protected Health Information)

**Testing:**

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

| Test Name | Date of Test | Result | Needs referral |
|---|---|---|---|
| • HIV ag/ab (4th gen) test: | _____/_____/_____ | □ *reactive* □ *indeterminate* □ negative | □ *Yes* |
| *Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing.* NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing. | | | |
| • Syphilis/Treponemal antibody: | _____/_____/_____ | □ *reactive* □ *indeterminate* □ negative | □ *Yes* |
| *Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.* | | | |
| • Hepatitis B surface antigen: | _____/_____/_____ | □ *positive* □ negative | □ *Yes* |
| *Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.* | | | |
| • Gonorrhea/Chlamydia: | _____/_____/_____ | | □ *Yes* |
| Urinalysis result: □ *reactive* □ *indeterminate* □ negative | Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative | Rectal test result: □ *reactive* □ *indeterminate* □ negative | |
| *All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.* | | | |
| • Renal function (CrCl): SCr _____mg/dL | _____/_____/_____ | _____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min* | □ *Yes* |
| CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.* | | | |
| • Signs/symptoms of STI not otherwise specified: | _____/_____/_____ | □ *Present* | □ *Yes* |
| • Condomless sex in past two weeks | _____/_____/_____ | □ *Yes* | □ *Yes* |

**2. Is HIV ab/ag 4th gen test complete?** □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

**3. Are all required labs are complete?** □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

*Sample language for reactive or indeterminate tests:*

*Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.*

→ *See next page for sample language for reactive (indeterminate) STI tests.*

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Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

**Medical History:** The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

| Medical history factor | Notes and considerations |
|---|---|
| | **REFERRAL CONDITIONS** |
| 1. Positive HIV test<br>*Needs Referral:*<br>□ *yes* □ no | • A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.<br>• Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management. |
| 2. Presence of Hepatitis B infection<br>*Needs Referral:*<br>□ *yes* □ no | • Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare.<br>• People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist. |
| 3. Impaired kidney function (<30mL/min)<br>*Needs Referral:*<br>□ *yes* □ no | • Truvada is approved for patients with a CrCl >60mL/min.<br>• Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.<br>• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease. |
| 4. Other medications<br>*Needs Referral:*<br>□ *yes* □ no | • Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density.<br>• For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada. |
| | **CONSIDERATIONS** |
| 5. NSAID use<br>Precaution- Counseled on limiting use:<br>□ yes □ no | • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage.<br>• Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use. |
| 6. Hepatitis B vaccinated<br>If not, would the patient like to be vaccinated?<br>□ yes □ no | • Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP.<br>• Counsel on risk factors for Hepatitis B and recommend vaccination.<br>• If patient would like to be vaccinated, proceed according to OAR 855-019-0280. |
| 7. Pregnant or breastfeeding | • Pregnancy and breastfeeding are not contraindications for PrEP.<br>• Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence.<br>• Truvada is preferred due to better data in these populations. |

**4. Are one or More Referral Condition(s) Present? □ *yes* □ no**

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

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# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

## (CONFIDENTIAL- Protected Health Information)

**Regimen Selection:**

| Considerations* | Preferred regimen |
|---|---|
| Cis-gender male or male to female transgender woman.<br>• Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference. | May choose Truvada or Descovy |
| Cis-gender female or female to male transgender man.<br>• Only Truvada is FDA approved in these populations.<br>• If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management. | Truvada |
| NSAID use<br>• If patient is male or a male to female transgender woman, consider Descovy | Descovy |
| Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist.<br>• If patient is male or male to female transgender woman, consider Descovy | Descovy |
| Patient has decreased bone mineral density or on medications that affect bone mineral density.<br>• If patient is male or male to female transgender woman, consider Descovy. | Descovy |
| Patient is pregnant or breastfeeding<br>• Descovy has not been studied in these populations. Truvada is approved in these populations. | Truvada |

*generic versions are acceptable in all cases if available.

# PrEP Prescription

*Optional-May be used by pharmacy if desired*

| Patient Name: | Date of birth: |
|---|---|
| Address: | |
| City/State/Zip Code: | Phone number: |

☐ Verified DOB with valid photo ID

*Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate*

# Rx

☐ **Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

***-or-***

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____ Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

***-or-***

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____

_____

_____

_____

**Manufacturer Copay Card Information:**

| RXBIN: | RXPCN: | GROUP: |
|---|---|---|
| ISSUER: | ID: | |

# Provider Notification
## Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____
Dear Provider_____ (name) (____) _____-_____ (FAX)
Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

**This regimen consists of the following (check one):**

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily for 90 days
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily for 90 days

**Your patient has been tested for and/or indicated the following:**

| Test Name | Date of Test | Result | Needs referral |
|---|---|---|---|
| • HIV ag/ab (4th gen): | _____/_____/_____ | ☐ *reactive* ☐ *indeterminate* ☐ negative | ☐ *Yes* |
| • Syphilis/Treponemal antibody: | _____/_____/_____ | ☐ *reactive* ☐ *indeterminate* ☐ negative | ☐ *Yes* |
| • Hepatitis B surface antigen: | _____/_____/_____ | ☐ *positive* ☐ negative | ☐ *Yes* |
| • Gonorrhea/Chlamydia: | _____/_____/_____ | | ☐ *Yes* |
| Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ negative | Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative | Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative | |
| • Renal function (CrCl): ☐ CrCl >60mL/min | _____/_____/_____ ☐ CrCl 30mL/min - 60mL/min | _____ mL/min ☐ *CrCl <30mL/min* | ☐ *Yes* |
| • Signs/symptoms of STI not otherwise specified: | _____/_____/_____ | ☐ *present* | ☐ *Yes* |
| • Condomless sex in past two weeks | _____/_____/_____ | ☐ *yes* | ☐ *Yes* |

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

**Provider pearls for HIV PrEP:**

- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

**Pharmacy monitoring of HIV PrEP:**

- The pharmacy prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

**PREVENTIVE CARE**

# HIV POST-EXPOSURE PROPHYLAXIS (PEP)

**STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST**

**AUTHORITY and PURPOSE:** Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe post-exposure prophylaxis (PEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 4-6)

  **PHARMACIST TRAINING/EDUCATION:**
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

## Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

*(confidential-protected health information)*

Name_____Date of Birth_____ Age_____ Today's Date_____

Health Care Provider's Name_____

Do you have health insurance? *Yes / No* Name of Insurance Provider_____

Any allergies to Medications? *Yes / No* If yes, list them here _____

**Background Information:**

| | | |
|---|---|---|
| 1. | Do you think you were exposed to Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 2. | What was the date of the exposure? | ___/___/___ |
| 3. | What was the approximate time of the exposure? | ___:___ *AM/PM* |
| 4. | Was your exposure due to unwanted physical contact or a sexual assault? | □ Yes □ No □ Not sure |
| 5. | Was the exposure through contact with any of the following body fluids? Select any/all that apply:<br>□ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____ | □ Yes □ No □ Not sure |
| 6. | Did you have vaginal or anal sexual intercourse without a condom? | □ Yes □ No □ Not sure |
| 7. | Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner? | □ Yes □ No □ Not sure |
| 8. | Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner? | □ Yes □ No □ Not sure |
| 9. | Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin? | □ Yes □ No □ Not sure |
| 10. | Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals?<br>□persons with known HIV infection<br>□men who have sex with men with unknown HIV status<br>□persons who inject drugs<br>□sex workers | □ Yes □ No □ Not sure |
| 11. | Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____ | Yes □ No □ Not sure |

**Medical History:**

| | | |
|---|---|---|
| 12. | Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 13. | Are you seeing a provider for management of Hepatitis B? | □ Yes □ No □ Not sure |
| 14. | Have you ever received immunization for Hepatitis B? If yes, indicate when:_____<br>If no, would you like this vaccine today? *Yes/No* | □ Yes □ No □ Not sure |
| 15. | Are you seeing a kidney specialist? | □ Yes □ No □ Not sure |
| 16. | Are you currently pregnant? | □ Yes □ No □ Not sure |
| 17. | Are you currently breast-feeding? | □ Yes □ No □ Not sure |
| 18. | Do you take any of the following over-the-counter medications or herbal supplements?<br>□ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®/Motrin®)<br>□ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum | □ Yes □ No □ Not sure |
| 19. | Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____<br>_____ | □ Yes □ No □ Not sure |

Signature_____ Date_____

*Optional-May be used by pharmacy if desired*

| Patient Name: | Date of birth: |
|---|---|
| Address: | |
| City/State/Zip Code: | Phone number: |

☐ Verified DOB with valid photo ID

*Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication*

# Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg (Truvada®)
  Sig: Take one tablet by mouth once daily in combination with Isentress® for 30 days
  Quantity: #30
  Refills: none

**AND**

- Drug: raltegravir 400mg (Isentress®)
  Sig: Take one tablet by mouth twice daily in combination with Truvada® for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____ Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

*-or-*

Patient Referred

☐Hepatitis B Vaccination administered:

Lot:_____Expiration Date:_____ / Dose ___ of 3

Notes:_____

_____

_____

_____



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**Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)-Assessment and Treatment Care Pathway**

Name_____ Date of Birth_____ Today's Date_____

| | | |
|---|---|---|
| 1. Is the patient less than 13 years old? | | Notes: According to the CDC PEP treatment guidelines, Truvada® plus Isentress® is a preferred regimen for individuals 13 years and older. |
| Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic | No: Go to #2 | |
| 2. Is the patient known to be HIV-positive? | | Notes: |
| Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic. | No: Go to #3. Conduct 4th generation HIV fingerstick test if available (optional). | |
| 3. What time did the exposure occur? | | Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure. |
| ☐≤72 hours ago: go to #4 | ☐>72 hours ago: PEP not recommended. Refer patient to local primary care provider, infectious disease specialist, or public health department. | |
| 4. Was the patient a survivor of sexual assault? | | Notes: |
| Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #5) and then refer the patient to the emergency department for a sexual assault workup.** | No: Go to #5 | |
| 5. Was the exposure from a source person known to be HIV-positive? | | |
| Yes: Go to #6 | No: Go to #7 | |
| 6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids: | | Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood. |
| Please check any/all that apply:<br>☐Blood<br>☐Semen<br>☐Vaginal secretions<br>☐Rectal secretions<br>☐Breast milk<br>☐Any body fluid that is visibly contaminated with blood<br><br>If any boxes are checked, go to #9. | Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*):<br>☐Urine<br>☐Nasal Secretions<br>☐Saliva<br>☐Sweat<br>☐Tears<br>☐None of the above<br><br>Go to #7 | |
| 7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status? | | Notes: This type of exposure puts the patient at a high risk for HIV acquisition |
| Yes: Go to #9 | No: Go to #8 | |
| 8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status? | | Notes: Consider calling the HIV PEPline (888) 448-4911 for guidance. |
| Yes: Please check all that apply and go to #9:<br>☐Was the source person known to be HIV-positive?<br>☐Were there cuts/openings/sores/ulcers on the oral mucosa?<br>☐Was blood present?<br>☐Has this happened more than once without PEP treatment?<br>☐None of the above | No: Use clinical judgment. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9. | |



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| | | |
|---|---|---|
| 9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up? | | Notes: Connection to care is critical for future recommended follow-up. |
| Yes: Go to #10 | No: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP. | |
| 10. Does the patient have history of known Hepatitis B infection (latent or active)? | | Notes: Tenofovir disoproxil fumurate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare. |
| Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP. | No. Go to #11 | |
| 11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No<br>Verify vaccine records or AlertIIS. Dates:_____ | | |
| Yes: Go to #13 | No: Go to #12 | |
| 12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.<br>☐Vaccine administered<br>Lot:_____ Exp:_____ Signature:_____ | | |
| 13. Does the patient have known chronic kidney disease or reduced renal function? | | Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min |
| Yes: Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. Do not prescribe PEP. | No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient. | |

| Recommended regimen: | |
|---|---|
| Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days<br><br>PLUS<br><br>Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days | Notes:<br>• There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.<br>• Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.<br>• Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com<br>• If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance. |

Counseling points:

Truvada®:

- Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset. Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.

Isentress®:

- Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset. If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.

Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.

Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.

Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

Pharmacist mandatory follow-up:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____ Date_____

**Agenda Topic:**

Adopt recommended emergency regulations for Board of Pharmacy consideration to implement provisions.

**Included in Agenda Packet:**

Draft amendments of 18VAC110-20-150 and 18VAC110-21-46

**Action Needed:**

Members of the Boards of Pharmacy and Medicine to recommend to the Board of Pharmacy to adopt the draft amendments of 18VAC110-20-150 and 18VAC110-21-46 as presented or as amended.

**Emergency Regulations Effective Until 7/22/22**

**Board of Pharmacy**

**Implementation of legislation for pharmacists initiating treatment**

Chapter 20

Regulations Governing the Practice of Pharmacy

## 18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs, ~~and~~ devices, controlled paraphernalia, and other supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

**18VAC110-21-46. Initiation of treatment by a pharmacist.**

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs, ~~and~~ devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § **54.1-3466** of the Code of Virginia, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; ~~and~~

6. ~~Medications~~ Drugs as defined in §54.1-3401, devices as defined in §54.1-3401, controlled paraphernalia as defined in §54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;

8. Tuberculin purified protein derivative for tuberculosis testing; and

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

B. Pharmacists who initiate treatment with, dispense, or administer a drug, ~~or~~ device, controlled paraphernalia, or other supplies or equipment pursuant to subsection A shall:

1. Follow the statewide protocol adopted by the board for each drug, ~~or~~ device, controlled paraphernalia, or other supplies or equipment.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug, ~~or~~ device, controlled paraphernalia, or other supplies or equipment or that such drug, ~~or~~ device, controlled paraphernalia, or other supplies or equipment has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of §32.1-46.01.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

# Written Comment
# as of
# August 6, 2021

**Virginia Board of Pharmacy, Statewide Protocol Work Group Meeting, August 9, 2021**

Handout:

DRAFT TB One-Step and Two-Step Protocols provided by VDH for Consideration

**TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL**
**v1**

**Approved: Date**

**PURPOSE**

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

**PHARMACIST EDUCATION AND TRAINING**

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing
- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

Provider of Training: _____

**Commented [JKL1]:** Does the Board of Pharmacy intend for the pharmacist to document their training provider and dates on this protocol?

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**
[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf
[3] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration
[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w
[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

Date of Training: _____

**Inclusion Criteria**

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance, occupational requirements, insurance purposes, or other administrative purposes

**Exclusion Criteria**

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[6] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

**Considerations**

- If an individual has a history of documented previous Bacilli Calmette-Guerin (BCG) vaccine, consider referral to a healthcare provider for interferon gamma release assay (IGRA) testing. Individuals from high-burden TB countries may have received the BCG vaccination and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification should be made to the local health department.

**MEDICATIONS**

This protocol authorizes pharmacists to administer TST antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The TST is one of two standard methods for

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[6] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

| Product | Mfr. / Dist. | NDCs* |
|---|---|---|
| **Tubersol** | Sanofi Pasteur | 1mL (10 tests) = 49281-752-21<br>5mL (50 tests) = 49281-752-22 |
| **Aplisol** | Parkdale | 1 mL (10 tests) = 42023-104-05<br>5mL (50 tests) = 42023-104-05 |

**or any other FDA-approved tuberculin skin test antigen*

**PROCEDURES FOR INITIATION OF TB SCREENING**

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined below and in the American Thoracic Society (ATC)/CDC Guideline.[1] A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self administered by the client. While the questions on the risk assessment may be asked by a licensed healthcare provider (MD, PA, NP, RN, LPN, RPh/PharmD) consistent with Virginia professional practice acts, only physicians, physician's assistants, nurse practitioners, registered nurses, and pharmacists can assess risk for TB infection and/or disease based on the answers. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A ), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of a TST and reactions to a TST

Contraindications and Precautions (Refer to Exclusion Criteria)

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site

- Live vaccination administered within the last month (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

**Considerations**

- If an individual has a history of documented previous BCG vaccination, consider referral to a healthcare provider for interferon gamma release assay (IGRA) testing. Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix B for detailed procedures).

**PROCEDURES FOR MONITORING AND FOLLOW UP**

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021) [3] (Appendix C ). Consistent with Virginia professional practice acts, only a physician, physician's assistant, nurse practitioner, registered nurse, or pharmacist may interpret the results of the reading of the TST. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A ), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

**EDUCATION REQUIREMENTS**

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to

treat the itchiness.

- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

**DOCUMENTATION**

Pharmacists will document via prescription record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. A template for a Report of TB Screening is included as Appendix D. The individual should sign a release of information indicating their consent that this information can be shared.
4. Certain regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

**Commented [2]:** May need to update the Code of Virginia to allow for pharmacists to also sign documentation.

**NOTIFICATION AND REFERRAL**

The pharmacist shall ask all persons receiving TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

**Commented [3]:** Is it desired by the Board of Pharmacy that the timeframe be defined in the protocol? If so, we feel this is reasonable.

Sections 32.1-36 and 32.1-37 of the Code of Virginia and 12 VAC 5-90-80 of the Board of Health Regulations for Disease Reporting and Control requires **all positive results** be sent to

the local health department, ideally electronically, within three business days and, if available, the individual's primary care provider for follow-up. Reports to the local health department may be made electronically here.

All individuals with a positive result should be referred to a healthcare provider for additional evaluation. Reporting of a positive result to the local health department, as required by the Code of Virginia, does not ensure linkage of the individual to care.

If the authorizing prescriber is different from the primary care provider, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving TST under this protocol within six days of initiating dispensing.

**TERMS**

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

**SIGNATURES**

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

Virginia Board of Pharmacy
***TB Risk Assessment Form***

Patient name (L,F,M): _____ DOB: _____ Race: _____ Sex: _____

Address: _____ Social Security Number: _____

City, State, ZIP: _____ Home/Work #: _____

Cell #: _____ Language: _____ Patient Pregnant: ___No ___Yes; If Yes, LMP: _____

Country of Origin: _____ Year arrived in US: _____ Interpreter needed: ___No ___Yes Last Live Vaccine: _____

**I. Screen for TB Symptoms (Check all that apply)**

___None (Skip to Section II, "Screen for Infection Risk")
___Cough for ≥ 3 weeks → Productive: ___YES ___NO
___Hemoptysis
___Fever, unexplained
___Unexplained weight loss
___Poor appetite
___Night sweats
___Fatigue
*Evaluate these symptoms in context*

**II. Screen for TB Infection Risk *(Check all that apply)***

Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.

**A. Assess Risk for Acquiring LTBI**
**The Patient...**

___is a current high risk contact of a person known or suspected to have TB disease: Name of Source case: _____
___lived in or visited another country where TB is common for 3 months or more, regardless of length of time in the U.S.
___is a resident or an employee of a high TB risk congregate setting
___is a healthcare worker who serves high-risk clients
___is medically underserved
___has been homeless within the past two years
___injects illicit drugs or uses crack cocaine
___is a member of a group identified by the health department to be at an increased risk for TB infection
___needs baseline/annual testing approved by the health department

**B. Assess Risk for Developing TB Disease if Infected**
**The Patient...**

___is HIV positive
___has risk for HIV infection, but HIV status is unknown
___was recently infected with *Mycobacterium tuberculosis*
___has certain clinical conditions, placing them at higher risk for TB disease:
_____
___injects illicit drugs (determine HIV status): _____
___has a history of inadequately treated TB
___is >10% below ideal body weight
___is on immunosuppressive therapy – includes treatment with TNF-α antagonists (Remicaid, Humira, etc.), other biologic response modifiers or prednisone ≥ 1 mo. ≥15 mg/day

**History of BCG / TB Test / TB Treatment:**

History of prior BCG: ___NO ___YES → Year: _____
History of prior (+) TST/IGRA: ____NO ____YES
Date of (+) TST _____ Reading: _____mm
CXR Date: _____ CXR result: ___ABN ___WNL
Dx: ___LTBI ___Disease
Tx Start: _____ Tx End: _____
Rx: _____
Completed: ___NO ___YES
Location of Tx: _____

**III. Finding(s) *(Check all that apply)***

___Previous Treatment for LTBI and/or TB disease
___No risk factors for TB infection
___Risk(s) for infection and/or progression to disease
___Possible TB suspect
___Previous positive TST or IGRA, no prior treatment

**IV. Action(s) *(Check all that apply)***

___Issued screening letter ____Referred for medical Evaluation
___Referred for CXR
___Administered the Tuberculin Skin Test
___Referred for interferon-gamma release assay
___Other: _____

**__#1 TST Lot#**_____
Date Given or Drawn _____Time _____Site_____
Signature _____
**TST READING** Date Read_____
Time _____Signature _____
Induration ____mm ___Pos ___Neg

**__#2 TST Lot#**_____
Date Given or Drawn _____Time _____Site_____
Signature _____
**TST READING** Date Read_____
Time _____Signature _____
Induration ____mm ___Pos ___Neg

Screener's signature: _____
Screener's name(print): _____
Date: _____ Phone #: _____

I hereby authorize the pharmacist to administer the Tuberculin Skin Test (TST).
I agree that the results of this test may be shared with other health care providers.
I acknowledge that I have received the Notice of Privacy Practices.
I understand that:
- this information will be used by health care providers for care and for statistical purposes only.
- this information will be kept confidential.
- medical records must be kept at a minimum for 10 years after my last visit or 5 years after death, whichever is greater.

X _____ Date: _____
Client or Guardian Signature

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Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

| | Virginia Board of Pharmacy Instructions for the TB Risk Assessment |
|---|---|
| **Purpose of Form**<br>The this form is a tool to assess and document a patient's symptoms and/or risk factors. Completing this form will also help in determining the need for future medical testing and evaluation. | **Directions for Completing the Form**<br>Print clearly and complete this form according to the instructions provided below. |

**I. Screen for Presence of TB Symptoms**

Screen the patient for symptoms of active TB disease

- All symptomatic individuals should: (1) receive a test for TB infection if not previously positive (TSTor IGRA); (2) have their sputum collected; (3) be referred for an immediate chest x-ray and medical evaluation, regardless of the TST result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- Anyone under the age of 18 should be referred to their PCP or other provider for testing.

**II. Screen for TB Infection Risk (In subsections A and B, check all the risk factors that apply)**

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III and administer the TST or IGRA.
- If a patient does not have risk factors for LTBI, do not administer the TST or IGRA. Go to Section III and place a check next to "No Risk Factors for TB Infection."
- If the patient's school, employment, etc. requires a TB screening, place a check next "Issued Screening Letter" (Section IV) and provide this document to the patient.

**A. Assess Risk for Acquiring LTBI – The following are definitions of select categories of persons at risk for LTBI**

- *Person is a current close contact of another individual known or suspected to have TB disease –*
  Person is part of a current TB contact investigation
- *Lived in or visited another country where TB is common for 3 months or more, regardless of time in the U.S. –*
  Person lived or visited a high endemic country ≥ 3 months.
  High endemic country is defined as a case rate of ≥ 20/100,000.
  See VDH list for high TB endemic countries.
- *Person is a resident/employee of high TB risk congregate settings–*
  These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill and persons with AIDS.
- *Person is a health care worker who serves high risk clients –*
  Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- *Person is medically underserved –*
  Person doesn't have a regular health care provider, and has not received medical care within the last 2 years.
- *Person is a member of a group identified by a local health department to be at an increased risk for TB infection –*
  Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group.
- *Person needs baseline/annual testing approved by health department* – includes those entering health professions; new health care workers need 2-step TST unless documented negative TST in prior 12 months. A single IGRA is also acceptable. May include screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI.

**B. Assess Risk for Developing TB Disease if infected - The following are definitions of select categories of persons at risk for TB disease if infected**

- *Person's HIV Status is unknown but has risk for HIV infection–*
  Recommend an HIV test. Administer the TB Skin Test, even if the patient refuses the HIV test.
- *Person with clinical conditions that place them at high risk –*
  Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- *Person is on immunosuppressive therapy –*
  Person is taking ≥ 15 mg/day of prednisone for ≥ 1 month; person is receiving treatment with TNF-α antagonists (Remicaid, Humira, etc.) or other biologic response modifiers and/or person needs baseline evaluation prior to start of treatment with the medications cited here.

**III. Finding(s) (Check all findings that apply.)**

In this section, indicate findings from the assessments in all previous sections.

**IV. Action(s) (Check all actions that apply.)**

**NOTE: TST and IGRA blood tests should NOT be done within a month of a live viral vaccine.**

- Indicate the action(s) to take as a result of the findings in Section III.
- If administering a TB Skin test, provide all requested data.
- Document referral for IGRA.
- Repeat TB Skin test, if appropriate.

***Additional follow-up to a Mantoux TB skin test or IGRA blood test***

- If the patient's TST reaction is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for medical evaluation and a chest x-ray.
- If a person has a history of a positive TST or IGRA and is currently asymptomatic, then refer for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment; *and*, 2) patient is willing to adhere to the treatment.
- If treatment for LTBI is not planned and TB was previously ruled out with a normal chest x-ray, then repeat chest x-rays are not indicated unless symptomatic.

**Report to the local health department. Electronic reporting can be done here.

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Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

## Virginia Board of Pharmacy Algorithm for Pharmacists to Assess Tuberculosis Risk

**1) Screen for TB Symptoms and History of BCG/TB Skin Test/TB Treatment**
Complete TB Symptom Screen section of Virginia TB Risk Assessment with client.
**-If less than 18 years of age, refer to PCP or other provider for testing.**
**-If YES to at least one question - Refer.**
**-If NO to All questions, proceed to next step.**

Complete TB History Screen section of Virginia TB Risk Assessment with client.
**-If YES to BCG vaccination, consider referral for IGRA testing. However, TST testing should not necessarily be denied.**
**-If YES to prior positive TB test, but no subsequent normal chest radiograph – Refer. **Individual must have documentation of prior positive test, otherwise retesting will be needed for documentation for administrative/school purposes.***
**-If YES to prior positive TB test with subsequent normal chest radiograph – no repeat TB testing indicated if asymptomatic. If symptomatic, refer for evaluation. **Individual must have documentation of prior positive test, otherwise retesting will be needed for documentation for administrative/school purposes.***
**– Refer for LTBI treatment if previously untreated.**
**-If NO prior positive TB test, proceed to next step.**

Symptoms; needs evaluation for active TB disease

Prior positive test; but no normal chest radiograph

Prior positive test, normal chest radiograph, but LTBI previously untreated

Refer; provide info per protocol if no PCP

No TB symptoms/ No prior positive TB test

**2) Screen for TB Infection Risk**
Complete Section A of the Virginia TB Risk Assessment with client.
**-If YES, to contact of a person with known or suspected TB disease, report to local health department. TST may still be performed.**
**-If YES and born in or traveled to/resided in country ≥ 3 months a country on current VDH *High Burden TB Countries* list, question about BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, the TST may still be performed.**
**-If NO or country did NOT appear on VDH *High Burden TB Countries* list, proceed to next step.**
**-If YES to remaining questions, a TST is indicated.**

Complete Section B of the Virginia TB Risk Assessment with client.
**-If YES to HIV positive questions or on immunosuppressive therapy, consider referral for IGRA testing.**
**-If YES to other questions, TST test is indicated.**

Born in High Burden country/BCG vaccinated, refer for IGRA

HIV positive or on immunosuppressive therapy, refer for IGRA

Refer; provide info per protocol if no PCP

No close contacts with active TB disease or

**3) Findings**
Complete findings section

**4) Actions**
Complete actions section

**5) Complete TST. Schedule appointment for return reading.**

****All patients with a positive TB skin test must be referred to PCP or provided contact information for local providers, as specified in protocol, for appropriate follow-up care and treatment.****

*****All positive TB skin tests must be reported to the local health department. They can be reported electronically here. *****

******Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment. ******

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Appendix B: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[7]



## Appendix F. Quality control (QC) procedural observation checklists

### Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

*Date* _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

*Scoring:* ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

**1. Preliminary**

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

**2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§**

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

**3. TST administration site selected and cleaned**

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

**4. Needle inserted properly to administer antigen**

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

**5. Explanation to the client regarding care instructions for the injection site**

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.
† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.
§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.
¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.
** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.
**SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.
†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

[7] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

**Appendix F. (*Continued*) Quality control (QC) procedural observation checklists**

**Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method**

**Date** _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

**Scoring:** ✓ or Y = Yes X or N = No NA = Not Applicable

**1. Preliminary**

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

**2. Palpate — finding margin ridges (if any)**

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

**If induration is present, continue with these steps†:**

**3. Placing marks**

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

**4. Placing and reading ruler**

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

**5. Documenting results**

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

**NOTE:** In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

Appendix C: Interpretation of the Tuberculin Skin Test

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

**Classification of the Tuberculin Skin Test Reaction[8]**

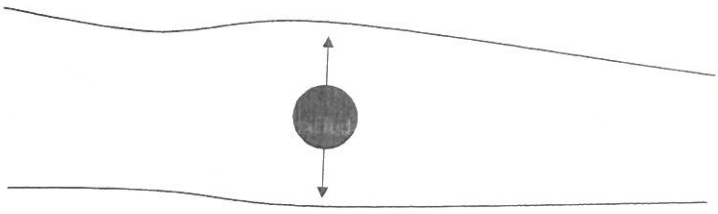
| ≥5 mm Induration | ≥10 mm Induration | ≥15 mm Induration |
|---|---|---|
| Considered positive in the following persons:<br>• Persons living with the human immunodeficiency virus (HIV)<br>• Recent contacts of a person with Tuberculosis (TB) disease<br>• Persons with a chest radiography (CXR) findings suggestive of previous TB disease<br>• Patients with organ transplants<br>• Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists) | Considered positive in the following persons:<br>• Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB<br>• Persons with substance use disorders<br>• Mycobacteriology laboratory personnel<br>• Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities<br>• Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions<br>• Persons <90% of ideal body weight<br>• Children aged <5 years<br>• Infants, children, and adolescents exposed to adults in high-risk categories | Considered positive in any person, inducing persons with no known risk factors for TB. |

*All tests should be interpreted based on patient risk and test characteristics.

[8] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

Appendix C: Interpretation of the Tuberculin Skin Test

A negative TST result does not exclude LTBI or active TB disease.



Measure TSTs Transversely

**CDC LTBI: A Guide for Primary Health Care Providers**

**https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf**

Appendix C: Interpretation of the Tuberculin Skin Test

Appendix D: Report of Tuberculosis Screening

VIRGINIA DEPARTMENT OF HEALTH
REPORT OF TUBERCULOSIS SCREENING

Name_____ Date of Birth_____ Date_____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by: _____
(PLEASE PRINT name of health department, facility or clinician)

TB Screening and/or Testing Conclusions

I. No Symptoms nor Other Risks Identified on TB Risk Assessment

_____ A tuberculin skin test (TST) or blood test (IGRA) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and has no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need testing.

_____ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If neither applies, go to section II.
If in a health-care setting that *requires* a test for TB infection but no symptoms are present, go to section III.
If one of these two statements applies, select the appropriate statement and skip to Section V and select statement 'A'.

II. Symptoms Consistent with Potential Tuberculosis are Present

**Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Proceed to Section V and select statement 'B.'**
If there are no symptoms consistent with TB, go to Section III.

III. Testing for TB Infection – Choose TST or IGRA

Tuberculin Skin Test (TST): (record both tests if a 2-step TST was required)
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive

Interferon Gamma Release Assay (TB infection blood test):
Date drawn: _____ Test done: ____ T-Spot TB ____ Quantiferon TB Gold
Result: ___ negative ___ positive ___ indeterminate ___ borderline ___ invalid

If test above is negative, proceed to Section V and select statement 'A'. If either test for TB infection is positive, proceed to Section IV.

IV. Chest X-Ray to Evaluate for Potential TB Disease

Date of chest x-ray: _____ Location of chest x-ray: _____
Interpretation:
___ no evidence of active tuberculosis
___ chest x-ray abnormal, active tuberculosis to be ruled out

V. TB Screening/Testing Conclusion

_____ A. Based on the TB Screening and/or further testing, the individual listed above is free of communicable tuberculosis in a communicable form.

_____ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual has been referred to their physician and the local health department for further evaluation.

Signature _____ Date _____ Phone _____
(Clinician with prescriptive authority or health department official)

Address _____

_____

November 2017

Electronic version of this form may be accessed here:
https://www.vdh.virginia.gov/tuberculosis/screening-testing/

**TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL:**
**FOR INITIAL TESTING IN ADULTS WHO MAY BE UNDERGOING ANNUAL TESTING**
**v1**
**Approved: *Date***

## PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control. The two-step testing will help in reducing the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

## PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing
- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

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[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

[3] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at:

Provider of Training: _____

Date of Training: _____

Commented [JKL1]: Does the Board of Pharmacy intend for the pharmacist to document the training provider and date on this protocol?

**Inclusion Criteria**

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who are receiving initial TB skin testing and may continue to receive an annual TST for employment purposes. The 2020 CDC Guidelines for Screening, Testing and Treatment of Healthcare Personnel no longer include a recommendation for serial screening for the majority of healthcare personnel after the initial screening, unless they fall into a particular high risk group (e.g., pulmonologists) or there is an exposure or on-going transmission at the healthcare facility[6].

**Exclusion Criteria**

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[7] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST

**Considerations**

- If an individual has a history of documented previous Bacilli Calmette-Guerin (BCG) vaccination, consider referral to a healthcare provider for interferon gamma release assay (IGRA) testing. Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification

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https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[7] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

should be made to the local health department.

**MEDICATIONS**

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

| Product | Mfr. / Dist. | NDCs* |
|---|---|---|
| **Tubersol** | Sanofi Pasteur | 1mL (10 tests) = 49281-752-21<br>5mL (50 tests) = 49281-752-22 |
| **Aplisol** | Parkdale | 1 mL (10 tests) = 42023-104-05<br>5mL (50 tests) = 42023-104-05 |

**or any other FDA-approved tuberculin skin test antigen*

**PROCEDURES FOR INITIATION OF TB SCREENING**

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined below and in the American Thoracic Society (ATS)/CDC Guideline.[1] In addition, the need for periodic retesting and the presence of individual risk factors for occupational exposures will be used to determine the need for two-step testing. A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-administered by the client. While the questions on the risk assessment may be asked by a licensed health care provider (MD, PA, NP, RN, LPN, RPh/PharmD) consistent with Virginia professional practice acts, only physicians, physician's assistants, nurse practitioners, registered nurses, and pharmacists can assess risk for TB infection and/or disease based on the answers. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions

Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of a TST and reactions to a TST

Contraindications and Precautions (refer to Exclusion Criteria)

- Allergy to any component of the TST or those individuals with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST

Considerations

- If an individual has a history of documented previous BCG vaccination, consider referral to a healthcare provider for interferon gamma release assay (IGRA) testing. Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix B for detailed procedures).

**PROCEDURES FOR MONITORING AND FOLLOW UP**

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix C ). Consistent with Virginia professional practice acts, only a physician, physician's assistant, nurse practitioner, registered nurse, or pharmacist may interpret the results of the reading of the TST. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

An initial positive reaction is considered a TB infection and a second TST is not required. The patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case a TST can be repeated annually, if required. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. A referral is required for this follow-up and so that treatment considerations can be made if latent TB infection is diagnosed(see Appendix D)[2].

**EDUCATION REQUIREMENTS**

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for a second TST in 1-3 weeks if the initial result is negative
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

**DOCUMENTATION**

Pharmacists will document via prescription record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. A template for a Report of TB Screening is included as Appendix D. The individual should sign a release of information indicating their consent that this information can be shared.
4. Certain regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may

have to be referred back to their primary care provider to obtain necessary certification.

**NOTIFICATION AND REFERRAL**

The pharmacist shall ask all persons receiving a TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

Sections 32.1-36 and 32.1-37 of the Code of Virginia and 12 VAC 5-90-80 of the Board of Health Regulations for Disease Reporting and Control requires **all positive results** be sent to the local health department, ideally electronically, within three business days and, if available, the individual's primary care provider for follow-up. Reports to the local health department may be made electronically here.

All individuals with a positive result should be referred to a healthcare provider for additional evaluation. Reporting of a positive result to the local health department, as required by the Code of Virginia, does not ensure linkage of the individual to care.

If the authorizing prescriber is different from the primary care provider, the pharmacist(s), shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving a TST under this protocol within six days of initiating dispensing.

**TERMS**

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than 60 days.

**SIGNATURES**

_____

Prescriber Name

_____

Date

_____

Prescriber Signature

**Commented [2]:** May need to update the Code of Virginia to allow for pharmacists to also sign documentation.

**Commented [3]:** Is it desired by the Board of Pharmacy that the timeframe be defined in the protocol? If so, we feel this is reasonable.

Pharmacist Name _____ Date _____

Pharmacist Signature _____

Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

Virginia Board of Pharmacy
***TB Risk Assessment Form***

Patient name (L,F,M): _____ DOB: _____ Race: _____ Sex: _____

Address: _____ Social Security Number: _____

City, State, ZIP: _____ Home/Work #: _____

Cell #: _____ Language: _____ Patient Pregnant: ___No ___Yes; If Yes, LMP: _____

Country of Origin: _____ Year arrived in US: _____ Interpreter needed: ___No ___Yes Last Live Vaccine: _____

**I. Screen for TB Symptoms (Check all that apply)**

___None (Skip to Section II, "Screen for Infection Risk")
___Cough for ≥ 3 weeks → Productive: ___YES ___NO
___Hemoptysis
___Fever, unexplained
___Unexplained weight loss
___Poor appetite
___Night sweats
___Fatigue
*Evaluate these symptoms in context*

**History of BCG / TB Test / TB Treatment:**

History of prior BCG: ___NO ___YES → Year: _____
History of prior (+) TST/IGRA: ___NO ___YES
Date of (+) TST _____ Reading: _____mm
CXR Date: _____ CXR result: ___ABN ___WNL
Dx: ___LTBI ___Disease
Tx Start: _____ Tx End: _____
Rx: _____
Completed: ___NO ___YES
Location of Tx: _____

**II. Screen for TB Infection Risk *(Check all that apply)***

Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.

**A. Assess Risk for Acquiring LTBI The Patient...**

___is a current high risk contact of a person known or suspected to have TB disease: Name of Source case: _____
___lived in or visited another country where TB is common for 3 months or more, regardless of length of time in the U.S.
___is a resident or an employee of a high TB risk congregate setting
___is a healthcare worker who serves high-risk clients
___is medically underserved
___has been homeless within the past two years
___injects illicit drugs or uses crack cocaine
___is a member of a group identified by the health department to be at an increased risk for TB infection
___needs baseline/annual testing approved by the health department

**B. Assess Risk for Developing TB Disease if Infected The Patient...**

___is HIV positive
___has risk for HIV infection, but HIV status is unknown
___was recently infected with *Mycobacterium tuberculosis*
___has certain clinical conditions, placing them at higher risk for TB disease:
_____
___injects illicit drugs (determine HIV status): _____
___has a history of inadequately treated TB
___is >10% below ideal body weight
___is on immunosuppressive therapy – includes treatment with TNF-α antagonists (Remicaid, Humira, etc.), other biologic response modifiers or prednisone ≥ 1 mo. ≥15 mg/day

**III. Finding(s) *(Check all that apply)***

___Previous Treatment for LTBI and/or TB disease
___No risk factors for TB infection
___Risk(s) for infection and/or progression to disease
___Possible TB suspect
___Previous positive TST or IGRA, no prior treatment

**IV. Action(s) *(Check all that apply)***

___Issued screening letter ___Referred for medical Evaluation
___Referred for CXR
___Administered the Tuberculin Skin Test
___Referred for interferon-gamma release assay
___Other: _____

**___#1 TST Lot#_____**
Date Given or Drawn _____ Time _____ Site_____
Signature _____
**TST READING** Date Read_____
Time _____ Signature _____
Induration _____mm ___Pos ___Neg

**___#2 TST Lot#_____**
Date Given or Drawn _____ Time _____ Site_____
Signature _____
**TST READING** Date Read_____
Time _____ Signature _____
Induration _____mm ___Pos ___Neg

Screener's signature: _____
Screener's name(print): _____
Date: _____ Phone #: _____

I hereby authorize the pharmacist to administer the Tuberculin Skin Test (TST).
I agree that the results of this test may be shared with other health care providers.
I acknowledge that I have received the Notice of Privacy Practices.
I understand that:
- this information will be used by health care providers for care and for statistical purposes only.
- this information will be kept confidential.
- medical records must be kept at a minimum for 10 years after my last visit or 5 years after death, whichever is greater.

X _____ Date: _____
Client or Guardian Signature

2021

Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

| | Virginia Board of Pharmacy Instructions for the TB Risk Assessment |
|---|---|
| **Purpose of Form**<br>The this form is a tool to assess and document a patient's symptoms and/or risk factors. Completing this form will also help in determining the need for future medical testing and evaluation. | **Directions for Completing the Form**<br>Print clearly and complete this form according to the instructions provided below. |

**I. Screen for Presence of TB Symptoms**

Screen the patient for symptoms of active TB disease

- All symptomatic individuals should: (1) receive a test for TB infection if not previously positive (TSTor IGRA); (2) have their sputum collected; (3) be referred for an immediate chest x-ray and medical evaluation, regardless of the TST result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- Anyone under the age of 18 should be referred to their PCP or other provider for testing.

**II. Screen for TB Infection Risk (In subsections A and B, check all the risk factors that apply)**

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III and administer the TST or IGRA.
- If a patient does not have risk factors for LTBI, do not administer the TST or IGRA. Go to Section III and place a check next to "No Risk Factors for TB Infection."
- If the patient's school, employment, etc. requires a TB screening, place a check next "Issued Screening Letter" (Section IV) and provide this document to the patient.

**A. Assess Risk for Acquiring LTBI – The following are definitions of select categories of persons at risk for LTBI**

- *Person is a current close contact of another individual known or suspected to have TB disease* –
  Person is part of a current TB contact investigation
- *Lived in or visited another country where TB is common for 3 months or more, regardless of time in the U.S.* –
  Person lived or visited a high endemic country ≥ 3 months.
  High endemic country is defined as a case rate of ≥ 20/100,000.
  See VDH list for high TB endemic countries.
- *Person is a resident/employee of high TB risk congregate settings*–
  These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill and persons with AIDS.
- *Person is a health care worker who serves high risk clients* –
  Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- *Person is medically underserved* –
  Person doesn't have a regular health care provider, and has not received medical care within the last 2 years.
- *Person is a member of a group identified by a local health department to be at an increased risk for TB infection* –
  Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group.
- *Person needs baseline/annual testing approved by health department* – includes those entering health professions; new health care workers need 2-step TST unless documented negative TST in prior 12 months. A single IGRA is also acceptable. May include screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI.

**B. Assess Risk for Developing TB Disease if infected - The following are definitions of select categories of persons at risk for TB disease if infected**

- *Person's HIV Status is unknown but has risk for HIV infection*–
  Recommend an HIV test. Administer the TB Skin Test, even if the patient refuses the HIV test.
- *Person with clinical conditions that place them at high risk* –
  Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- *Person is on immunosuppressive therapy* –
  Person is taking ≥ 15 mg/day of prednisone for ≥ 1 month; person is receiving treatment with TNF-α antagonists (Remicaid, Humira, etc.) or other biologic response modifiers and/or person needs baseline evaluation prior to start of treatment with the medications cited here.

**III. Finding(s) (Check all findings that apply.)**

In this section, indicate findings from the assessments in all previous sections.

**IV. Action(s) (Check all actions that apply.)**

**NOTE: TST and IGRA blood tests should NOT be done within a month of a live viral vaccine.**

- Indicate the action(s) to take as a result of the findings in Section III.
- If administering a TB Skin test, provide all requested data.
- Document referral for IGRA.
- Repeat TB Skin test, if appropriate.

***Additional follow-up to a Mantoux TB skin test or IGRA blood test***

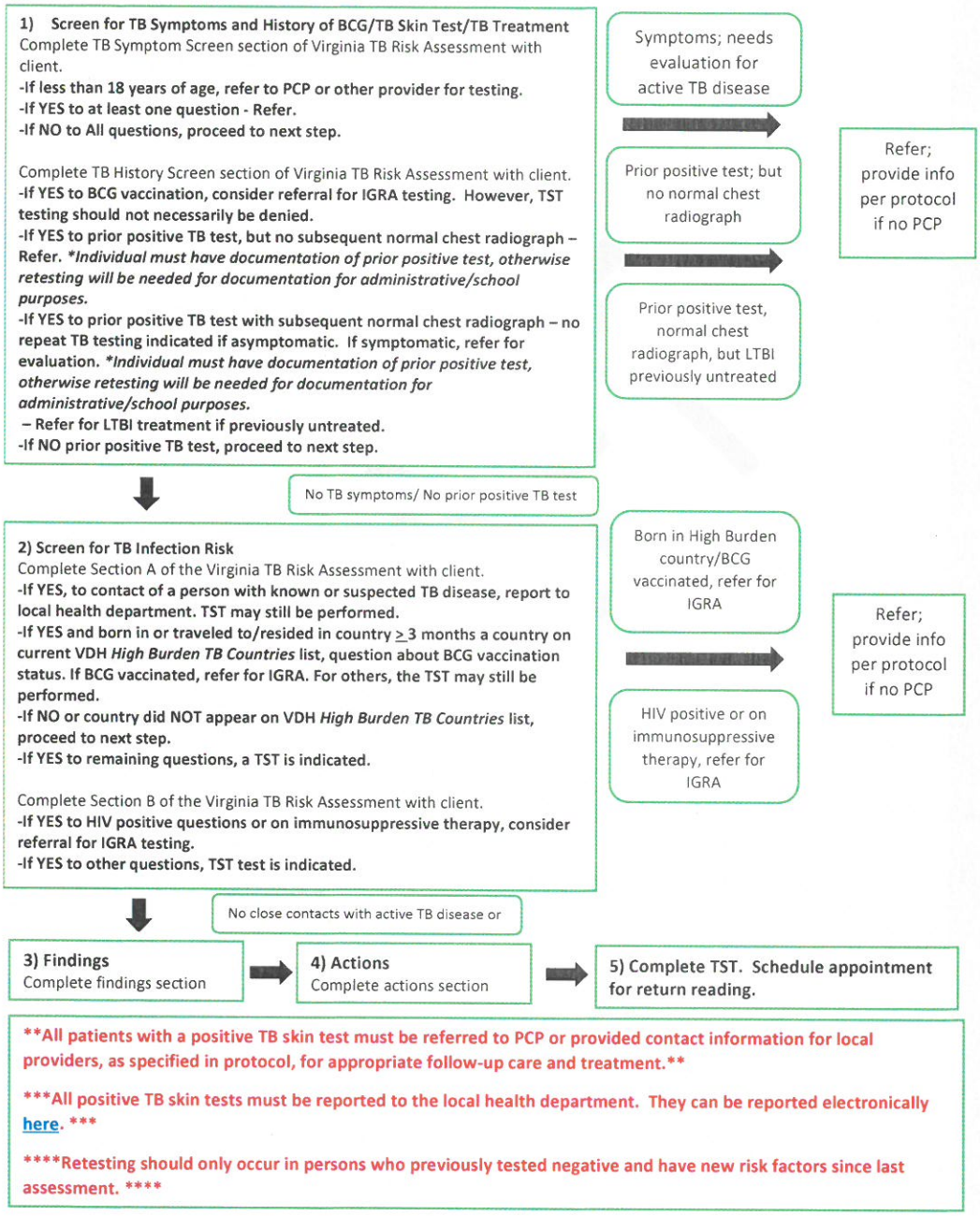
- If the patient's TST reaction is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for medical evaluation and a chest x-ray.
- If a person has a history of a positive TST or IGRA and is currently asymptomatic, then refer for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment; *and*, 2) patient is willing to adhere to the treatment.
- If treatment for LTBI is not planned and TB was previously ruled out with a normal chest x-ray, then repeat chest x-rays are not indicated unless symptomatic.

**Report to the local health department. Electronic reporting can be done here.

2021

Appendix A: The Virginia Department of Health Risk Community Assessment Form and Algorithm

## Virginia Board of Pharmacy Algorithm for Pharmacists to Assess Tuberculosis Risk




**All patients with a positive TB skin test must be referred to PCP or provided contact information for local providers, as specified in protocol, for appropriate follow-up care and treatment.**

***All positive TB skin tests must be reported to the local health department. They can be reported electronically here. ***

****Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment. ****

2021

Appendix B: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[8]



## Appendix F. Quality control (QC) procedural observation checklists

### Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

*Date* _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

*Scoring:* ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

**1. Preliminary**

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

**2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§**

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

**3. TST administration site selected and cleaned**

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

**4. Needle inserted properly to administer antigen**

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

**5. Explanation to the client regarding care instructions for the injection site**

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC. Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site. **SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

[8] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

## Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

### Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

**Date** _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

**Scoring:** ✓ or Y = Yes X or N = No NA = Not Applicable

**1. Preliminary**

- _____ Uses appropriate hand hygiene methods before starting.
- _____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
- _____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
- _____ Uses well-lit area.
- _____ Inspects for the site of the injection.

**2. Palpate — finding margin ridges (if any)**

- _____ Palpates with arm bent at elbow at a 90° angle.
- _____ Lightly sweeps 2-inch diameter from injection site in four directions.
- _____ Uses zigzag featherlike touch.
- _____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

**If induration is present, continue with these steps†:**

**3. Placing marks**

- _____ Holds palm over injection site.
- _____ Cleanse site with antiseptic swab using circular motion from center to outside.
- _____ Uses fingertips to find margins of the induration.
- _____ Marks the induration by placing small dots on both sides of the induration.
- _____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
- _____ Marks dots transverse (perpendicular) to long axis of forearm.

**4. Placing and reading ruler**

- _____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
- _____ Uses appropriate hand hygiene methods after reading TST result.

**5. Documenting results**

- _____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
- _____ Correctly records results in mm; only a single measured induration in mm should be recorded.

Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

**NOTE:** In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.

† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).

§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

Appendix C: Interpretation of the Tuberculin Skin Test

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

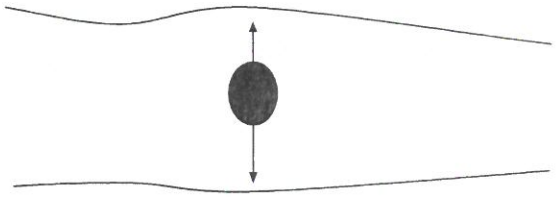
**Classification of the Tuberculin Skin Test Reaction[9]**

| ≥5 mm Induration | ≥10 mm Induration | ≥15 mm Induration |
|---|---|---|
| Considered positive in the following persons:<br>• Persons living with the human immunodeficiency virus (HIV)<br>• Recent contacts of a person with Tuberculosis (TB) disease<br>• Persons with a chest radiography (CXR) findings suggestive of previous TB disease<br>• Patients with organ transplants<br>• Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists) | Considered positive in the following persons:<br>• Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB<br>• Persons with substance use disorders<br>• Mycobacteriology laboratory personnel<br>• Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities<br>• Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions<br>• Persons <90% of ideal body weight<br>• Children aged <5 years<br>• Infants, children, and adolescents exposed to adults in high-risk categories | Considered positive in any person, inducing persons with no known risk factors for TB. |

*All tests should be interpreted based on patient risk and test characteristics.

[9] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

A negative TST result does not exclude LTBI or active TB disease.



**Measure TSTs Transversely**

**CDC LTBI: A Guide for Primary Health Care Providers**

**https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf**

Appendix D: Booster Phenomenon and Two-step TST Testing [2]

**Figure 1: The TST Booster Phenomenon**

As the years pass, the person's ability to react to tuberculin lessens. Occurs mainly in previously infected older adults whose ability to react to tuberculin has decreased over time. These people should still be considered for LTBI treatment after ruling out TB disease, particularly if they have risk factors for progression to disease.

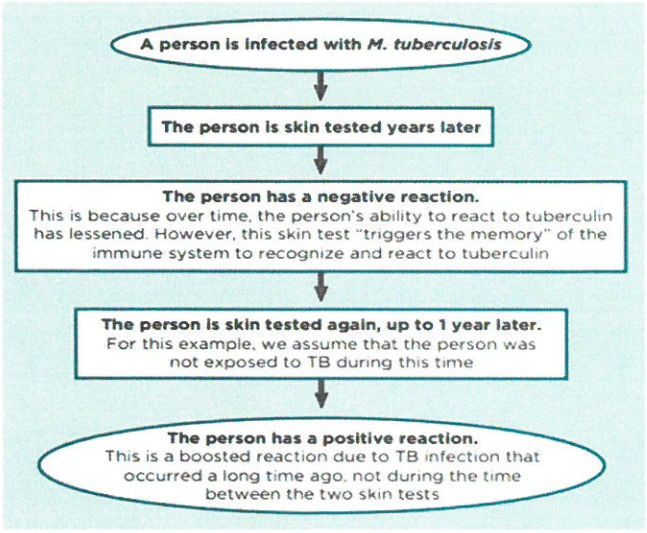
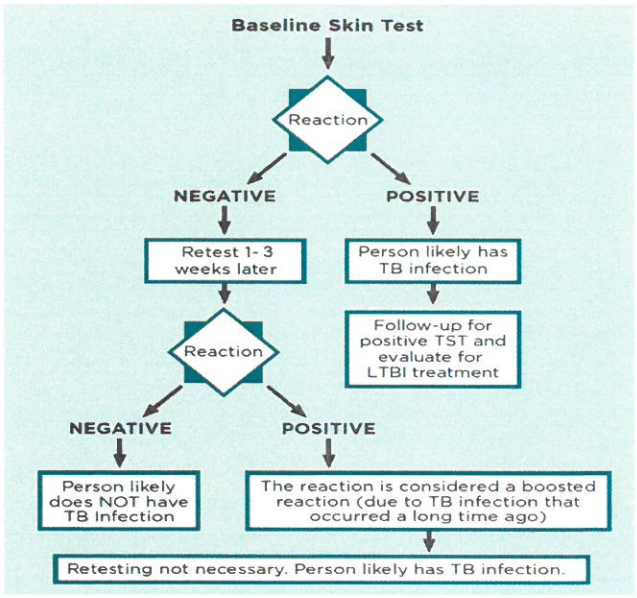



**Figure 2: Two-Step TST Testing**

Two-step testing is a strategy used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection (Figure 2). Two-step testing should be used for the initial skin testing of persons who will be retested periodically. If the reaction to the first TST is classified as negative, a second TST should be repeated 1 to 3 weeks later. A positive reaction to the second TST likely represents a boosted reaction. Based on this second test result, the person should be classified as previously infected. This would not be considered a skin test conversion or a new TB infection; however, the patient may still be a candidate for LTBI treatment. If the second skin test result is also negative, the person should be classified as having a negative baseline TST result. **If either the first or second test result is positive, the individual should be referred for follow-up and evaluation for LTBI treatment.**


Baseline Skin Test
Reaction
NEGATIVE
POSITIVE
Retest 1- 3 weeks later
Person likely has TB infection
Reaction
Follow-up for positive TST and evaluate for LTBI treatment
NEGATIVE
POSITIVE
Person likely does NOT have TB Infection
The reaction is considered a boosted reaction (due to TB infection that occurred a long time ago)
Retesting not necessary. Person likely has TB infection.

Appendix E: Report of Tuberculosis Screening

VIRGINIA DEPARTMENT OF HEALTH
REPORT OF TUBERCULOSIS SCREENING

Name_____ Date of Birth_____ Date_____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by: _____
(PLEASE PRINT name of health department, facility or clinician)

TB Screening and/or Testing Conclusions

I. No Symptoms nor Other Risks Identified on TB Risk Assessment

_____ A tuberculin skin test (TST) or blood test (IGRA) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and has no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need testing.

_____ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If neither applies, go to section II.
If in a health-care setting that *requires* a test for TB infection but no symptoms are present, go to section III.
If one of these two statements applies, select the appropriate statement and skip to Section V and select statement 'A'.

II. Symptoms Consistent with Potential Tuberculosis are Present

**Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Proceed to Section V and select statement 'B.'**
If there are no symptoms consistent with TB, go to Section III.

III. Testing for TB Infection – Choose TST or IGRA

Tuberculin Skin Test (TST): (record both tests if a 2-step TST was required)
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive
Date given: _____ Date read: _____ Results: _____mm Interpretation: ___ negative ___ positive

Interferon Gamma Release Assay (TB infection blood test):
Date drawn: _____ Test done: ____ T-Spot TB ____ Quantiferon TB Gold
Result: ___ negative ___ positive ___ indeterminate ___ borderline ___ invalid

If test above is negative, proceed to Section V and select statement 'A'. If either test for TB infection is positive, proceed to Section IV.

IV. Chest X-Ray to Evaluate for Potential TB Disease

Date of chest x-ray: _____ Location of chest x-ray: _____
Interpretation:
___ no evidence of active tuberculosis
___ chest x-ray abnormal, active tuberculosis to be ruled out

V. TB Screening/Testing Conclusion

_____ A. Based on the TB Screening and/or further testing, the individual listed above is free of communicable tuberculosis in a communicable form.

_____ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual has been referred to their physician and the local health department for further evaluation.

Signature _____ Date _____ Phone _____
(Clinician with prescriptive authority or health department official)

Address _____

_____

November 2017

Electronic version of this form may be accessed here:
https://www.vdh.virginia.gov/tuberculosis/screening-testing/

**Virginia Board of Pharmacy, Statewide Protocol Work Group Meeting, August 9, 2021**

Handout:

HIV PrEP and PEP Statewide Protocol DRAFT version as of 8/5/2021, offered by VDH

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

## I. Professional Requirements:

This statewide pharmacy protocol authorizes qualified Virginia-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and provide HIV pre-exposure and post-exposure prophylaxis (PrEP and PEP, respectively) medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may initiate and dispense FDA-approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the US Centers for Disease Control and Prevention (CDC)[1] and the United States Preventive Services Task Force (USPSTF)[2]. *Note: Updated CDC Guidelines will be available soon. Included references are expected changes.*

Prior to initiating and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Virginia.

2. Complete a training program by the Board of Pharmacy or the Accreditation for Pharmacy Education. Training components will include:
    a. HIV basics and testing including signs and symptoms of acute HIV
    b. PrEP/PEP medications pharmacology
    c. Awareness of initiating and dispensing limitations specific to VA
    d. Clinical eligibility for PrEP/PEP based on the most recent CDC Guidelines
    e. Counseling on STIs/sexual health
    f. Resources for pharmacists including patient referral information
    g. Education on financial assistance programs
    h. Pharmacists must maintain proof of training for four years.
    i. Training will need to be updated whenever CDC Guidelines are updated or as new FDA-approved medications become available.

3. Agree to follow the rules included in these protocols.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

1. Pursuant to Pharmacy Board Regulation 18VAC110-21-46, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.
2. Pharmacists shall comply with all aspects of Pharmacy Board Regulation 18VAC110-21-46 with respect to the maintenance of proper records.

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

## I. Provision of PrEP

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table I according to the following criteria:

1. Evidence of HIV-negative status as documented by an FDA-approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within seven days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

A. MSM (men who have sex with men)
- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following:
- any anal sex without condoms (receptive or insertive) in the past 6 months
- A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months

B. Heterosexually Active Men and Women
- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following:
- Is a man who has sex with both women and men (behaviorally bisexual)
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (persons who inject drugs (PWID) or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

C. Persons Who Inject Drugs (PWID)
- Adult person
- Without acute or established HIV infection

- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following:

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (see above)

D. Any adult who asks for PrEP, even without disclosure of the above risk factors, provided they do not have any contraindications.

From draft of CDC PrEP Guidelines 2021

PrEP is indicated for:

- Sexually-active adults and adolescents who have had anal or vaginal sex in the past six months AND any of the following:
  - HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
  - Bacterial STI in past 6 months
  - History of inconsistent or no condom use with sexual partner(s)
- Persons who inject drugs who
  - Have an HIV-positive injecting partner OR
  - Share injection equipment

Patients who should **NOT** be prescribed PrEP under this protocol and should be referred to primary care provider for further action:

- Patients with baseline HIV test indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
- CrCl < 60 ml/min for FTC/TDF or CrCl $\leq$ 30 ml/min for FTC/TAF.

**TABLE 1 – MEDICATION OPTIONS**

Other FDA-approved/CDC-recommended medications or regimens can be used if they become available. Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Frequency | Duration of Therapy | Notes |
|---|---|---|---|
| **FTC/TDF emtricitabine 200mg/ tenofovir disoproxil fumarate 300mg (Truvada® or generic)** | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed.<br><br>Refill quantity only until next scheduled lab follow up. | May take with or without food.<br><br>Not recommended for CrCl <60 ml/min.<br><br>Pharmacist must review drug/drug interaction considerations as per package insert. |
| **FTC/TAF emtricitabine 200mg/ tenofovir alafenamide 25mg (Descovy®)** | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed.<br><br>Refill quantity only until next scheduled lab follow up. | May take with or without food.<br><br>Not recommended for CrCl ≤30 ml/min.<br><br>Should only be used for at-risk cis-gender men and transgender women.<br><br>Pharmacist must review drug/drug interaction considerations as per package insert. |

**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**

**Labs:**

- If the pharmacist accepts test results ordered by another provider, PrEP cannot be initiated without a negative HIV test at baseline.
- If the pharmacist orders the HIV test, they can initiate PrEP while waiting for the test results.
    - If the HIV result is positive - PrEP must be immediately discontinued and the pharmacist is responsible for delivering the positive result to the client within 10 days of receiving it. The pharmacist must also report the result to the Virginia Department of Health with 10 days of receiving the result.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.

- PrEP refills will not be authorized past the initial 30-day supply if recommended baseline testing is not done by one of the above mechanisms.

| Test | Frequency | CDC Recommendations | Notes |
|---|---|---|---|
| **HIV, 4th generation** | **Baseline + Every 3 months** | **Required** | **If positive, refer to care (*see note 1 )** |
| Syphilis | Baseline + At 3 months if symptomatic. Every 6 months if asymptomatic. | Recommended | If positive, refer to care (*see note 2) |
| Extragenital Gonorrhea/ Chlamydia | Baseline + At 3 months if symptomatic. Every 6 months if asymptomatic. | Recommended | If positive, refer to care (*see note 2) |
| Serum creatinine | Baseline, at 3 months, and thereafter every 6 months | Recommended | If CrCl <60 ml/min, cannot use FTC/TDF If CrCl <30 ml/min cannot use FTC/TAF (*see note 3) |
| Hepatitis B | Baseline | Recommended | If positive, refer to care (*see note 4 ) |
| Hepatitis C | Baseline | Recommended | If positive, refer to care (*see note 5) |
| Pregnancy | Baseline | Recommended | If positive, refer to care (*see note 6) |

From draft of CDC PrEP Guidelines 2021:

| Test | Screening/ Baseline Visit | Q 3 months | Q 6 months | Q 12 months | When stopping PrEP |
|---|---|---|---|---|---|
| **HIV test** | X* | X | [redacted] | | X |
| **eCrCl** | X | | If age ≥50 or eCrCl <90ml/min at PrEP initiation | If age ≥50 or eCrCl <90ml/min at PrEP initiation | X |
| **Syphilis** | X | MSM/TGW | X | | MSM/TGW |

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

| | | | | |
|---|---|---|---|---|
| **Gonorrhea** | X | MSM/TGW | X | MSM/TGW |
| **Chlamydia** | X | MSM/TGW | X | MSM/TGW |
| **Hepatitis B** | X | | | |
| **Hepatitis C** | MSM and PWID only | | | MSM and PWID only |
| **Pregnancy** | Persons with childbearing potential | Persons with childbearing potential | X | Persons with childbearing potential |

*Assess for acute HIV infection

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/PEP and alternative dosing regimens (i.e. PrEP on demand, PrEP 2-1-1)
- Individualized strategies for optimum adherence
    - Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
- Signs/symptoms of acute HIV infection and recommended actions
- Appropriate counseling regarding on-going risk for HIV and other STI acquisition
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care.
- The importance and requirement of testing for HIV, renal function, hepatitis B, hepatitis C and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Regulation 18VAC110-21-46.

Referrals to primary care provider:

* (note 1) If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a

list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: Insert Virginia link

* (note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. Insert Virginia link

*(note 3) If a patient test has abnormal renal values and/or signs of acute renal injury, refer for urgent evaluation. Insert Virginia link

*(note 4) If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. Insert Virginia link

*(note 5) If a patient tests positive for Hepatitis C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. Insert Virginia link

*(note 6) If a female patient becomes pregnant while on PrEP, refer for care. Insert Virginia link



[1] CDC. Pre-exposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

[2] USPTF. Pre-exposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

## II. Non-Occupational Post-Exposure Prophylaxis (PEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (PEP) is the use of antiretroviral drugs after a single, high-risk event to decrease the risk of HIV seroconversion. It must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non-occupational post-exposure prophylaxis (PEP) only; those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients aged 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. This regimen should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. Providers include local health departments. For more information contact the Disease Prevention Hotline at: 800-533-4148.

**If the following criteria are met, antiretroviral agents in Table 1 are recommended:**

- The exposure must have occurred within 72 hours
- A rapid antibody CLIA-waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and PEP is otherwise indicated, therapy should still be initiated.
- Exposure to a source individual known to be HIV-positive or someone of unknown HIV status.
- Exposure of:
    - Vagina
    - Rectum
    - Eye
    - Mouth
    - Other mucous membrane
    - Broken skin
    - Percutaneous contact( (e.g. injecting drugs with contaminated needle or needle stick injury)

  WITH
    - Blood
    - Semen
    - Vaginal secretions
    - Rectal secretions
    - Any body fluid visibly contaminated with blood
- Exposure types with highest risk of transmission of HIV are:
    - Needle sharing during injection drug use
    - Percutaneous needle stick

  - Receptive anal intercourse
- If exposure with a source in which the HIV status is not known, PEP may be considered and antiretroviral agents in Table 1 may be prescribed. PEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Virginia Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

**Patients who should NOT be prescribed PEP under this protocol and should be referred to primary care provider for further action:**

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for PEP and is potentially a victim of child abuse, child protective services MUST be contacted.

**Other Considerations:**

- Vaginal or rectal sex that occurred during a period when the patient may have been under the influence of drugs or alcohol and does not remember the entire event.
- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). For resources, contact the Virginia Family Violence & Sexual Assault Hotline at 1-800-838-8238 (24 hours/day, toll-free). For additional resources, please visit Virginia Sexual and Domestic Violence Action Alliance at www.vsdvalliance.org. For assistance, contact the Victim Assist Virginia Helpline at 1-888-887-3418.
- If a child presents to the pharmacy with a request for PEP and is potentially a victim of child abuse, child protective services (CPS) MUST be contacted at 800-552-7096. For more details about CPS, go to www.dss.virginia.gov/family/CPS, and to find your local CPS agency, go to www.dss.virginia.gov/localagency .

**Table 1 - Medication Options**

Other FDA-approved/CDC-recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Dose | Duration | Notes |
|---|---|---|---|---|
| **emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)**<br><br>**PLUS**<br><br>**raltegravir 400mg**<br><br>**OR**<br><br>**Dolutegravir 50mg** | ≥ 13 years | Once daily<br>No refills<br><br>Twice daily<br>No refills<br><br>Once daily<br>No refills | 28 days | Dosing adjustments with renal dysfunction if CrCl <60 ml/min.<br><br>Dolutegravir should not be used in pregnant women<br><br>If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used. |

**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is. If the patient refuses an HIV test, pharmacists may initiate PEP without an HIV test result.
    - If the HIV result is positive then the pharmacist is responsible for delivering the positive result to the client within 10 days of receiving it and reporting the result to the Department of Health.
- Ask the following screening question:
    - Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

      In this event, pharmacist should make arrangements to refer patient for a serum creatinine blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCl <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.
- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and

make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

| Test: | Frequency: | CDC Recommendations: | Notes: |
|---|---|---|---|
| **HIV, 4th generation** | **Baseline + Post exposure at week 4-6, and months 3 and 6** | **Required** | **If positive refer to care (*see note 1)** |
| Syphilis | Baseline | Recommended | If positive refer to care (*see note 2) |
| Extragenital Gonorrhea/ Chlamydia | Baseline | Recommended | If positive, refer to care (* see note 2) |
| Serum creatinine | Baseline + at 4-6 weeks. | Recommended | If elevated refer to care (*see note 3) |
| ALT/AST | Baseline + at 4-6 weeks. | Recommended | |
| Hep B | Baseline + 6 months | Recommended | If positive, refer to care (*see note 4 ) |
| Hep C | Baseline + 6 months | Recommended | If positive, refer to care (*see note 4) |
| Pregnancy | Baseline + at 4-6 weeks. | Recommended | Pregnancy is not a contraindication to PEP |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

**Virginia State Board of Pharmacy Statewide Protocol for the Provision of HIV Pre-exposure and Post-exposure Prophylaxis**

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in 18VAC110-21-46.

Referrals:

- *(note 1) Patient should have urgent evaluation referral for signs or symptoms of acute HIV infection. If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: Insert VA Insert Virginia link
- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B. Insert Virginia link
- *(note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: Insert Virginia link
- *(note 3) Urgent evaluation referral for symptoms or signs of acute renal injury. Insert Virginia link
- *(note 4)If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: Insert Virginia link
- Signs of symptoms of acute drug toxicities or serious side effects
- Usual care for any other issues, stress importance of routine primary care and health maintenance.

**Resources and References**

**CDC.** Preexposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

**National Clinicians Consultation Center**

- Pre-Exposure Prophylaxis consultation for clinicians **(855) 448-7737** or **(855) HIV-PrEP** Monday – Friday, 9 a.m. – 8 p.m. ET https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/
- Non-occupational PEP consultation for clinicians **(888) 448-4911** Hours of operation for are **9 a.m. – 8 p.m. ET Monday – Friday**, and **11 a.m. – 8 p.m. ET on weekends & holidays** .https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/

**USPTF.** Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

**Virginia Department of Health** Disease Prevention Hotline answers questions and provides crisis intervention, referrals, and written educational materials regarding Sexually Transmitted Diseases (STDs), HIV/AIDS, and Viral Hepatitis. Reach a hotline counselor toll free at (800) 533-4148 or by email at hiv-stdhotline@vdh.virginia.gov. To view or request educational materials, please visit the resources page. Hotline hours are Monday-Friday from 8 am until 5 pm. The hotline is closed for Virginia State Holidays.

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August 6, 2021

**Dale St. Clair, Jr, PharmD**
Perimeter Center
9960 Mayland Drive, Second Floor
Richmond, VA 23233

Re: Medical Society of Virginia Comment Re: Pharmacist Statewide Protocol

Dear Chairman St. Clair,

On behalf of the PAs, medical students, and physicians of the Commonwealth, thank you for your unwavering support of Virginia's healthcare workforce and for your leadership of the Board of Pharmacy through the COVID-19 pandemic.

I write representing the Medical Society of Virginia (MSV) to offer comment for consideration by the Statewide Protocol Work Group. The MSV has been an active stakeholder in conversations around regulations authorizing pharmacists to initiate treatment with, dispense or administer certain drugs, devices, controlled paraphernalia, and other supplies over the past several years.

The MSV believes some of the proposed protocols require significant clinical judgment for which pharmacists are not suited. We offer the following modifications to ensure patient safety is not breached while still acknowledging the importance of physician-pharmacists collaborative practice as part of the clinical care team.

**Vaccines in the CDC adult immunization schedule:**

On Page 9, under "Patient Exclusion Criteria," we request consideration of adding the following language:

- An individual for whom a vaccine is only recommended by the CDC if the individual possesses an additional risk factor or another indication
- An individual for whom a vaccine is only recommended by the CDC based on shared clinical decision-making

Administering the vaccines in the above vaccine schedule requires clinical decision making, therefore, patients should be referred to a physician before receiving these vaccinations.

These two recommendations should also be added to the Emergency Regulations (pg. 106, point 7), as this section allows pharmacists to also administer a wide range of vaccines currently indicated by the CDC to require extra attention as listed above.

**HIV PEP and PrEP:**

On Page 68 we ask the word "prescribe" the be changed to "initiate treatment" as per the Code of Virginia.

Further, in speaking with several Virginia physicians, they all agreed that the determination of kidney function prior to administrating PEP and PrEP is critical, as decreased kidney function is an established contraindication to PrEP and PEP.

The MSV ask for consideration of changing the listed metrics for kidney function. Notably, the standard of care in 2021 is not CrCL but eGFR. When metabolic labs are measured, eGFr is the value that is included. If the following changes are not accepted, equivalents should be considered for clarification purposes, i.e., including both CrCL and eGFR metrics.

- Page 70, under "Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care providers for further action:
    - "CrCL<60 ml/min" should be changed to "eGFR <90ml/min."
- Page 70, Table 1, Notes under row 1:
    - "CrCL<60 ml/min" should be changed to "eGFR <90ml/min."
- Page 70, Table 1, Notes under row 2:
    - "Not recommended for Cr Cl <30 ml/min" should be changed to "Not recommended for eGFR < 60 ml/min."
- Page 71, Table 2, extragenital/gonorrhea/chlamydia row:
    - Testing for extragenital gonorrhea typically requires a pharyngeal and rectal swab. Pharmacies are not an appropriate setting for such testing.
        - We encourage discussion of how these will be performed.
- Page 72, under "Counseling":
    - There should be training on patient sensitivity, particularly for individuals with positive HIV test results. A pharmacy is not an optimal environment to receive and discuss such news on one's health.
        - We encourage discussion by the workgroup as to how to strengthen the Counseling guidelines to meet these concerns.

**Tuberculin purified protein derivative for TB testing**

The MSV offers the following recommendations be included in the TB skin testing protocol to assure the highest standard of patient safety:

- If a pharmacist reads what they believe is a positive test, an immediate referral to a physician or ACP must be required. The individual with a positive PPD will likely need a chest x-ray or require a QuantiFERON TB Gold blood-test, which cannot be ordered by a pharmacist. Immediate care is imperative under these circumstances.
- Individuals using steroids or other immunosuppressives should be referred to a physician for testing as these individuals will not react to PPD, making it possible to generate a false negative diagnosis.
- Patients with autoimmune diseases may not react to PPD and should therefore only be tested by a physician.
- Require all pharmacists complete a full training specified by VDH or the Board of Medicine as well as the CDC's online training module. Records of training completion must be maintained by the pharmacists.

- Mandatory reporting of positive test screenings to VDH and the individual's primary care physician within 15 days of test administration. Such requirement is mandatory in New Mexico and Idaho, and we believe a similar model should be implemented in Virginia.

The MSV commends all the work that staff, stakeholders, and work group members have put in towards this effort. The MSV and our members are grateful for the opportunity to be involved in the creation of these protocols and will continue to offer whatever input and feedback we can.

Should you have any questions, please do not hesitate to contact Medical Society of Virginia Assistant Vice President of Government Affairs and Public Policy, Clark Barrineau at cbarrineau@msv.org or 704-609-4948.

Sincerely,

Clark Barrineau
Assistant Vice President of Government Affairs and Public Policy
Medical Society of Virginia