TUBERCULOSIS
(TB)

REPORTING INFORMATION

- **Class B:** Report the case, suspected case, and/or a positive laboratory result to the local TB Control Unit where the patient resides by the close of the next business day. If patient residence is unknown, report to the local TB Control Unit where the reporting health care provider or laboratory is located.
- Reporting Form(s) and/or Mechanism:
    - The Ohio Disease Reporting System (ODRS) should be used to report lab findings to the Ohio Department of Health (ODH). For healthcare providers without access to ODRS, you may use the Ohio Confidential Reportable Disease form (HEA 3334).
- Local TB control units report all information on the Report of Verified Case of Tuberculosis, (RVCT; CDC 72.9A; 72.9B; 72.9C) which is the national TB surveillance reporting form. All the fields in RVCT form are available in ODRS. The RVCT form has 3 sub-components:
    1. Form 72.9A to report the initial evaluation of a TB case/suspect such as demographics, initial laboratory specimens collected, initial radiography evaluation, risk factors for TB, and initial treatment regimen.
    2. Form 72.9B, Follow-Up Report 1, required for all culture-positive cases to report initial drug susceptibilities and genotyping.
    3. Form 72.9C, Follow-Up Report 2, should be completed for all TB cases to report ongoing treatment monitoring, response to treatment, and treatment completion. It should also be completed for all suspect cases on treatment, to document treatment end date and reason treatment stopped or to report that a suspect case does not have TB.
- Key fields for ODRS reporting include: patient address; race; ethnicity; patient country of birth and date arrived in the U.S. if born outside the U.S.; did patient live outside of the U.S. for >2 months and if yes, in which countries; guardian country of birth (for pediatric patients); site of disease; was lab testing done for TB including all smear, culture, and drug susceptibility results; type of specimen; collect date; result; result date; organism (when applicable); treatment regimen and date treatment started; chest radiograph or CT scan results; Mantoux skin test results; interferon gamma release assay (IGRA) test results; HIV status; sputum culture conversion; did the patient move during treatment; was patient on directly observed therapy (DOT) or self-administered therapy; number of doses in intensive and continuation phase if DOT; reason treatment stopped and date treatment stopped; TB risk factors; drug and alcohol use; resident of a correction facility at the time of diagnosis; resident of a long-term care facility at time of TB diagnosis; primary occupation within past year; additional TB risk factors; count status; should this suspect be confirmed as a positive TB case; how should this suspect be confirmed as a case (e.g. culture, clinical or provider diagnosis); linking state case number; notes with provider diagnosis information and other relevant clinical information not included on the RVCT form.

AGENTS

Mycobacterium tuberculosis complex, which includes *M. tuberculosis*, *M. bovis, M. bovis BCG*, *M. africanum*, *M. microti*, *M. canetti*, and *M. pinnipedii*.

CASE DEFINITION

Clinical Description

A chronic bacterial infection caused by a member of the *Mycobacterium tuberculosis* complex, usually characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical Case Definition

A case that meets all of the following criteria:

- A positive tuberculin skin test (TST) or positive blood assay for M*ycobacterium tuberculosis* (BAMT) *and*
- Other signs and symptoms compatible with TB (e.g. abnormal chest radiograph, abnormal chest computerized tomography scan, or other chest imaging study, or clinical evidence of current disease) *and*
- Treatment with two or more anti-TB medications *and*
- A completed diagnostic evaluation

Laboratory Criteria for Diagnosis

- Isolation of *M. tuberculosis* complex from a clinical specimen[1] *or*
- Demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification (NAA)[2] *or*
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be performed or is falsely negative or contaminated

Case Classification

Suspected: A person with signs or symptoms of TB that are sufficient for the physician to suspect that the individual has TB prior to the completion of diagnostic studies, or a person with or without a positive Mantoux TST or a positive BAMT who meets any of the following criteria:

- Has a specimen that is positive for acid-fast bacilli (AFB) on smear *or*
- Has been prescribed anti-tuberculosis medications for the treatment of active TB *or*
- Has a radiologic finding consistent with active TB *or*
- Has clinical symptoms or findings consistent with active TB.

Confirmed: A case that meets the clinical case definition or is laboratory confirmed. A suspected TB case may also be confirmed when it does not meet either the laboratory or clinical case definition if a provider diagnoses TB. This is confirmed as a "Provider Diagnosed" case.

Not a Case: This status will not generally be used when reporting a case but may be used to reclassify a report if investigation revealed that it was not a case.

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[1] Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acid high-pressure liquid chromatography (HPLC) performed on a culture from a clinical specimen) are acceptable under this criterion.

[2] Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species for clinical purposes. A culture isolate of *M. tuberculosis* complex is required for complete drug susceptibility testing and genotyping. However, for surveillance purposes, CDC 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.

Comment

A case should not be counted twice within any consecutive 12-month period. However, a case occurring in a patient previously diagnosed with TB disease should be reported and counted again if more than 12 months have elapsed since the patient completed therapy. A case should also be reported and counted again if the patient was lost to supervision for greater than 12 months and TB disease can be verified again. Mycobacterial disease other than those caused by *M. tuberculosis* complex should not be counted in TB morbidity statistics unless there is concurrent tuberculosis.

SIGNS AND SYMPTOMS

Indications of TB range from a significant TST test or IGRA test in an asymptomatic patient to fever, night sweats, weight loss, cough with or without sputum production (especially if lasting 3 weeks or longer), hemoptysis, chest pain, and extensive infiltration with cavitation in the lung on chest x-ray in the very ill patient. *M. tuberculosis* complex can cause disease in any organ of the body. Most patients will experience symptoms of malaise, fatigue, anorexia, productive cough, and a low-grade fever. More specific symptoms will depend on the organs involved and the extent of disease process.

DIAGNOSIS

The definitive diagnosis of TB requires the isolation of *M. tuberculosis* complex from the patient. The greatest single problem in recovering mycobacteria from clinical specimens is the presence of large numbers of contaminating microorganisms. This problem is partially solved by obtaining a fresh specimen and by refrigeration of any specimen that cannot be processed promptly.

Since mycobacteria might be released from the lung sporadically, sputum specimen quality may fluctuate. For this reason, a minimum of three sputum specimens should be collected in 8-24 hour intervals with at least one being an early morning specimen.
In cases where *Mycobacterium bovis* (BCG) is the suspected causative agent, urine may also be submitted for analysis. The preferred specimen is a first morning, cleanly voided midstream sample. One specimen each day for three consecutive days should be evaluated. Do not use bottles with preservatives. A minimum of 40 ml of urine is required.

The ODH Laboratory, in addition to preparing smears, culturing, detecting mycobacteria by Nucleic Acid Amplification (NAA) and identifying mycobacteria, also provides antibiotic susceptibility testing and confirmatory testing on *M. tuberculosis* complex isolates. Reference cultures sent to the ODH Laboratory may be shipped at ambient temperatures.

EPIDEMIOLOGY

Source

M. tuberculosis complex (*M. tuberculosis*, *M. bovis, M. bovis BCG*, *M. africanum*, *M. microti*, *M. canetti*, and *M. pinnipedii*) is found primarily in humans.

Occurrence

Present in all parts of the world. Incidence normally increases with age, is higher in males than in females, and is higher among the poor.

Mode of Transmission

Person-to-person, by inhaling the organism coughed or sneezed into the air by a person with infectious pulmonary disease.

Period of Communicability

As long as infectious tubercle bacilli are being discharged and the patient is untreated or inadequately treated, the organism is communicable.

Incubation Period

In general, it takes two to ten weeks after infection for a person to develop an immune response measurable with the TST or BAMT. Risk of progressive disease is greatest during the first 1-2 years after infection, but active disease may take only a few weeks to develop in an individual with a compromised immune system.

PUBLIC HEALTH MANAGEMENT

Case

All pulmonary/laryngeal suspects/cases should be interviewed within three days to identify persons who were exposed during the infectious period, in accordance with section 339.80 of the Ohio Revised Code (ORC). TB cases must be isolated and monitored to ensure that they become non-infectious and complete adequate treatment. Treatment should be provided via directly observed therapy (DOT) in accordance with section 339.82 of the (ORC). When pediatric TB is diagnosed, an interview should be done to identify the source case.

Treatment

Treatment should be made available to all individuals with suspected or confirmed TB and their infected contacts, in accordance with section 339.73 of the ORC. The most current recommended treatment guidelines from the Centers for Disease Control and Prevention and the American Thoracic Society should be followed, in accordance with Ohio Administrative Code (OAC) 3701-15-03.

Isolation

OAC 3701-3-13 (AA) states:
"Tuberculosis (TB): a person with infectious tuberculosis shall be isolated according to Chapter 3701-15 of the Administrative Code until the person has three negative AFB sputum smear results, collected eight to twenty-four hours apart (with at least one being an early morning specimen) and the person has responded clinically to an antituberculosis treatment regimen consistent with the results of any susceptibility testing performed and until the local authorized TB authority, as set out in section 339.72 of the Revised Code, or his or her designee approves that person's removal from isolation."

Contact

All persons identified as being exposed to an infectious TB suspected/case should be administered a TST using the Mantoux method or BAMT test. All contacts with an initial non-significant TST or negative BAMT should be retested eight to ten weeks following the last date of exposure to the suspected/active case. If the reaction of either test is significant, a chest x-ray and medical evaluation are necessary to rule out active disease. All contacts who are infected and do not have active disease should be offered treatment for latent TB infection (LTBI). Asymptomatic contacts <5 years of age should receive prophylactic treatment, which can be discontinued if the TST is non-significant or the BAMT is negative eight to ten weeks following the last date of exposure to the suspected/active case and the child is at least 6 months of age. If eight to ten weeks since the last exposure have already passed at the time of contact evaluation, a single test with TST or BAMT should suffice.

Prevention and Control

An individual that has been diagnosed with active TB shall be instructed to follow contagion precautions in accordance with section 339.82 of the ORC. Contagion precautions should include covering their mouth and nose when coughing and sneezing and adhering to the treatment program as prescribed. Persons suspected or confirmed to have infectious TB disease should be given, and encouraged to use, a surgical mask to minimize the risk of expelling droplet nuclei containing TB bacilli into the air. Respirators (N95, PAPRs) should be used by health care workers and close contacts of individuals with suspected or confirmed TB disease.

What is tuberculosis?
Tuberculosis (TB) is a bacterial disease usually affecting the lungs (pulmonary TB), caused by *Mycobacterium tuberculosis* complex, which includes *M. tuberculosis, M. bovis*, and *M. africanum.* Other parts of the body (extrapulmonary TB) can also be affected, for example, brain, lymph nodes, kidneys, bones, joints, larynx, intestines, or eyes.

Who gets TB?
The bacteria that cause TB are spread through the air. When a person with TB, who is not taking appropriate medication, coughs or sneezes, the germs get into the air. Prolonged exposure to the TB bacteria is normally necessary for infection to occur. Certain populations are at high risk of getting TB disease such as: people who have spent time with someone who has TB disease, people from a country where TB disease is endemic, people who live or work in high-risk settings (for example: correctional facilities, long-term care facilities or nursing homes, and homeless shelters), people who have Latent TB Infection (LTBI) and have an immunosuppressive condition are at risk of developing TB disease.

What is the difference between TB infection and TB disease?
TB infection may result after close contact with a person who has TB disease. TB **infection** is diagnosed by a significant reaction to the Mantoux skin test or a positive blood assay for tuberculosis with no symptoms of TB and no TB bacteria found in the sputum. TB **disease** is characterized by the appearance of symptoms, a significant reaction to a Mantoux skin test or a positive blood assay for tuberculosis, abnormal chest radiograph and TB bacteria found in the sputum.
To spread the TB bacteria, a person must have TB disease. Someone with TB infection cannot spread the bacteria. TB may last for a lifetime as an infection, never developing into disease. TB disease is most likely to develop during the first 2 years after acquiring the infection. Additionally, individuals with weakened immune systems, such as persons infected with HIV, are at high risk of developing TB disease if TB infection is left untreated.

What are the symptoms of TB?
The symptoms of TB include low-grade fever, night sweats, fatigue, weight loss, and persistent cough. Some people do not have obvious symptoms.

How soon do symptoms appear?
Evidence of infection (a positive skin test) usually occurs 4-12 weeks after exposure. The most common period for developing clinical disease is 1-2 years after infection. Infection can remain latent with disease occurring much later in life.

When and for how long is a person able to spread TB?
TB disease may remain contagious until the person has been on appropriate treatment for at least two weeks. It is important to note that a person with TB infection, but not disease, cannot spread the infection to others, since there are no TB bacteria in the sputum.

What is the treatment for TB?
People with active TB disease must complete the prescribed course of medicine, which usually involves taking medications for 6 to 12 months. TB infection is treated with a single

drug or two drug combination; treatment of TB disease usually requires three or more drugs. The exact medication plan must be determined by a physician.

What can be the effect of not being treated for TB?
In addition to spreading the disease to others, an untreated person can become severely ill or die.

What can be done to prevent the spread of TB?
The most important way to stop the spread of tuberculosis is to cover the mouth and nose when coughing and to take prescribed medicine as directed. Persons with disease should have respiratory precautions until symptoms are improved and there is documentation of adequate response to therapy by three consecutive negative sputum smears collected on different days. All household and close contacts of a person with active TB disease should be screened, using the Mantoux skin test or blood test, for evidence of infection. All contacts with evidence of infection should be evaluated for treatment by a physician. All high-risk populations should be TB skin tested routinely.