# **Technical Notes**

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#### **National Surveillance for Tuberculosis**

All 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) report tuberculosis (TB) cases to CDC using a standard case report form, Report of Verified Case of Tuberculosis (RVCT). Reported TB cases are verified according to the TB case definition for public health surveillance (MMWR 1997;46[No. RR-10]:40–41).

Cases may be verified using the laboratory, the clinical case definition, or a provider diagnosis. A case may be verified by the laboratory case definition either by 1) isolation of *Mycobacte-rium tuberculosis* from a clinical specimen, or 2) detection of *M. tuberculosis* nucleic acid using an FDA approved nucleic acid amplification test and testing methods, or 3) demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained.

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, 2) signs and symptoms compatible with TB, such as an abnormal, unstable (worsening or improving) chest radiograph, or clinical evidence of current disease, 3) treatment with two or more antituberculosis medications, and 4) a completed diagnostic evaluation.

When cases of TB are diagnosed but do not meet the clinical case definition, reporting areas also have the option of verifying TB cases based on provider diagnosis. Currently, the RVCT does not collect information on results from interferon gamma release (IGRA) assays. If this test is performed in lieu of the TST, then the RVCT should reflect that the TST was not performed. Cases without a TST that are diagnosed by a positive IGRA test result should be considered to have been confirmed by provider diagnosis. Another example of a provider diagnosis would

be an ergic patients with a clinical picture consistent with TB but without laboratory evidence of *M. tuberculosis*.

In January 1993, in conjunction with state and local health departments, CDC implemented an expanded surveillance system for TB that would collect additional data to better monitor and target groups at risk for TB disease, to estimate and follow the extent of drug-resistant TB, and to evaluate outcomes of TB cases. The RVCT form for reporting TB cases was revised to collect information on occupation, the initial drug regimen, human immunodeficiency virus (HIV) test results, history of substance abuse and homelessness, and residence in correctional or longterm care facilities at the time of diagnosis. RVCT Follow Up Report-1 was added to collect drug susceptibility results for the initial M. tuberculosis isolate from patients with culture-positive disease.

To evaluate the outcomes of TB therapy, RVCT Follow Up Report-2 was added to collect information on the reason and date therapy was stopped, the type of healthcare provider, sputum culture conversion, the use of directly observed therapy (DOT), and the results of drug-susceptibility testing for the final *M. tuberculosis* isolate from patients with culture-positive disease.

Since 1993, RVCT data have been reported to CDC using software specifically developed for expanded TB surveillance (i.e., SURVS-TB, 1993–1997; TIMS, 1998–present). The instructions for completing the RVCT forms and the definitions for all data items were included in the software user's guide. The summary data presented in this publication for 2006 (and for 2004, Tables 39–44) and the trend data for 1993–2006 (Tables 1–14) were received at CDC by April 1, 2007.

### **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, moved, was lost) 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>2</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 during therapy with the need for a longer duration of therapy was also not considered in this analysis.

In Table 41, the first column shows the total number of cases reported during 2004. 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 one 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 tuberculosis, regardless of age. In addition, tuberculosis cases under the age of 15 were not eligible to complete therapy within one year if they had disseminated disease (disseminated disease is defined as miliary tuberculosis and/or a positive tuberculosis blood culture). For patients with culture-negative disease, those with an unknown culture status, and those with culture-positive disease but unknown initial drug-susceptibility test results, data were included under the category of 1 year or less of therapy indicated. Table 12 presents data only for cases where therapy of 1 year or less was indicated. This is a change in COT calculation from previous years.

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  $\leq$ 1 year) and for COT, regardless of duration (i.e., duration of therapy  $\leq$ 1 year, >1 year, or unknown). For COT  $\leq$ 1 year, the numerator included only those patients completing therapy in  $\leq$ 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  $\leq 1$  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.

#### 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.

# **Reporting of HIV Status**

Table 37 shows information on HIV status for persons with TB aged 25-44 years, the age group in which 73% of AIDS cases occur (CDC. HIV/AIDS Surveillance Report 2003; 15). The information on HIV status for TB cases reported in 2006 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, healthcare 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. HIV testing is performed after a patient receives counseling and gives informed consent. Since testing is voluntary, some TB patients may decline HIV testing. (Current CDC policy, not reflected in 2006 data, recommends all patients in healthcare setting be notified that testing will be performed unless patient declines, or opts out.) TB patients who are tested anonymously may choose not to share the results of HIV testing with their healthcare 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 overrepresent or underrepresent the proportion of TB patients known to be HIV infected in a reporting area.

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

This report primarily presents summary data for TB cases reported to CDC in 2006. Data from the RVCT Follow Up Report-2 (i.e., completion of therapy, use of directly observed therapy, and type of health care provider) are presented for cases reported in 2004. In addition, trend data are presented in Tables 1 through 14. TB cases are tabulated by the year in which the reporting area verified that the patient had TB and included the patient in its official annual TB case count. In contrast to previous annual summaries, in which TB case counts for preceding years were not updated, the current summary reflects updated information on the numbers of cases of confirmed TB for each year from 1993 to 2005. Therefore, case counts for these years differ from those reported in the annual summaries previously published. Totals for the United States only include data from the 50 states, the District of Columbia, and New York City. 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 (see Appendix B: "Recommendations for Counting Reported Tuberculosis Cases").

Tables 46 through 50 present data by metropolitan statistical areas (MSAs) with an estimated 2006 population of 500,000 or more. MSAs are defined by the federal Office of Management and Budget, and the definitions effective as of December 2006 were used for this publication (www.census.gov/population/www/estimates/metro\_general/2006/List4.txt). On June 6, 2003,

the OMB announced new MSA definitions based on Census 2000 data, and the information has been updated annually. Some MSAs added or dropped counties and some MSAs 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.

#### 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) postcensal estimates from the U.S. Census Bureau. Specifically, in Tables 1 and 20, the U.S. total populations for 2000 to 2006 were obtained from the Annual Estimates of the Population for the United States and States, and for Puerto Rico (July 1, 2000– July 1, 2006).3 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 to 2006 were obtained from the Annual Estimates of the Population by Sex, Race, and Hispanic or Latino Origin for the United States: April 1, 2000, to July 1, 2006.<sup>4</sup> To calculate rates for Table 4, denominators were obtained from the Annual Estimates of the Population by Sex

and Five-Year Age Groups for the United States: April 1, 2000, to July 1, 2006.<sup>5</sup> Denominators for computing 2006 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, 2006.<sup>6</sup> In 2004, the method for calculating the annual percentage change in the TB case rate was modified. In contrast to methods used in previous summaries, unrounded figures are now applied to calculate the percentage change in the case rate, providing a greater degree of precision and accuracy than in the past.

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, to July 1, 1999.<sup>7</sup> Denominators for computing the 1995–2006 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 2005 (preliminary) was obtained from the National Center for Health Statistics, e-Stat Deaths: Preliminary Data for 2005, September 2007. For previous years, official tuberculosis mortality statistics were compiled by the National Center for Health Statistics, CDC. The number of deaths for 2006 was not available at the time of this publication.

http://www.census.gov/popest/states/tables/NST-EST2006-01.xls

http://www.census.gov/popest/national/asrh/NC-EST2006/NC-EST2006-03.xls

<sup>&</sup>lt;sup>5</sup> http://www.census.gov/popest/national/asrh/NC-EST2006/NC-EST2006-01.xls

<sup>6</sup> http://www.census.gov/popest/national/asrh/files/NC-EST2005-ALLDATA-R-Files14.txt

<sup>&</sup>lt;sup>7</sup> http://www.census.gov/popest/archives/1990s/nat-nativity-sum.txt