



DSHS Epi Case Criteria and Case Definitions for Public Health Surveillance

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What is TB?

Tuberculosis (TB) is an infectious airborne disease caused by *Mycobacterium tuberculosis* usually affecting the lungs, but can attack almost any part of the body. It is not a highly communicable disease and usually requires; prolonged exposure to someone with infectious TB disease.

Clinical Description

TB is a chronic bacterial infection, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

TB Surveillance

For purposes of surveillance, a case of TB is defined on the basis of laboratory or clinical evidence of active disease due to *M. tuberculosis complex*.

Because most laboratories use tests that do not routinely distinguish *Mycobacterium tuberculosis* from very closely related species, these laboratories report culture results as being positive or negative for "*Mycobacterium tuberculosis complex*". Although in almost all cases of human disease, isolates in the *M. tuberculosis complex* are, in fact, *M. tuberculosis*, other species are possible.

Mycobacterium tuberculosis complex include

- ***M. tuberculosis***...causes most of the disease in many mammals, including humans. It is transmitted through the airborne route and is only rarely found in animals.

- ***M. bovis***...is a species of mycobacteria that can cause disease in many mammals including humans. Before the pasteurization of milk became common practice, TB was often spread to humans through milk or milk products such as fresh cheese (e.g., queso fresco) imported from countries or areas where the bacterium is common in cattle. Although rare in Texas, *M. bovis* still occurs in humans and should be reported as TB since it can also be transmitted through the air. *M. bovis* is resistant to the anti-tuberculosis medication pyrazinamide (PZA).
- ***M. africanum***...is a member of the *M.tb complex* and has been isolated from humans in equatorial Africa, Europe and recently from five persons in California.
- ***M. microti***...is also a species of the *M.tb complex* and mainly found in rodents such as voles and llamas, but has also been isolated from immunosuppressed humans.
- ***M. canettii***...was originally described as a subspecies of **M.tb** but subsequently was elevated to species status and has been isolated from humans with a history of living in Eastern Africa.
- ***M. caprae***...has been added to the *M.tb complex* since advancement of technical methods for testing for genetic differences. The National Institutes of Health list several as yet unnamed species in their Taxonomy Browser.
- ***M. piniipedii***...has also been added to the *M.tb complex*.

Although most of these other species are newly described, their inclusion in *M. tuberculosis complex* should not impact public health laboratories or programs, because only a few laboratories identify to the species level.

These species are almost identical in DNA homology studies. In terms of their ability to cause clinical disease or be transmissible from person to person, these species behave like *M. tuberculosis*; therefore, disease cause by any of the organisms should be reported as TB. The only exception is the BCG strain of *M. bovis* which may be isolated from persons who have received the vaccine for protection against TB or as cancer immunotherapy.

Disease caused by the BCG strain of *M. bovis* should not be reported as lab confirmed TB. Therefore, all isolates reported as *M. tuberculosis* complex should be further evaluated to determine if they are *M. bovis* or *M. bovis* (BCG).

Laboratory Criteria for Diagnosis

- Isolation of *M. tuberculosis complex* from a clinical specimen. The use of rapid identification techniques for *M. tuberculosis* performed on a culture from a clinical specimen, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion,

OR

- Demonstration of *M. tuberculosis complex* from a clinical specimen by nucleic acid amplification test (NAAT). *Note: NAA tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of M. tuberculosis is required for complete drug susceptibility testing and also genotyping. However, for surveillance purposes, DSHS will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.*

OR

- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated.

Clinical Case Definition

A case that meets the following criteria, in the absence of laboratory confirmation of *M. tuberculosis complex*, after a diagnostic evaluation has been completed

- A positive tuberculin skin test result or positive interferon gamma release assay for *M. tuberculosis* **(and)**
- One of the following
 - (1) Signs and symptoms compatible with current pulmonary TB disease such as an abnormal chest radiograph or abnormal chest computerized tomography scan or other chest imaging study **(or)**
 - (2) Clinical evidence of current extra-pulmonary disease **(and)**
- Current treatment with two or more anti-TB medications **(and)**
- A complete diagnostic evaluation

A **complete diagnostic evaluation** is necessary to exclude pulmonary TB disease and/or to confirm extra-pulmonary disease. There are five different components to a complete TB medical evaluation

- Medical history, includes current signs and symptoms
- Physical examination
- Testing for TB infection
- Chest radiographs
- Bacteriologic and histologic examinations

Clinical Case by Provider Diagnosis

A case that meets at least one of the following criteria

- A negative tuberculin skin test result or negative interferon gamma release assay for *M. tuberculosis* and considerable improvement on an abnormal chest radiograph after started on at least two anti-TB medications

OR

- Considerable clinical improvement based on symptoms from onset after started on at least two anti-TB medications

OR

- A **child** that has had recent contact to an active case

OR

- Active TB disease reported at death, based on autopsy or medical examiner report

OR

- Active TB disease is confirmed on the basis of a DSHS recognized TB medical consultant.

TB disease in children under 15 years of age (also called pediatric tuberculosis) is a public health problem of special significance because it is a marker for recent transmission of TB. Confirming the diagnosis of TB disease in children with a laboratory test can be challenging. This is because

- It is difficult to collect sputum specimens from infants and young children; and
- The laboratory tests used to find TB in sputum are less likely to have a positive result in children; this is due to the fact that children are more likely to have TB disease caused by a smaller number of bacteria (paucibacillary disease).

For these reasons, the diagnosis of TB disease in children is often made without laboratory confirmation and instead based on combination of the following factors

- Clinical signs and symptoms typically associated with TB disease,
- Positive tuberculin skin test (TST) or positive TB blood test (IGRA),
- Chest x-ray that has patterns typically associated with TB disease, and
- History of contact with a person with infectious TB disease.

Other Case Classifications

Confirmed Case: a case that meets the clinical case definition or is laboratory confirmed.

Verified Case: a case that is verified by an authorized TB surveillance designee, on the basis of laboratory or clinical evidence of active disease due to *M. tuberculosis complex* and meets the criteria for a Texas Resident.

Counted Case: a case that is confirmed, verified and reported to the CDC for inclusion in statistics for annual incidence in Texas and national morbidity reports.

Recurrent...A case occurring in a patient who had previously had verified TB disease when more than 12 months have elapsed since the patient completed therapy or was lost to supervision and TB disease can be verified again. This can result when there is a negative smear and/or culture result while receiving anti-TB therapy, but at some point after therapy is completed, either the culture result becomes positive for *M. Tuberculosis* or the patient has clinical or radiologic deterioration that is consistent with TB disease.

Recurrent less than 365 days...A case occurring in a patient who had previously had verified TB disease but less than 12 months have elapsed since the patient completed therapy or was lost to supervision and TB disease can be verified again.

MDR (Multidrug-resistant) Case: a case that is resistant to at least isoniazid and rifampin; MDR TB is more difficult to treat than drug-susceptible TB. Drug-resistant TB disease can develop in two different ways, called primary and secondary resistance. Primary resistance occurs in persons who are initially exposed to and infected with resistant organisms. Secondary resistance, or acquired resistance, develops during TB therapy, either because the patient was treated with an inadequate regimen or because the patient did not take the prescribed regimen appropriately or because of other conditions such as drug malabsorption or drug-drug interactions leading to low serum levels (see Chapter 2, Transmission and Pathogenesis of Tuberculosis).

XDR (Extensively drug resistant) Case: the occurrence of TB whose *M. tuberculosis* isolates are resistant to isoniazid and rifampin, plus resistant to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin).

Source: Appendix A, Tuberculosis Case Definition for Public Health Surveillance, CDC Tuberculosis Surveillance Data Training, Report of Verified Case of Tuberculosis (RCT), June 2009.

Other References or Definitions for TB Cases

Case of Tuberculosis...a patient in whom tuberculosis has been confirmed by bacteriology or diagnosed by a clinician

Definite case of TB...a patient with positive culture for the *M. TB Complex* in countries where culture is not routinely available; a patient with one sputum smear positive for acid fast bacilli (AFB) is also considered a definite case.

Pulmonary case...a patient with tuberculosis disease involving the lung parenchyma (any form of lung tissue).

Smear-positive pulmonary case...a patient with one or more initial sputum smear examinations (direct smear microscopy) that are AFB positive.

Extra-pulmonary case...a patient with tuberculosis of organs other than the lungs (e.g., pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges, etc.). Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extra-pulmonary disease, followed by a decision by a clinician to treat with a full course of anti-tuberculosis chemotherapy. A patient in whom both pulmonary and extra-pulmonary tuberculosis has been diagnosed should be classified as a pulmonary case.

Miliary case... a patient with TB disease that is the result of a TB lung infection eroding into the bloodstream and disseminating throughout the body to multiple organs. Miliary TB is evident when more than 1 organ or disease site is involved, **and/or** there is a miliary or bilateral micro-nodular pattern in the chest x-ray or other chest imaging study.

New Case...a patient who has never had treatment for tuberculosis or who has taken anti-tuberculosis drugs for less than 14 days.

Empirically treated case...patient is initiated on empirical anti-therapy on the basis of clinical presentation and a chest x-ray or other imaging result that is strongly suspicious for TB, despite negative sputum or other specimen type results. The patient is monitored closely for the response

that signals that the finding was correct; therefore, length of treatment may vary from the standard regimens.

Culture negative case...patient who may or may not be symptomatic but where there is strong evidence on x-ray findings indicating active TB disease despite negative cultures. Failure to isolate *M. tuberculosis* from appropriately collected specimens in persons who, because of clinical or radiographic findings, are suspected of having pulmonary TB disease does not exclude a diagnosis of TB disease. Provider may determine 4 months of therapy to be adequate.

Mexican Case Definitions

Probable Tuberculosis Case

- A person with productive prolonged cough or hemoptysis regardless time of evolution. In children, cough with or without expectoration for two or more weeks

Tuberculosis Case

A person with TB diagnosis

- Confirmed or unconfirmed by smear or histopathology

Tuberculosis Confirmed

- AFB smear,
- MTB culture
- Histopathology

Tuberculosis Unconfirmed

- A smear negative person with signs, symptoms or abnormal chest x-ray denoting tuberculosis
- In children smear or histopathology is not necessary.

Source: Norma Oficial Mexicana, September 2005 A.C April 18 2006

Binational (Binacional) Case Definitions

Border Crosser or Transnational

- TB disease patients who crossed the US/MX border during treatment
- OR**
- Patients who were referred to a binational or transnational TB program

Binational Programs	Sister Cities
Grupos Sin Fronteras	<ul style="list-style-type: none"> ○ Harlingen/Matamoros ○ McAllen/Reynosa
Los Dos Laredos	<ul style="list-style-type: none"> ○ Laredo/Nuevo Laredo
Esperanza Y Amistad	<ul style="list-style-type: none"> ○ Eagle Pass/Piedras Negras ○ Del Rio/Cuidad Acuna
Juntos	<ul style="list-style-type: none"> ○ El Paso/Cuidad Juarez
Transnational TB Programs	Countries
Cure TB San Diego, California	<ul style="list-style-type: none"> ○ All countries with established TB programs
TBNET Austin, Texas	<ul style="list-style-type: none"> ○ Most countries with established TB programs and other medical resources

Contacts

- The case-patient who resides in Texas, is a contact to a Mexican National case patient

OR

- The case-patient who resides in Texas is the TB source case for contacts who reside in Mexico

OR

- The case-patient who resides in Mexico is the TB source case for contacts who reside in Texas

Laboratory/Radiologic Testing Only

- Laboratory or radiologic testing was performed by a DSHS facility or TB clinic in Texas, for a Mexican National who was never seen, screened, evaluated, or treated in nor by a binational program.

Source: CDC Workgroup Surveillance Definition for Binational TB Cases

Revised: 07.22.2015

Probable Case of TB

A case where there is a probability of a new case of active TB disease that was discovered thru surveillance activities but has not yet been confirmed by the local or regional authority or verified by DSHS. Some activities may include but not limited to

- ELR (Electronic Lab Report)
- Initiation of a contact investigation
- Genotype Results
- Pharmacy Records
- Cross matching of records with HIV, STD or Vital Statistics
- Hospital admissions or discharges
- Extracts from electronic medical records

Suspected Case of TB

A case where there is clinical suspicion of active TB disease

AND

The provider intends for the client to be placed in isolation (due to probable infection)

OR

Placed on 4-drug therapy

AND

A complete evaluation has been performed, pending final laboratory results.

TB disease should be suspected in clients who have the following symptoms

- Unexplained weight loss
- Loss of appetite
- Night sweats
- Fever
- Fatigue
- Shortness of breath

If TB disease is in the lungs, symptoms may include

- Coughing for \geq 3 weeks
- Hemoptysis
- Chest pain

If TB disease is in other parts of the body, symptoms will depend on the area affected. See Reference.

Criteria for Case Classification of TB Infection

Confirmed TB Infection

- TB infection is determined by a positive result from an Interferon-Gamma Release Assay (IGRA) test such as T-Spot or QuantiFERON-TB GOLD In-Tube (QFT-G) or tuberculin skin test (TST), a normal chest radiograph with no presenting symptoms of TB disease.
- Clients should be reported when treatment for TB infection is initiated based on provider judgment, regardless of the test result, e.g., clients who may be at risk for developing TB disease but may have a false negative TB test, such as children or immunocompromised clients.

Source: Texas Notifiable Conditions E59-11364 (Rev.1/18)
<http://www.dshs.texas.gov/idcu/investigation/conditions/>

Confirmed TB Infection in Special Populations:

- Jail facilities

- Jails that meet Texas Health and Safety Code Chapter 89 criteria must report TB infection according to the schedule set by TAC 97.178
- Waivers
 - Class B2 TB, Latent TB Infection (LTBI) Evaluation... Applicants who have a tuberculin skin test ≥ 10 mm or a positive IGRA test but otherwise have a negative evaluation for active TB disease
 - Class B3 TB, Contact Evaluation... applicants who are a recent contact of a known tuberculosis case and who have a tuberculin skin test ≥ 10 mm or a positive IGRA test but otherwise have a negative evaluation for active TB disease

Source: U.S. Department of Homeland Security, U.S. Citizenship and Immigration Services: <http://uscis.gov> Accessed March 2009.

Clinical criteria...Clinical criteria alone are not sufficient to classify a case of TB Infection. Clinical criteria to confirm a suspected case of TB infection are as follows:

No clinical evidence compatible with TB Disease including:
No signs or symptoms consistent with TB Disease

AND

- 1) Chest imaging without abnormalities consistent with TB (chest radiograph or CT scan)

OR

- 2) Abnormal chest imaging that could be consistent with TB Disease with microbiologic testing that is negative for MTB complex AND where TB Disease has been clinically ruled out.

Laboratory Criteria...Laboratory/diagnostic criteria alone are not sufficient to confirm a case of TB infection. Laboratory criteria to identify suspected cases of TB infection are as follows:

A positive tuberculin skin test (TST) [as defined by DSHS see reference]

OR

A positive interferon gamma release assay (IGRA)

Suspected TB Infection

A case that meets one of more of the laboratory criteria

AND

M. tuberculosis complex was not isolated from a clinical specimen, if a specimen was collected

Source: Council of State and Territorial Epidemiologists (CSTE) 09-ID-65

<https://www.cste.org/resource/resmgr/PS/09-ID-65.pdf>