

Appendix C

Recommendations for Counting Reported Tuberculosis Cases (Revised July 1997)

Since publication of the “Recommendations for Counting Reported Tuberculosis Cases”¹ in January 1977, numerous changes have occurred and many issues have been raised within the field of tuberculosis (TB) surveillance. This current version updates and supersedes the previous version; it clarifies the parameters for counting TB cases among (a) immigrants, resident aliens, and border crossers, (b) military personnel stationed in the United States and abroad, and (c) persons diagnosed within the Indian Health Service and correctional facilities.

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

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 based on the current “Case Definition for Public Health Surveillance.”² This notification is essential in order for TB programs to

- ! Ensure case supervision
- ! Ensure completion of appropriate therapy
- ! Ensure completion of timely contact investigations
- ! Evaluate program effectiveness
- ! 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 and/or clinical evidence of active disease due to *M. tuberculosis* complex.*

**Mycobacterium tuberculosis* complex (*M. tuberculosis* complex) consists of three mycobacterial species: *M. tuberculosis*, *M. bovis*, and *M. africanum*. These species are identical in DNA homology studies. In terms of their ability to cause clinical disease and be transmissible from person to person, *M. bovis* and *M. africanum* behave like *M. tuberculosis*; therefore, disease caused by any of the three organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). 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 this *M. bovis* strain should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

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, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion.

OR

- ! Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification (NAA) test. NAA tests must be accompanied by cultures of mycobacterial species. However, for surveillance purposes, CDC will accept results obtained from NAA tests that are approved by the Food and Drug Administration (FDA). Current FDA-approved NAA tests are only approved for use on smear-positive respiratory specimens.

OR

- ! Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained; historically this criterion has been most commonly used to diagnose 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 clinical TB:

- ! Evidence of TB infection based on a positive tuberculin skin test

AND

- ! One of the following:

- (1) Signs and symptoms compatible with current TB disease, such as an abnormal, unstable (worsening or improving) chest radiograph, or
(2) Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis)

AND

- ! Current treatment with two or more anti-TB medications

NOTE: The case definition described herein was developed for use in this document and is not intended to replace the case definition for TB as stated in the current “Case Definitions for Infectious Conditions Under Public Health Surveillance.”

In addition, 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 current “Case Definitions for Infectious Conditions Under Public Health Surveillance” publication. CDC’s national morbidity reports have traditionally included all 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 current CDC surveillance case definition for verified TB are counted by 52 reporting areas with count authority (50 states, District of Columbia, and New York City) to determine annual incidence for the United States. The remaining 7 reporting areas (American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, and the U.S. Virgin Islands) report cases to the CDC but are not included in the annual incidence for the United States. Laboratory and clinical case definitions are the two primary diagnostic categories used by the CDC “Case Definitions for Infectious Conditions Under Public Health Surveillance.”

Most verified TB cases are accepted for counting based on laboratory confirmation of *M. tuberculosis* complex from a clinical specimen.

A person may have more than one discrete (separate and distinct) episode of TB. If disease recurs in a person within any 12-consecutive-month period, count only one episode as a case for that year. However, if TB disease recurs in a person, **and** if more than 12 months have elapsed since the person was discharged from or lost to supervision, the TB 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 there is concurrent TB.

a. Verified TB Cases.

COUNT

Count only verified TB cases that meet the laboratory or clinical case definitions (see Section II). The diagnosis of TB must be verified by the TB control officer or designee. The current CDC surveillance case definition for TB 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 a case for which two or more anti-TB medications have been prescribed for preventive therapy for exposure to multidrug-resistant (MDR) TB, or while the diagnosis is still pending.

b. Nontuberculous Mycobacterial Diseases (NTM).

COUNT

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

DO NOT COUNT

Disease attributed to or caused by nontuberculous mycobacteria 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 that the person had current disease at the time of death. The TB control officer should verify the diagnosis of TB.

DO NOT COUNT

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

d. Immigrants, Refugees, Permanent Resident Aliens, Border Crossers,* and Foreign Visitors.⁴

COUNT

Immigrants and refugees who have been screened overseas for TB and

- ! have been classified as Class B (B1, B2, or B3)³ or resident aliens
- ! are not already on anti-TB medications for treatment of tuberculous disease, and
- ! are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications

should be counted by the locality of their current residence at the time of diagnosis regardless of citizenship status.

Border crossers* and permanent resident aliens who are diagnosed with TB and plan to receive anti-TB therapy from a locality in the United States for 90 days or more should be counted by the locality where they receive anti-TB therapy.

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

*Border crosser - defined, in part, by the Immigration and Naturalization Service (INS)⁴ as "a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours." Border crossers may go back and forth across the border many times in a short period.

DO NOT COUNT

TB cases in immigrants or refugees who have been classified as Class A with a waiver (TB, infectious, "Noncommunicable for travel purposes")³ should not be counted as new cases even if the persons receive routine initial work-ups in the United States.

TB in persons who are temporarily (<90 days) in the United States, for whom therapy may have been started but who plan to return to their native country to continue therapy, should

not be counted in the United States.

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 that diagnosed and is treating the TB. The TB control officer should notify the appropriate out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has already been counted 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 newly diagnosed TB patient 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 in transient TB patients should not be counted when there is evidence that they have already been counted by another locality.

g. Federal Facilities (e.g., Military and Veterans Administration Facilities).

COUNT

Cases in military personnel, 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. Indian Health Service.

COUNT

TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment initiated. However, for a specific group such as the Navajo Nation, which is geographically 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. Correctional Facilities (e.g., Local, State, Federal, and Military).

COUNT

Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in 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 in persons diagnosed outside the United States should not be counted. TB in 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 work-up or treatment.

IV. Suggested Administrative Practices.—To promote uniformity in TB case counting, the following administrative procedures are recommended:

(a) All TB cases verified during the calendar year by the 52 reporting areas with count authority (50 states, District of Columbia, and New York City) by December 31 will be included in the annual U.S. incidence count for that year. All tuberculosis cases verified during the calendar year by a reporting area with count authority from one of the remaining 7 reporting areas (American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, and the 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 one calendar year could be included in the morbidity count for the following year. The reporting area with count authority should ensure that there is agreement between final local and state TB figures reported to CDC. Currently, some reporting areas may not use this suggested protocol. Some of these areas 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 TB trends may change.

(b) TB is occasionally reported to health departments over the telephone, by letter or fax, or on forms other than the Report of Verified Case of Tuberculosis (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) which 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 the document “Case Definitions for Infectious Conditions Under Public Health Surveillance”² (see Section II for criteria).

Suspect - a person for whom there is a high index of suspicion for active TB (e.g., a known contact to an active TB case or a person with signs/symptoms consistent with TB) who is currently under evaluation for TB disease.

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 (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.

***Mycobacterium tuberculosis* complex** (*M. tuberculosis* complex) - consists of three mycobacterial species: *M. tuberculosis*, *M. bovis*, and *M. africanum*. These species are identical in DNA homology studies. In terms of their ability to cause clinical disease and to be transmissible from person to person, *M. bovis* and *M. africanum* behave like *M. tuberculosis*; therefore, disease caused by any of the three organisms should be reported as TB, using the Report of Verified Case of Tuberculosis (RVCT). The only exception is the BCG strain of *M. bovis*, which may be isolated from persons who have received the vaccine to protect against TB or as cancer immunotherapy; disease caused by this *M. bovis* strain should not be reported as TB because the transmission is iatrogenic (treatment-induced), rather than person-to-person or communicable.

Nontuberculous mycobacteria (NTM) - mycobacteria other than *Mycobacterium tuberculosis* complex that can cause human infection or disease. Common nontuberculous mycobacteria include *M. avium* complex or 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. Currently there are 59 reporting areas; 50 states, District of Columbia, New York City, American Samoa, Federated States of Micronesia, Guam, Northern Mariana Islands, Puerto Rico, Republic of Palau, and the U.S. Virgin Islands. Annual incidence of tuberculosis for the United States is based on 52 reporting areas (50 states, District of Columbia, and New York City).

Alien - defined by the Immigration and Naturalization Service (INS)⁴ as “any person not a citizen or national of the United States.”

Border crosser - defined, in part, by the Immigration and Naturalization Service (INS)⁴ as “a nonresident alien entering the United States across the Mexican border for stays of no more than 72 hours.” Border crossers may go back and forth across the border many times in a short period.

Class A (TB, Infectious) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of current pulmonary TB and one or more positive sputum smear examinations for acid-fast bacilli.” This person is not authorized to enter the United States unless a waiver has been granted (see definition for Class A - TB, Infectious, “Noncommunicable for travel purposes.”)

Class A (TB, Infectious, “Noncommunicable for travel purposes”) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, a history of one or more positive sputum smear examinations for acid-fast bacilli, currently on recommended treatment, and sputum smears that are negative for acid-fast bacilli on 3 consecutive days.” This person is authorized to enter the United States if a waiver has been granted.

Class B1 (TB, clinically active, not infectious) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, and sputum smears that are negative for acid-fast bacilli on 3 consecutive days.” This person may be on anti-TB medications when entering the United States.

Class B1 (Extrapulmonary TB, clinically active, not infectious) - defined by the Division of Quarantine³ as an alien “with radiographic or other evidence of extrapulmonary TB, clinically active.” This person may be on anti-TB medications when entering the United States.

Class B2 (TB, not clinically active) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs suggestive of active TB, not clinically active (e.g., fibrosis, scarring, pleural thickening, diaphragmatic tenting, blunting of costophrenic angles.) Sputum smears are not required.” Such a person who “completed the recommended course of anti-TB therapy and whose chest radiographs are stable should be reported as Class B2 - TB, treatment completed.” This person may be on anti-TB medications when entering the United States.

Class B3 (Consistent with TB, old or healed) - defined by the Division of Quarantine³ as an alien “with an abnormal chest radiograph or series of chest radiographs (the only abnormality is a calcified lymph node, calcified primary complex, or calcified granuloma). Sputum smears are not required.”

Immigrant - defined by the Immigration and Naturalization Service (INS)⁴ 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 Department of State overseas or adjusted to permanent resident status by the Immigration and Naturalization Service of the United States.”

Permanent Resident Alien - see Immigrant.

References

1. *Recommendations for Counting Reported TB Cases*. Atlanta: CDC, January 1977.
2. CDC. Case definitions for infectious conditions under public health surveillance. *MMWR* 1997;46(No. RR-10):40-41.
3. *Technical Instructions for Medical Examination of Aliens*. Atlanta: CDC, Division of Quarantine, revised July 13, 1992.
4. *Statistical Yearbook of the Immigration and Naturalization Service, 1994*. Washington, DC: US Department of Justice, Immigration and Naturalization Service, 1995.

Note: Reference to details of FDA approved labeling for NAA (IIa) was deleted from this document in August 2002.

