

Appendix B

Recommendations for Reporting and Counting Tuberculosis Cases (Revised May 13, 2009)

Since publication of the “Recommendations for Counting Reported Tuberculosis Cases”¹ in July 1997, substantial changes have occurred, and questions have been raised within the field of tuberculosis (TB) surveillance. This appendix updates and supersedes previous versions.

A distinction should be made between *reporting* TB cases to a health department and *counting* TB cases for determining disease incidence. Throughout each year, TB cases and suspected cases are reported to public health authorities by such sources as clinics, hospitals, laboratories, and health care providers. From these reports, the state or local TB control officer must determine which cases meet the surveillance definition for TB disease and whether the case is countable. These countable TB cases are then reported to the Centers for Disease Control and Prevention (CDC).

Beginning in 2009, state and local TB control officers may also report to CDC those TB cases that are verified but not countable for morbidity statistics, as a measure of programmatic and case management burden. The noncountable report can include persons with TB disease recurring within a consecutive 12-month period after the patient completed TB therapy.

I. Reporting TB Cases. CDC recommends that health care providers and laboratories be required to report all TB cases or suspected cases to state and local health departments on the basis of “Tuberculosis Case Definition for Public Health Surveillance” (Appendix A). This notification is essential for TB programs to

- ensure case supervision,
- ensure completion of recommended therapy,
- ensure completion of contact investigations,
- evaluate program effectiveness, and
- assess trends and characteristics of TB morbidity.

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

* Because the majority of laboratories use tests that do not routinely distinguish *Mycobacterium tuberculosis* from 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. Other species in the *M. tuberculosis* complex include *M. bovis*, *M. africanum*, *M. microti*, *M. canettii*, *M. caprae*, *M. pinnipedii*, and *M. mungi*; the inclusion of these species in *M. tuberculosis* complex should not affect public health laboratories or programs because only a few laboratories identify to the species level. These seven species are approximately identical in DNA homology studies. In terms of their ability to cause clinical disease or be transmissible from person to person, *M. bovis*, *M. africanum*, *M. microti*, *M. canettii*, *M. pinnipedii*, and *M. mungi* behave like *M. tuberculosis*; therefore, disease caused by any of the organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the bacillus Calmette-Guérin (BCG) strain of *M. bovis*, which can 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 TB.

A. Laboratory Case Definition

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 (e.g., DNA probes or high-pressure liquid chromatography) is acceptable under this criterion.

or

Demonstration of M. tuberculosis from a clinical specimen by nucleic acid amplification test. Nucleic acid amplification (NAA) tests must be accompanied by cultures of mycobacterial species. 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 regulations.

or

Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated. Historically, this criterion has been most commonly used in diagnosing TB in the postmortem setting.

B. Clinical Case Definition. In the absence of laboratory confirmation of *M. tuberculosis* complex after a diagnostic process has been completed, persons must have ***all*** of the following criteria for a clinical TB diagnosis:

1. Evidence of TB infection based on a positive tuberculin skin test result or positive interferon gamma release assay for *M. tuberculosis*, and
2. current treatment with two or more anti-TB medications.

and

One of the following:

1. Signs and symptoms compatible with current TB disease (e.g., an abnormal chest radiograph or abnormal chest computerized tomography scan or other chest imaging study,

or

2. Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis).

NOTE: The software for TB surveillance developed by CDC includes a calculated variable called “Vercrit,” for which one of the values is Provider Diagnosis. Provider Diagnosis is selected when the user chooses to override a Suspect default value in the case verification screen as Verified by Provider Diagnosis. Thus, Provider Diagnosis is not a component of the case definition for TB in the “Tuberculosis Case Definition for Public Health Surveillance” (Appendix A). CDC’s national morbidity reports have traditionally included all TB cases that are

considered verified by the reporting areas, without a requirement that cases meet the published case definition.

III. Counting TB Cases. Cases that meet the CDC surveillance case definition for verified TB are counted by 52 reporting areas with count authority (50 states, the District of Columbia [DC], and New York City) to determine annual incidence for the United States. The remaining 8 reporting areas (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands) report cases to CDC but are not included in the annual incidence for the United States. The laboratory and clinical case definitions are the two diagnostic categories used in the CDC “Tuberculosis Case Definition for Public Health Surveillance” (Appendix A).

The majority of verified TB cases are accepted for counting on the basis of laboratory confirmation of *M. tuberculosis* complex from a clinical specimen.

A person might have more than one discrete (separate and distinct) episode of TB. If disease recurs *within* any 12-month consecutive period after the patient completed therapy, count only one episode as a case. However, if TB disease recurs in a person, *and* if >12 months have elapsed since the person completed TB therapy or the person was lost to supervision, the TB case is considered a separate episode and should be counted as a new case.

Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in TB morbidity statistics unless concurrent TB occurs.

A. Verified TB Cases

COUNT

Count only verified TB cases that meet the laboratory or clinical case definitions (see Section II). TB diagnosis must be verified by the TB control officer or designee. The CDC surveillance case definition for TB (Appendix A) describes and defines the criteria to be used in the case definition for TB disease.

DO NOT COUNT

If diagnostic procedures have not been completed, do not count; wait for confirmation of disease. Do not count as a case of illness in a patient for whom two or more anti-TB medications have been prescribed for preventive therapy for exposure to multidrug-resistant TB or while the diagnosis is still pending.

B. Nontuberculous Mycobacterial Disease

COUNT

An episode of TB disease diagnosed concurrently with another nontuberculous mycobacterial disease (NTM) should be counted as a TB case.

DO NOT COUNT

Disease attributed to or caused by NTM alone should not be counted as a TB case.

C. TB Cases Reported at Death

COUNT

TB cases first reported to the health department at the time of a person's death are counted as incident cases, provided the person had current disease at the time of death. The TB control officer should verify the TB diagnosis.

DO NOT COUNT

Do not count as a case of TB if no evidence exists of current disease at the time of death or at autopsy.

D. Immigrants, Refugees, Permanent Resident Aliens, Border Crossers,[†] and Foreign Visitors²

COUNT

Immigrants and refugees who are examined after arriving in the United States and who receive a diagnosis of clinically active TB requiring anti-TB medications should be reported and counted by the locality of their residence at the time of diagnosis, regardless of citizenship status.

Border crossers[†] who receive a TB diagnosis and who plan to receive anti-TB therapy from a locality in the United States for ≥ 90 days should be reported and counted by the locality where they receive anti-TB therapy.

Foreign visitors (e.g., students, commercial representatives, and diplomatic personnel) who receive a diagnosis of TB, are receiving anti-TB therapy, *and* have been or plan to remain in the United States for ≥ 90 days should be reported and counted by the locality of current residence.

DO NOT COUNT

Any person who received a TB diagnosis and who started anti-TB drugs in another country should not be counted as a new case but should be reported as a person with a verified noncountable TB case.

Border crossers[†] and foreign visitors who receive a TB diagnosis and who receive anti-TB therapy from a locality in the United States for ≤ 89 days but who plan to return to their native country to continue therapy should not be reported or counted by the locality where they receive anti-TB therapy.

[†] *Border crosser* is defined by the U.S. Citizenship and Immigration Services³ as “an alien resident of the United States reentering the country after an absence of less than six months in Canada or Mexico, or a nonresident alien entering the United States across the Canadian border for stays of no more than six months, or across the Mexican border for stays of no more than 72 hours.” Border crossers might go back and forth across the border frequently in a short period.

E. Out-of-State or Out-of-Area Residents

COUNT

A person's TB case should be counted by the locality in which he or she resides at the time of diagnosis. TB in a person who has no address should be counted by the locality where TB is diagnosed and treated. The TB control officer should notify the out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has been counted already to avoid double counting, and (2) agree on which TB control office should count the case if it has not yet been counted.

DO NOT COUNT

Do not count a case in a patient with newly diagnosed TB who is an out-of-area resident and whose TB has already been counted by the out-of-area TB control office.

F. Migrants and Other Transients

COUNT

Persons without any fixed U.S. residence are considered to be the public health responsibility of their present locality, and their TB case should be reported and counted where diagnosed.

DO NOT COUNT

Cases among transient TB patients should not be counted when evidence exists that they have already been counted by another locality.

G. Cases Occurring in Federal Facilities (e.g., Military and Veterans Administration Facilities)

COUNT

Cases among military personnel, their dependents, or veterans should be reported and counted by the locality where the persons are residing in the United States at the time of diagnosis and initiation of treatment.

However, if military personnel or dependents are discovered to have TB at a military base outside the United States but are referred elsewhere for treatment (e.g., a military base located within the United States), the TB case should be reported and counted where treated and not where the diagnosis was made.

DO NOT COUNT

Do not count if the case was already counted by another locality in the United States.

H. Cases Associated with the Indian Health Service

COUNT

TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment is initiated. However, for specific groups (e.g., the Navajo Nation) located in multiple states, health departments should discuss each case

and determine which locality should count the case.

DO NOT COUNT

Do not count if the case was already counted by another locality.

I. Cases Occurring in Correctional Facilities (e.g., Local, State, Federal, and Military)

COUNT

Frequently, persons who reside in local, state, federal, or military correctional facilities are transferred or relocated within or between different correctional facilities. TB among these persons should be reported to the local health authority and counted by the locality where the diagnosis was made and treatment plans were initiated.

DO NOT COUNT

Do not count correctional facility residents' TB cases that were counted elsewhere by another locality or correctional facility, even if treatment continues at another locale or correctional facility.

J. Peace Corps, Missionaries, and Other Citizens Residing Outside the United States

DO NOT COUNT

TB among persons who received their diagnosis outside the United States should not be counted. TB among these persons should be counted by the country in which they are residing, regardless of their plans to return to the United States for further evaluation or treatment.

IV. Recommended Administrative Practices

To promote uniformity in TB case counting, the following administrative procedures are recommended:

- A. All TB cases verified by the 52 reporting areas with count authority (50 states, DC, and New York City) during the calendar year (by December 31) will be included in the annual U.S. incidence count for that year. All TB cases verified during the calendar year by a reporting area with count authority from one of the remaining eight reporting areas (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands) are also counted but are not included in the annual incidence for the United States. Cases for which bacteriologic results are pending or for which confirmation of disease is questionable for any other reason should not be counted until their status is clearly determined; they should be counted at the time they meet the criteria for counting. This means that a case reported in 1 calendar year might be included in the morbidity count for the following year. All reporting areas should ensure that agreement exists between final local and state TB figures reported to CDC. Reporting areas might not use this recommended protocol. They may wait until the beginning of the following year when they have received and processed all of the TB cases for inclusion in the annual case count for the previous year. If reporting areas decide to revise their protocols, they should be aware that their TB trends might change.

B. Occasionally, TB is reported to health departments by telephone, by letter or fax, or on forms other than the RVCT. Such information should be accepted as an official morbidity report if sufficient details are provided; otherwise, the notification should be used as an indicator of a possible TB case (suspect) that should be investigated promptly for confirmation.

V. TB Surveillance Definitions

Case: An episode of TB disease in a person meeting the laboratory or clinical criteria for TB as defined in “Tuberculosis Case Definition for Public Health Surveillance” (see Section II for criteria).

Suspect: A case for which a high index of suspicion exists for active TB (e.g., in a known contact of a person with active TB or in a person with signs or symptoms consistent with TB) and that is currently under evaluation.

Verification of a TB case: The process whereby a TB case, after the diagnostic evaluation is complete, is reviewed at the local level (e.g., state or county) by a TB control official who is familiar with TB surveillance definitions; if all the criteria for a TB case are met, the TB case is then verified and eligible for counting.

Counting of a TB case: The process whereby a reporting area with count authority evaluates verified TB cases against count criteria (e.g., assesses for case duplication). These cases are then counted for morbidity in that locality (e.g., state or county) and reported to CDC for national morbidity counting. Noncountable, verified cases may also be sent to CDC.

***M. tuberculosis* complex:** Because the majority of laboratories use tests that do not routinely distinguish *M. tuberculosis* from closely related species, those laboratories report culture results as being positive or negative for *M. tuberculosis* complex. Although in approximately all cases of human disease, isolates in the *M. tuberculosis* complex are, in fact, *M. tuberculosis*, other species are possible. For example, one study in San Diego reported that 6% of human tuberculosis was caused by *M. bovis*; cultures from these cases would be reported by the majority of laboratories as being positive for *M. tuberculosis* complex⁴. Other species in the *M. tuberculosis* complex include *M. africanum*, *M. microti*, *M. canettii*, *M. caprae*, and *M. pinnipedii*. Although *M. microti*, *M. canettii*, *M. caprae*, and *M. pinnipedii* are newly described species, their inclusion in *M. tuberculosis* complex should not affect public health laboratories or programs because only a few laboratories identify to the species level. These seven species are almost identical in DNA homology studies. In terms of their ability to cause clinical disease or be transmissible from person to person, *M. bovis*, *M. africanum*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii* behave similar to *M. tuberculosis*; therefore, disease caused by any of the organisms should be reported as TB by using the RVCT form. The only exception is the BCG strain of *M. bovis*, which might 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 TB.

Nontuberculous mycobacteria: Mycobacteria other than *M. tuberculosis* complex that can cause human infection or disease. Common nontuberculous mycobacteria (NTM) include *M. avium* complex (also known as “MAC”) (*M. avium*, *M. intracellulare*), *M. kansasii*, *M. marinum*, *M. scrofulaceum*, *M. chelonae*, *M. fortuitum*, and *M. simiae*. Other terms have been used to represent NTM, including “MOTT” (mycobacteria other than TB) and “atypical” mycobacteria.

Reporting area: Areas responsible for counting and reporting verified TB cases to CDC. A total of 60 areas report cases to CDC: the 50 states, DC, New York City, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Puerto Rico, Republic of Palau, and U.S. Virgin Islands. The annual incidence of tuberculosis for the United States is based on 52 of these reporting areas (the 50 states, DC, and New York City).

Alien: Defined by USCIS³ as “any person not a citizen or national of the United States.” The term *alien* is further defined as follows:

Border crosser: Defined by USCIS³ as “an alien resident of the United States reentering the country after an absence of less than six months in Canada or Mexico, or a nonresident alien entering the United States across the Canadian border for stays of no more than six months, or across the Mexican border for stays of no more than 72 hours.” Border crossers may go back and forth across the border frequently in a short period.

Class A TB with waiver²: All applicants who have tuberculosis disease and have been granted a waiver.

Class B1 TB, Pulmonary²:

No Treatment

Applicants who have medical history, physical exam, HIV, or chest radiographic findings indicative of pulmonary TB but have negative AFB sputum smears and cultures and have not received a diagnosis of TB or who can wait to have TB treatment started after immigration.

Completed Treatment

Applicants who received a diagnosis of pulmonary TB and successfully completed directly observed therapy before immigration. The report cover sheet should indicate if the initial sputum smears and cultures were positive and if drug susceptibility testing results are available.

Class B1 TB, Extrapulmonary²:

Applicants with evidence of extrapulmonary TB. Document the anatomic site of infection.

Class B2 TB, Latent TB Infection (LTBI) Evaluation²:

Applicants who have a tuberculin skin test (TST) of ≥ 10 -mm induration but oth-

erwise have a negative evaluation for TB. The size of the TST reaction, the applicant's status with respect to latent TB infection treatment, and the medications used should be documented. For applicants who have had >1 TST, if the applicant's TST reaction converted, that should be documented (i.e., initial TST was ≤ 9 -mm induration but subsequent TST was ≥ 10 -mm induration).

Class B3 TB, Contact Evaluation²:

Applicants who are a recent contact of a known TB patient. The size of the applicant's TST reaction should be documented. Information about the source patient, including name, alien number, relationship to contact, and type of TB should also be documented.

Immigrant: Defined by the USCIS³ as “an alien admitted to the United States as a lawful permanent resident. Immigrants are those persons lawfully accorded the privilege of residing permanently in the United States. They may be issued immigrant visas by the [U.S.] Department of State overseas or adjusted to permanent resident status by the USCIS of the United States.”

Permanent Resident Alien: See *Immigrant*.

Waivers²: A provision allows applicants undergoing pulmonary or laryngeal TB treatment to petition for a Class A TB with waiver. Waivers should be pursued for any immigrant or refugee who has a complicated clinical course and would benefit from receiving TB treatment in the United States. Applicants with diagnosed TB disease who are both smear- and culture-negative and will be traveling to the United States before start of treatment do not need to complete the waiver process.

References

1. CDC. Recommendations for counting reported tuberculosis cases. In: *Reported Tuberculosis in the United States, 1996*. Atlanta, GA: US Department of Health and Human Services, CDC; 1997:61–8.
2. CDC. *2007 Technical Instructions for Tuberculosis Screening and Treatment for Panel Physicians*. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at: <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/tuberculosis-panel-technical-instructions.html>.
3. US Department of Homeland Security (DHS). U.S. Citizenship and Immigration Services [Homepage]. Washington, DC: DHS; 2016. Available at: <http://uscis.gov>.
4. TC Rodwell, M Moore, KS Moser, SK Brodine, SA Strathdee. Tuberculosis from *Mycobacterium bovis* in Binational Communities, United States. *Emerg Infect Dis*. 2008 Jun; 14(6): 909–916.