Chapter 7: Diagnosis of Latent Tuberculosis Infection

Contents

Introduction

Purpose

Use this section to understand and follow national and Wisconsin guidelines to do the following:

- Classify patients with latent TB infection (LTBI)
- Diagnose LTBI

In the 2005 guideline "Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, Centers for Disease Control and Prevention, and the Infectious Diseases Society of America," one of the recommended strategies to achieve the goal of reduction of TB morbidity and mortality is the identification of people with LTBI at risk for progression to tuberculosis (TB) disease, and treatment of those people with an effective drug regimen.[1] Additionally, the U.S. Preventative Task Force (USPTF) recommends screening for LTBI in populations at increased risk (Grade: B, 2023).

Contacts are mentioned within this section, but their evaluation and follow-up are covered in more depth in the Contact Investigation section. For information on treatment, refer to the Treatment of Latent Tuberculosis Infection section.

Policy

In Wisconsin:

Targeted **testing for LTBI should be conducted only among people in groups with identified risk factors** for LTBI or progression to TB disease.

Contacts should be evaluated as described in the Contact Investigation section.

For roles and responsibilities, refer to the "Roles, Responsibilities, and Contact Information" topic in the Introduction.

See Wisconsin DHS's recorded training on TB, LTBI, and contact investigation entry in WEDSS.

Forms

Required and recommended forms are available on the Wisconsin Tuberculosis Program website.

High-risk groups

Certain factors identify people at high risk for TB infection or for progression to TB disease. People in the high-risk groups listed in Table 3.1: **People at high risk for tuberculosis infection and progression to tuberculosis disease** are candidates for tuberculin skin testing in Wisconsin. People with risk factors from both columns may be at much higher risk than those with risk factors in only one column. For example, an individual born in a high-TB-prevalence country with HIV infection is at much higher risk of having active TB than a US-born individual with HIV infection.

Table 3.1. People at high risk for tuberculosis infection and progression to tuberculosis disease

For tuberculosis Infection:	For progression to tuberculosis disease:

• High-priority contacts such as housemates or coworkers or contacts of people who have smear-positive pulmonary or laryngeal TB
• Infants, children, and adolescents exposed to adults in high-risk categories
• Recent immigrants (5 years or less) from countries with high incidence of TB (Asian, African, Latin American, and Eastern European countries have TB rates 5–30 times higher than U.S. rates, and an increasing percentage of TB cases here are occurring among immigrants from those countries)
• Recent immigrants from Mexico
• Migrant or seasonal workers
• People who have recently spent over 3 months in high-incidence countries
• Native Americans
• People with high rates of TB transmission:
  ○ People experiencing homelessness
  ○ People who inject drugs
  ○ People living with HIV
• People living or working in institutions with individuals at risk for TB such as:
  ○ Hospitals, especially nursing staff, emergency department staff, and laboratory staff
  ○ Long-term care facilities
	• People living with HIV
	• Infants and children under age 5 years
	• People infected with *Mycobacterium tuberculosis* within the previous 2 years
	• People with a history of untreated or inadequately treated TB disease
	• People with radiographic findings consistent with previous TB disease
	• People who use alcohol or illegal drugs
	• People with any of the following clinical conditions:
	  ○ Silicosis
	  ○ Diabetes mellitus
	  ○ End-stage renal disease, chronic renal failure
	  ○ People on hemodialysis
	  ○ Some hematologic disorders (for example, leukemias and lymphomas)
	  ○ Other malignancies (for example, carcinoma of head, neck or lung)
	  ○ Body weight 10% or greater below ideal body weight.
	  ○ Prolonged corticosteroid use
	  ○ Use of other immunosuppressive treatments (for example, prednisone, tumor necrosis factor-alpha

○ Homeless shelters ○ Residences for people with acquired immunodeficiency syndrome (AIDS) ○ Correctional facilities	antagonists) ○ People with history of organ transplantation- especially if they take anti-rejection medications ○ Gastrectomy ○ Chronic malabsorption syndromes ○ Jejunoileal bypass

Source: Adapted from: CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005;54(No. RR-17):4–5; CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000;49(No. RR-6):7–9.; Wisconsin Department of Health Services. Wisconsin Tuberculosis Risk Assessment and Symptom Evaluation, 2021. https://www.dhs.wisconsin.gov/forms/f02314.pdf

See Wisconsin TB Program Risk Assessment and Symptom Evaluation form*.*

Diagnosis of latent tuberculosis infection

The diagnosis of latent tuberculosis infection (LTBI) has traditionally been based upon results of tuberculin skin testing. However, the QuantiFERON®, or T.spot.TB test, which are whole-blood interferon gamma release assays (IGRAs), are now other options for detecting LTBI.

Use the Mantoux tuberculin skin test (TST) or an IGRA to test for *Mycobacterium tuberculosis* infection. QuantiFERON®, or T.spot.TB tests can be used in all circumstances in which the TST is used, and QuantiFERON®, or T.spot.TB tests usually can be used in place of (and not in addition to) the TST.[2] Either of these test types are acceptable, but the state TB program prefers IGRA testing, when available.

For information on testing methods available in Wisconsin, refer to the Laboratory Services section.

Interferon gamma release assays

Interferon gamma release assays (IGRA) for *Mycobacterium tuberculosis* is a general term referring to in vitro diagnostic tests that assess for the presence of infection with *M. tuberculosis*. Currently two IGRA tests are approved for use by the United States Food and Drug Administration: The QuantiFERON® test (QFT) and the T-SPOT®. TB test (T-Spot). Other cytokine-based immunoassays are under development and may also become useful in the diagnosis of *M. tuberculosis* infection. Future FDA-licensed products, in combination with

Centers for Disease Control and Prevention (CDC)-issued recommendations, may provide additional diagnostic alternatives.[3]

The advantages of IGRA, compared with the TST, are that results can be obtained after a single patient visit, and that, because it is a blood test performed in a qualified laboratory, the variability associated with skin test reading can be eliminated.[4] In addition, the QFT and T-SPOT™ tests appear to be less affected by past Bacille of Calmette-Guérin (BCG) vaccination than the TST and may eliminate the unnecessary treatment of patients with BCG-related false-positive results.[5] However, the QFT and T-SPOT™ tests have practical limitations that include the need to draw blood and to ensure its receipt in a qualified laboratory in time for testing. For the QFT test, the blood may be stored at room temperature or refrigerated for up to 53 hours after collection to be incubated with the test antigens, while the lymphocytes are viable.[6] Neither IGRA should be performed until four weeks after vaccination with live-virus vaccines.

Mantoux tuberculin skin testing

The Mantoux method of tuberculin skin testing is also used to detect infection with *Mycobacterium tuberculosis.*

In general, it takes two to ten weeks after infection for a person to develop a delayed-type immune response to tuberculin measurable with the Mantoux tuberculin skin test (TST).[7] During the test, tuberculin is injected into the skin. The immune system of most people with tuberculosis (TB) infection will recognize the tuberculin, causing a reaction in the skin. Repeated TSTs do not produce hypersensitivity.

The size of the measured **induration** (a hard, dense, raised formation) **not erythema** (redness or bruised appearance) and the patient's individual risk factors should determine whether TB infection is diagnosed.[8] Based on the sensitivity and specificity of the purified protein derivative (PPD) TST and the prevalence of TB in different groups, three cut-off points have been recommended for defining a positive tuberculin reaction:

- Greater than or equal to 5 mm of induration
- Greater than or equal to 10 mm of induration
- Greater than or equal to 15 mm of induration[9]

For more information on cut-points for the TST, see the “Interpretation of the Tuberculin Skin Test” topic in this section.

Candidates for Mantoux tuberculin skin testing

The Mantoux TST can be administered to all people, including pregnant people,[10] people who have previously been vaccinated with bacille Calmette-Guérin (BCG),[11] and people living with HIV. TST is the preferred testing method for children under 2 years of age. However, any people with a documented prior positive TST does not need another TST, and the Mantoux TST should not be administered until four weeks after vaccination with live-virus vaccines.

If the person being tested is a contact, follow the procedures outlined in the Contact Investigation section.

Pregnancy

Tuberculin skin testing is entirely safe and reliable for pregnant people, and pregnant people at high risk for TB infection or disease should be tested. Screen pregnant people for TB infection if they have any of the following conditions:

- Symptoms suggestive of TB disease
- HIV infection
- Medical conditions other than HIV infection that increase the risk for TB disease
- Close contact with a person with infectious TB disease
- Birth or immigration from an area of the world where incidence of TB is high

Bacille Calmette-Guérin Vaccine

BCG vaccines are live vaccines derived from a strain of *Mycobacterium bovis.* Because their effectiveness in preventing infectious forms of TB has never been demonstrated in the United States, they are not recommended as a TB control strategy in the United States, except under rare circumstances. They are, however, used commonly in other countries. A history of BCG vaccination is not a contraindication for tuberculin skin testing, nor does it influence the indications for a TST, although IGRAs are the preferred test in BCG-vaccinated individuals to avoid possible boosting and false positives.

Diagnosis and treatment of LTBI should be considered for BCG-vaccinated people with a TST reaction of equal to or greater than 10 mm induration, especially any of the following:

- People continually exposed to populations with a high prevalence of TB (for example, some health care workers, employees and volunteers at homeless shelters, and workers at drug treatment centers)
- People born or who have lived in a country with a high prevalence of TB
- People exposed to someone with infectious TB, particularly if that person has transmitted TB to others[12]

Evaluate these patients for symptoms of TB. If a patient has symptoms of TB disease, obtain chest radiography and (if the patient can produce either spontaneously or via induction) collect sputum specimens for AFB smear and culture. PCR may be warranted, by request depending on risk profile. See laboratory section for more details on laboratory algorithm.

Bacille Calmette-Guérin talking points

- Tuberculin reactivity caused by BCG vaccination wanes with time but can be boosted with a TST.[13]

- A diagnosis of *M. tuberculosis* infection should be considered for any BCG-vaccinated person who has TST reaction ≥10 mm of induration.[14]
- Treatment for LTBI should be considered for a person who is TST positive and has previous BCG vaccination if the person is:
    - A contact of a person with infectious TB.
    - Vaccinated and born in (or resided in) a country of high prevalence of TB.
    - Exposed to people at risk for TB.[15]
- BCG vaccination may be considered for infants and children who reside in high morbidity countries to prevent meningeal TB. Procurement for this purpose in the U.S. is extremely difficult, consult the state program if LTBI therapy or window prophylaxis is not available or appropriate due to index case susceptibility profile.[16]
- There is no scientific evidence of protective ability of BCG for preventing pulmonary TB in adolescents or adults.[17]

Documented prior positive tuberculin skin test or IGRA

People who have tested positive in the past and can provide documentation of their status do not usually need another TST or IGRA. Instead, they should have a TB symptom assessment questionnaire administered to identify any symptoms of TB disease.[18] People who are symptomatic should receive a chest radiograph. People with a history of untreated LTBI should be encouraged to continue the process for LTBI therapy (updated CXR and symptom screen/ provider evaluation).

Live-virus vaccines

The Mantoux TST can be administered in conjunction with all vaccines. However, the measles (MMR) vaccine—and possibly mumps, rubella, varicella, and live attenuated influenza vaccines—may transiently suppress the response to PPD.[19] Therefore, if a vaccine containing live virus (for example, measles, smallpox) has already been given, the TST should be deferred until (or repeated) at least four weeks after the vaccine was administered. **IGRA tests should also not be drawn until at least four weeks have passed after the administration of vaccines containing live virus.**

When giving the TST and the MMR, one of the following three sequences should be used:

- Apply the TST at same visit as the MMR
- Delay the TST at least four weeks if the MMR is given first
- Apply the TST first and then give the MMR when the TST is measured[20]

Administration of the tuberculin skin test

The TST should be placed by a health care worker who has received appropriate training and is following written protocols.

Table 7.1: Before you begin to administer a tuberculin skin test

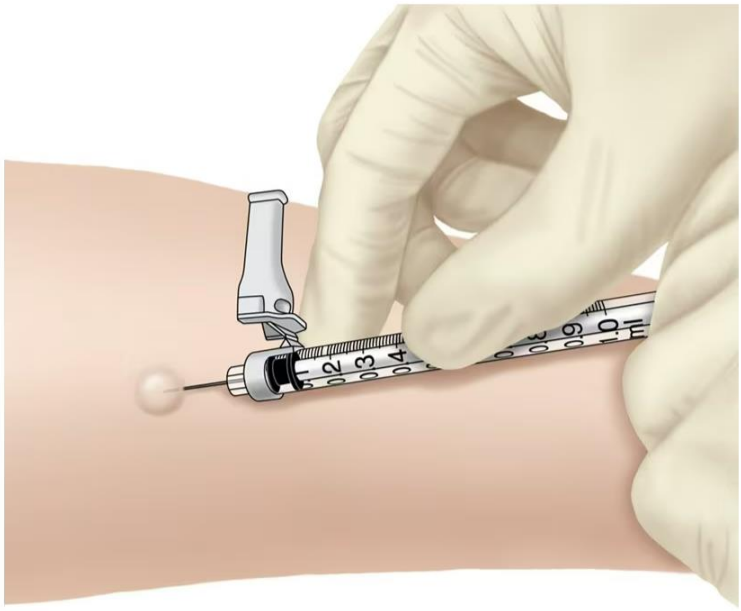
Before you begin to administer a tuberculin skin test	
Review information	CDC Mantoux Tuberculin Skin Test Toolkit Infection control procedures (including hand washing before and after the procedure and the use of gloves and a sharps container)
Gather equipment	Gloves Alcohol pads or alternative skin cleanser Safety needle Tuberculin syringe (Do not pre-draw tuberculin into syringes prior to test.) Purified protein derivative (PPD) (Tubersol® or Aplisol®: See the warning in the text below in this table.) Sharps container **Note:** Date PPD tuberculin vials when opened and discard them after 30 days. See the package insert for appropriate storage information.

Read the PPD labels carefully before administering a TST. The packaging of tetanus toxoid-containing vaccines (TTCVs) is similar to Tubersol® and Aplisol®, and all are refrigerated. See the CDC's "Notice to Readers: Inadvertent Intradermal Administration of Tetanus Toxoid-Containing Vaccines Instead of Tuberculosis Skin Tests."

How to administer a tuberculin skin test

1. Obtain the patient's written consent, if required by the health department.
2. Inject air into the vial air space (not into the solution). Injection of air into the air space in the vial prevents creation of negative pressure within the vial, allowing the antigen to be withdrawn easily. Injecting air into the solution creates bubbles and may interfere with withdrawing the correct amount of antigen.[21]
3. The injection should be placed on the palm-side-up surface of the forearm, about two to four inches below the elbow. Your local institutional policy may specify the right or left forearm for the skin test. The area selected should be free of any barriers to placing and reading the skin test, such as muscle margins, heavy hair, veins, sores, tattoos, or scars.
4. After choosing the injection site, clean the area with an alcohol swab by circling from the center of the site outward. Allow the site to dry completely before the injection.
5. Using a disposable tuberculin safety needle and syringe, inject 0.1 ml of PPD tuberculin containing 5 tuberculin units (TU) intradermally with the needle bevel facing upward. Because some of the tuberculin solution can adhere to the inside of the plastic syringe, the skin test should be given as soon as possible after the syringe is filled.

6. The injection should produce a discrete, pale elevation of the skin (a wheal) 6 to 10 mm in diameter. **Note:** If a 6- to 10-mm wheal is not produced, repeat the test on the opposite arm or the same arm, two inches from the original site.
7. Record the date and time of TST administration, location of injection site, dose, name of the person who administered the test; the name and manufacturer of the tuberculin product used, its lot number, its expiration date; and the reason for testing.[22]



On the first visit, a trained health care provider places a TB skin test.

Measurement of the tuberculin skin test

A trained health care worker should read the TST 48 to 72 hours after the intradermal injection. Patients should never be allowed to read their own TSTs.[23]

A positive reaction can be measured any time after 48 hours.

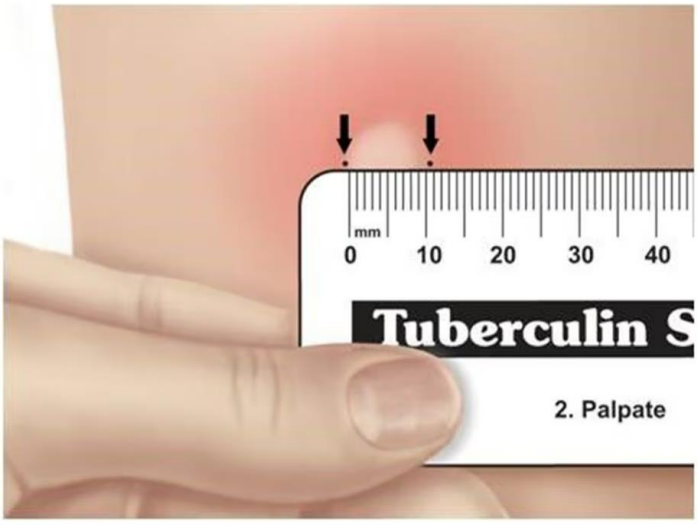
If the results appear negative and more than 72 hours have passed, the test should be repeated. It can be repeated immediately, or after one week, if two-step testing is required.

See the topic titled “Two-Step Tuberculin Skin Testing” in the Infection Control section.

Before you measure a TST, review information in the CDC’s *Mantoux Tuberculin Skin Test Toolkit*.

How to measure a tuberculin skin test

1. Measure the TST site crosswise to the axis of the forearm (from the thumb side of the arm to the little finger side of the arm or vice versa).
2. Induration is a hard, dense, raised formation. **Measure only induration hardness and not swelling around the site of the injection. Do not measure erythema (redness). A TST with erythema, but no induration, is nonreactive.**



A trained health care provider reads a TB skin test between 48 and 72 hours after placement.

3. Record the test result in mm, not as "positive" or "negative." An exact reading in mm may be necessary to interpret whether conversions occur on a subsequent test. Record a TST with no induration as "0 mm." Where there is induration, do not round off the reading, but record it exactly as read.

Report adverse reactions to as TST (for example, blistering, ulcerations, or necrosis) to the FDA's MedWatch Program online or call 1-800-FDA-1088.

How to interpret a tuberculin skin test

TSTs should be interpreted by a trained health care worker. Use Table 7.2 below to interpret TSTs.

Call the Wisconsin Tuberculosis Program at 608-261-6319 regarding TST reactions when interpretation and medical follow-up are unclear.

Before you interpret a TST, review information in the CDC's Mantoux Tuberculin Skin Test Toolkit

Use Table 7.2 below to determine when a reaction is positive.

Table 7.2: Positive tuberculin skin test reactions

Induration size	Considered positive for:
5 mm or more	People with human immunodeficiency virus (HIV) infection/acquired immunodeficiency syndrome (AIDS) Recent contacts to an infectious case of tuberculosis (TB) disease People with fibrotic lesions on chest radiograph consistent with healed TB People with organ transplants or other immunosuppressed people (such as those receiving the equivalent of >15 mg/day of prednisone for >1 month) People receiving treatment with tumor necrosis factor-alpha (TNF-α) antagonists
10 mm or more	Peoples 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 with substance use disorders or excessive substance use (including alcohol, IV drugs) People who live or work in high-risk, congregate settings (for example, correctional institutions; long-term residential care facilities, such as nursing homes, mental health facilities, homeless shelters; and refugee camps) Mycobacteriology laboratory personnel People with other medical conditions that increase the risk of TB disease (for example, silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions) Children younger than 5 years of age Infants, children, and adolescents exposed to adults in high-risk categories
15 mm or more	People with no known risk factors for TB

When interpreting TST results, be aware of the following.

Skin test conversions: For people previously skin tested, an increase in induration of 10 mm or more within a two-year period is classified as a conversion to positive.

False-negative reactions may be due to the following:

- Recent TB infection (within the past 10 weeks)
- Very young age (less than six months of age, because the immune system is not fully developed)
- Overwhelming TB disease (people with active TB disease may test negative on TST and IGRA, negative testing does not rule out TB disease)
- Vaccination with live viruses (for example, measles, mumps, rubella, varicella, oral polio, or yellow fever)
- Some viral infections (measles, mumps, chickenpox, or HIV)
- Corticosteroids or other immunosuppressive agents given for two or more weeks

TB testing should be done either on the same day as vaccination with live virus or at least four weeks after vaccination.

See “Live-Virus Vaccines” in this section.

False-positive reactions may be due to the following:[24]

Nontuberculous mycobacteria (NTM) or mycobacterium other than tuberculosis (MOTT)

BCG vaccination (for most individuals, reactivity wanes quickly in the early years of life)

See “Bacille Calmette-Guérin Vaccine” under “Candidates for Mantoux Tuberculin Skin Testing” in this section.

Human Immunodeficiency Virus screening

The Centers for Disease Control and Prevention (CDC) recommends the following:

- Routine HIV screening for all patients ages 13–64 seeking health care for any reason, without regard to patient’s known risks for HIV infection.
- Annual HIV screening of patients known to be at high risk.[25]

Follow-up activities

After testing, complete the following tasks:

If the person has signs or symptoms of TB, evaluate for TB disease as described in the “Diagnosis of Tuberculosis Disease” topic in the Diagnosis of Tuberculosis Disease section. Refer to Table 1: **When to Suspect Pulmonary Tuberculosis in Adults**.

If the person is a contact, follow the procedures for testing and evaluation in the Contact Investigation section.

If the person is a participant in two-step screening, see the topic titled “Two-Step Tuberculin Skin Testing” in the Infection Control section.

If the TST result is positive, a chest radiograph should be obtained for the patient, as specified in the “Chest Radiography” topic in this section.

Chest radiography

All individuals being considered for LTBI treatment should undergo a chest radiograph to rule out pulmonary TB disease. Refer to Table 7.3 below to determine when to obtain a chest radiograph and what follow-up is required for chest radiograph results.

A posterior-anterior radiograph of the chest is the standard view used for the detection and description of chest abnormalities in adults. In some instances, other views (for example, lateral or lordotic) or additional studies (for example, computed tomography [CT] scans) may be necessary.

Children younger than 5 years of age should receive posterior-anterior and lateral radiographs.[26] This is commonly known as a "2-view chest x-ray."

For more information on chest radiography, refer to the Francis J. Curry National Tuberculosis Center's Radiographic Manifestations of Tuberculosis: A Primer for Clinicians.

For people recently exposed to TB, follow the procedures for testing and evaluation in the Contact Investigation section.

Table 7.3: Targeted testing for latent tuberculosis infection: when chest radiographs are required and how to follow up on radiography results

Signs or symptoms of TB disease?	TST or IGRA result?	Recent exposure to infectious TB?	Chest radiograph: required and results?	Follow-up action
Yes	Positive or negative	Yes or no	CXR Required: Yes Results: Normal or abnormal	Evaluate for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.
No	Negative	No	CXR not recommended unless the patient has HIV infection or other forms of immunosuppression are present	No further action necessary.
No	Positive	No	CXR Required: Yes Results: Normal	Consider treatment for LTBI. Refer to the Treatment of Latent Tuberculosis Infection section.
			CXR Required: Yes Results: Abnormal noncalcified fibrotic lesions suggestive of old, healed TB; comparison film available and stable	Consider evaluating for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.
			CXR Required: Yes Results: Abnormal consistent with TB disease; no comparison film	Evaluate for TB disease. Refer to the Diagnosis of Tuberculosis Disease section.

Definitions of abbreviations: CXR = chest radiograph; HIV = human immunodeficiency virus; IGRA = interferon gamma release assay; LTBI = latent tuberculosis infection;
TB = tuberculosis; TST = tuberculin skin test.

Resources and references

Resources

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