

# Technical Notes



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## National Surveillance for Tuberculosis

Reporting areas (i.e., the 50 states, the District of Columbia, New York City, Puerto Rico, and other U.S. jurisdictions in the Pacific and Caribbean<sup>1</sup>) report tuberculosis (TB) cases to CDC using a standard case report form, Report of Verified Case of Tuberculosis (RVCT), through 2010. TB cases are verified according to the *Tuberculosis Case Definition for Public Health Surveillance* in Appendix A. TB cases are reported and counted according to the *Recommendations for Reporting and Counting Tuberculosis Cases* in Appendix B.

## TB Case Definition

In 2009 the case definition was modified. TB cases are verified according to the following specified laboratory and clinical criteria:

### Laboratory criteria for diagnosis

A case may be verified by the laboratory case definition with at least one of the following criteria: 1.) isolation of *M. tuberculosis* complex from a clinical specimen, OR 2.) demonstration of *M. tuberculosis* complex from a clinical specimen by nucleic acid amplification test (NAAT), OR 3.) 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.

### Clinical case criteria

A case may be verified by the clinical case definition in the presence of ALL of the following clinical criteria: 1.) a positive tuberculin skin test (TST) result or positive interferon gamma release assay (IGRA) for *M. tuberculosis*, AND 2.) 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 3.) treatment with two or more anti-TB drugs, AND 4.) a completed diagnostic evaluation.

### Provider Diagnosis

Provider diagnosis is not a component of the case definition for TB as described in Appendix A. However, when cases of TB are diagnosed but do not meet either the clinical or laboratory case definition, reporting areas have the option of verifying TB cases

based on provider diagnosis as described in Appendix B. Through 2008, the RVCT did not collect information on results from IGRA. If an IGRA was performed in lieu of the TST, then the RVCT would have indicated that the TST was not performed. Thus, culture- and smear-negative cases without a TST that are diagnosed by a positive IGRA result prior to 2008 were considered to have been confirmed by provider diagnosis. However, starting in 2009, positive results for an IGRA are included as part of the clinical case definition for TB confirmation. Anergic patients with a clinical presentation consistent with TB but without laboratory evidence of *M. tuberculosis* complex would also be an example of provider diagnosis and one which has not changed over time.

## TB Case Verification Criteria Calculation

The software for TB surveillance developed by CDC includes a calculated variable for TB case verification called “Vercrit” which was modified in 2009. The new variables: **Nucleic Acid Amplification Test Result, Interferon Gamma Release Assay (IGRA) for *Mycobacterium tuberculosis* at Diagnosis and Initial Chest CT Scan or Other Chest Imaging Study** were added in the Vercrit calculation.

“Vercrit” is calculated by using the following criteria in hierarchical order:

1. Positive culture
2. Positive nucleic acid amplification test
3. Positive acid-fast bacilli test
4. Clinical case confirmation
5. Provider diagnosis

## Changes in Reporting and Counting TB Cases

In 2009, the Recommendations for Reporting and Counting Tuberculosis Cases in Appendix B were modified. TB cases that are verified but not countable for morbidity statistics can now be reported to CDC as a measure of programmatic and case management burden. However, data on noncountable TB cases are incomplete and not included in this report.

The recommendations for counting TB cases among immigrants, refugees, and foreign visitors were revised based on the recommendations in the 2007 Technical Instructions for Tuberculosis Screening and Treatment for Panel Physicians.<sup>2</sup> Regardless of

<sup>1</sup>Other U.S. jurisdictions include American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, Guam, the Republic of the Marshall Islands, the Republic of Palau, and U.S. Virgin Islands.

<sup>2</sup>CDC. *Immigration Requirements: Technical Instructions for Tuberculosis Screening and Treatment, 2007*. Atlanta: CDC, Division of Global Migration and Quarantine, revised September 2007; [http://www.cdc.gov/ncidod/dq/pdf/ti\\_tb\\_8\\_9\\_2007.pdf](http://www.cdc.gov/ncidod/dq/pdf/ti_tb_8_9_2007.pdf).

Class B or citizenship status, immigrants and refugees examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications should be reported and counted by the locality of their current residence at the time of diagnosis. Foreign visitors diagnosed with TB, receiving anti-TB therapy, and planning to remain in the United States for 90 days or more should be reported and counted by the locality of current residence.

### **New and Expanded RVCT Variables**

Data on demographic, clinical, laboratory, initial treatment, and treatment outcomes are collected through the RVCT's three data collection reports:

1. Report of Verified Case of Tuberculosis: for all patients with a verified case of TB.
2. Initial Drug Susceptibility Report (Follow-Up Report 1): for all patients who had a culture that was positive for *M. tuberculosis* complex.
3. Case Completion Report (Follow-Up Report 2): for all patients who were alive when TB was diagnosed.

In 2009, the RVCT was modified and expanded to include 11 additional variables. Modifications to the RVCT accommodate the changing epidemiology of TB in terms of risk factors, new drug treatments, and enhanced laboratory capacity for diagnostic tests. These new variables will be made available in a future Annual Report.

The instructions for completing the RVCT forms and the definitions for all data items are available at: CDC. Report of Verified Case of Tuberculosis (RVCT) Instruction Manual. Atlanta, GA: U.S. Department of Health and Human Services, CDC, June 2009.

### **Tabulation and Presentation of TB Data**

This report presents summary data for TB cases reported to CDC in 2010. TB cases are tabulated by year in which the reporting area verified that the patient had TB and included the patient in its official annual TB case count. Since 2004, the published report has reflected updated information on the numbers of cases of confirmed TB for each year from 1993 onward. Totals for the United States include data from the 50 states, the District of Columbia, and New York City.

Trend data are presented in Tables 1 through 14. Age group tabulations are based on the patient's age in the month and year the patient was reported to the health department as a suspected TB case. State or metropolitan area data tabulations are based on the patient's residence at diagnosis of TB.

### **Rates**

Rates are expressed as the number of cases reported each calendar year per 100,000 population. Population denominators used in calculating TB rates were based on official census and midyear (July 1) post-censal estimates from the U.S. Census Bureau. In Tables 1 and 20, the U.S. total populations for 2000 – 2010 were obtained from the Annual Estimates of the Population for the United States and the individual states, and for Puerto Rico (July 1, 2000 – July 1, 2010). In 2003, two modifications were made to the RVCT form: 1.) entries for multiple race (two or more races reported for a person) were allowed, and 2.) the previous category of "Asian/Pacific Islander" was divided into "Asian" and "Native Hawaiian or Other Pacific Islander." To calculate rates in Tables 2 and 3, denominators for 2000 – 2010 were obtained from the Annual Estimates of the Population by Sex, Race, and Hispanic or Latino Origin for the United States: April 1, 2000, – July 1, 2010.

To calculate rates for Table 4, denominators were obtained from the Annual Estimates of the Population by Sex and 5-Year Age Groups for the United States: April 1, 2000, to July 1, 2010. Denominators for computing 2010 rates in Table 16 were obtained from U.S. Census Bureau Monthly Postcensal Resident Population, by single year of age, sex, race, and Hispanic origin: July 1, 2010. In 2004, the method for calculating the annual percentage change in the TB case rate was modified. Unrounded figures are applied to calculate the percentage change in the case rate.

In Table 5, the populations for U.S.-born and foreign-born persons for 1993 and 1994 were obtained from Quarterly Estimates of the United States Foreign-born and Native Resident Populations: April 1, 1990, - July 1, 1999. Denominators for computing the 1995–2010 rates were based on extrapolations from the U.S. Census Current Population Survey (March Supplement).

### **Mortality Data**

Official TB mortality statistics for the United States are compiled by the National Center for Health Statistics (NCHS), CDC. The annual mortality rate is calculated as the number of deaths due to TB in that year, divided by the estimated population for the year, multiplied by 100,000 (Table 1). The number of deaths for 2009 (preliminary) was obtained from the National Center for Health Statistics, National Vital Statistics Report, Vol. 59, No. 4, March 16, 2011. The numbers of deaths for 2010 were not available at the time of this publication.

### **Completion of Tuberculosis Therapy**

Tables 12, 41, 43, and 44 present rates of completion of TB therapy (COT). Data collected by RVCT Follow Up Report-2 on date and reason therapy stopped (e.g., patient completed therapy) were used to calculate rates of COT. Cases were stratified by the indicated length of therapy, based on American Thoracic Society/CDC/Infectious Diseases Society of America treatment guidelines<sup>3</sup> in effect during the period covered, and the patient's initial drug susceptibility test results, age, and site of disease. The adequacy of the treatment regimen (e.g., the sufficiency of the duration of therapy, the appropriateness of the prescribed TB drugs) was not evaluated in this analysis. Acquired drug resistance from an inadequate duration of therapy was also not considered in this analysis.

In Table 41, the first column shows the total number of cases reported during 2008. The remaining columns are grouped under three headings: therapy of 1 year or less indicated therapy, greater than 1 year indicated, and overall. Patients eligible to complete therapy within 1 year had to have been alive at diagnosis, and initiated therapy with at least one drug. Eligible patients did not have rifampin resistance, did not die during therapy, and did not have meningeal TB, regardless of age. In addition, TB cases under the age of 15 years were not eligible to complete therapy within 1 year if they had disseminated disease (disseminated disease is defined as miliary tuberculosis and/or a positive tuberculosis blood culture). Patients with culture-negative disease, those with an unknown culture status, and those with culture-positive disease but unknown initial drug-susceptibility test results were included under the category of 1 year or less of therapy indicated.

In Table 41, each group under an indicated length of

therapy has an initial column showing the number of cases in persons who were alive at diagnosis and prescribed an initial regimen of one or more drugs, and who did not die during therapy. This number was used as the denominator in COT rate calculations.

COT rates, shown as percentages, were only calculated for areas reporting reason therapy stopped for at least 90% of cases shown in the overall column. For the group with an indicated length of therapy of 1 year or less, rates are shown for both COT in 1 year or less (COT <1 year) and for COT, regardless of duration (i.e., duration of therapy <1 year, >1 year, or unknown). For COT <1 year, the numerator included only those patients completing therapy in <366 days (based on the dates therapy started and stopped). Patients with missing dates were classified as "treatment not completed" for this calculation.

Rates of COT, regardless of duration, were calculated by dividing the number of patients reported as having completed therapy by the number of total eligible patients. Patients with an outcome other than completed therapy (i.e., moved, lost, refused treatment, and other) were classified as "treatment not completed." Patients with an unknown outcome were also classified as "treatment not completed." For the remaining two groups of indicated therapy length (greater than 1 year and overall), only rates of COT, regardless of duration, are presented. Table 12 provides rates for COT <1 year and for COT, regardless of duration, only for the group with an indicated therapy of 1 year or less. Table 43 presents rates of COT by ethnicity and non-Hispanic race and by state for those in whom therapy less than 1 year was indicated.

Because streptomycin is no longer being used as part of the standard treatment for TB disease, streptomycin has been removed from the calculated variable for initial drug regimen. Consequently, in this report, the isoniazid, rifampin, pyrazinamide (IRZ), ethambutol, streptomycin (E/S) column was removed from Tables 12 and 35.

### **Site of TB Disease**

Miliary disease is classified as both an extrapulmonary and a pulmonary form of TB (Tables 8, 9, 26, 27, and 47). In publications prior to 1997, miliary disease was classified as extrapulmonary TB unless pulmonary disease was reported as the major site of TB disease. In 2009, miliary disease could not

<sup>3</sup>CDC. Treatment of Tuberculosis, American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2003;52(No.RR-11):1-77.

be classified as a site of TB disease because it is a clinical or radiologic finding and should be recorded under **Initial Chest Radiograph, Initial Chest CT Scan** or **Other Chest Imaging Study**.

### **Reporting of HIV Status**

Table 37 shows information on HIV status for persons with TB aged 25–44 years, the age group in which 71% of AIDS cases occur (CDC. HIV/AIDS Surveillance Report 2007; 15). The information on HIV status for TB cases reported in 2010 is incomplete. Reasons for incomplete reporting of HIV test results to the national TB surveillance system include concerns about confidentiality, which may limit the exchange of data between TB and HIV/AIDS programs; laws and regulations in certain states and local jurisdictions that have been interpreted as prohibiting the HIV/AIDS program from sharing the HIV status of TB patients with the TB program, or from reporting patients with TB and AIDS to the TB program; and reluctance by health care providers to report HIV test results to the TB surveillance program staff. In addition, health care providers may not offer HIV counseling, testing, and referral to some TB patients because of a lack of resources or of appropriately trained staff, or due to the perception that selected patients (e.g., foreign-born persons) are not at risk for HIV infection.

Data on the HIV-infection status of reported TB cases should be interpreted with caution. These data are not representative of all TB patients with HIV infection. Since testing is voluntary, some TB patients may decline HIV testing. TB patients who are tested anonymously may choose not to share the results of HIV testing with their health care provider. TB patients managed in the private sector may receive confidential HIV testing, but results may not be reported to the TB program in the health department. In addition, many factors may influence HIV testing of TB patients, including the extent to which testing is targeted or routinely offered to specific groups (e.g., 25- to 44-year-old males, injecting drug users, homeless persons), and the availability of and access to HIV testing services. These data may over represent or under represent the proportion of TB patients known to be HIV infected in a reporting area.

### **Primary Occupation for the Past Year**

Table 38, except for ten states, now reflects the new 2009 RVCT variable, **Primary Occupation Within the Past Year**, which replaces the **Occupation**

**Within Past 24 months of TB diagnosis** in previous reports. “Multiple Occupation” was removed and the “Retired” and “Not Seeking Employment” categories were added.

### **Reason Therapy Stopped**

Tables 14 and 42 report a new 2009 RVCT data entry option; these tables now include a patient’s adverse reaction to anti-TB drug therapy as an option for the reason therapy stopped.

### **Metropolitan Statistical Areas**

Tables 46 through 50 present data by metropolitan statistical areas (MSAs) with an estimated 2009 population of 500,000 or more. MSAs are defined by the federal Office of Management and Budget, and the definitions effective as of December 2009 were used for this publication (<http://www.whitehouse.gov/sites/default/files/omb/assets/bulletins/b10-02.pdf>). On June 6, 2003, the OMB announced new MSA definitions based on Census 2000 data and the information has been updated annually. Some MSA’s added or dropped counties and some MSA’s merged. The MSA definitions apply to all areas except the six New England states; for these states, the New England County Metropolitan Areas (NECMAs) are used. MSAs are named for a central city in the MSA or NECMA, may include several cities and counties, and may cross state boundaries. For example, the TB cases and case rates presented for the District of Columbia in Table 20 include only persons residing within the geographic boundaries of the District. However, the TB cases and case rates for the Washington, D.C., MSA (Table 46) include persons residing within the several counties in the metropolitan area, including counties in Maryland, Virginia, and West Virginia.

A city/MSA with incomplete or unavailable data was not included in the tables and some cities or MSA’s total numbers may be underreported due to missing information.