# Appendix A

## **Technical Notes**

## **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 a 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]:40-1). Cases may be verified using the laboratory or clinical case definition. A case may be verified by the laboratory case definition either by (1) isolation of *M. tuberculosis* from a clinical specimen, OR (2) 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: (a) a positive tuberculin skin test result, (b) other signs and symptoms compatible with TB, such as an abnormal, unstable (worsening or improving) chest radiograph, or clinical evidence of current disease, (c) treatment with two or more antituberculosis medications, and (d) a completed diagnostic evaluation. When patients are diagnosed with TB but do not meet the case definition (e.g., anergic patients with a clinical picture consistent with TB but without laboratory evidence of *M. tuberculosis*), reporting areas also have the option of verifying TB cases based on provider diagnosis.

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 long-term 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 health care provider, sputum culture conversion, the use of directly observed therapy, 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, 1998-2001). 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 2001 (and for 1999, Tables 35-37) and the trend data for 1993-2001 (Tables 8-11) were received at CDC via TIMS by April 10, 2002.

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<sup>&</sup>lt;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 the U.S. Virgin Islands. RVCT data for 2000 were available from the Commonwealth of the Northern Mariana Islands and Guam.

## **Completion of Tuberculosis Therapy**

Tables 10 and 37 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 current American Thoracic Society/CDC treatment guidelines<sup>2</sup> 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 37, the first column shows the total number of cases reported during 1999. The remaining columns are grouped under three headings: therapy of 1 year or less indicated, therapy greater than 1 year indicated, and overall. For patients with an initial isolate resistant to rifampin and for pediatric patients (age under 15 years old) with meningeal, bone or joint, or miliary disease, data were included under the category of greater than 1 year of therapy indicated. For all other patients, including those 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 10 presents data only for the category of therapy of 1 year or less indicated.

In Table 37, 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 <365 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 patients listed in the first column of each group. 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 10 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.

Acknowledgment: Tables 10 and 37 were developed in collaboration with the Field Services Branch, Division of Tuberculosis Elimination, CDC.

<sup>&</sup>lt;sup>2</sup>ATS/CDC. Treatment of tuberculosis and tuberculosis infection in adults and children. Am J Respir Crit Care Med 1994;149:1359-74.

#### Site of TB Disease

Miliary disease is classified as both an extrapulmonary and a pulmonary form of TB (Tables 6, 7, 23, 24, and 40). 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 Infection**

Table 33 shows information on HIV status for TB cases among persons aged 25-44 years, the age group in which 74% of AIDS cases occur (CDC. *HIV/AIDS Surveillance Report* 2001;13[No. 1]:14). The information on HIV status for TB cases reported in 2001 is incomplete. Reasons for incomplete reporting of HIV test results to the national 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 counseling and HIV testing 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 in 2001 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. 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 do not provide a minimum estimate of 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 2001. 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 1999. In addition, trend data are presented in Tables 1 through 11. 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. 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 C: "Recommendations for Counting Reported Tuberculosis Cases").

Tables 39 through 43 present data by metropolitan statistical areas (MSAs) with an estimated 2001 population of 500,000 or more. Metropolitan areas are defined by the federal Office of Management and Budget, and the definitions effective as of June 30, 1999, were used for this publication (www.census.gov/population/www/estimates/metrodef.html). The metropolitan area definitions apply to all areas except the six New England states; for these states, the New England County Metropolitan Areas (NECMAs) are used. Metropolitan areas 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 17 include only persons residing within the geographic boundaries of the District. However, the TB cases and case rates for Washington, D.C. (Table 39), 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) postcensus estimates from the U.S. Census Bureau. Specifically, in Tables 1 and 17, the U.S. total and state populations for 2001 were obtained from the U.S. Census Bureau Table St-20001EST-01-Time Series of State Population Estimates: April 1, 2000, to July 1, 2001, located at http://eire.census.gov/popest/data/states/tables/St-EST2001-01.php. To calculate rates in Tables 2, 3, and 13, the age, sex, and race/ethnicity proportions from the U.S. Census Bureau July 1, 2000, population estimates were applied to the July 1, 2001, total national population to estimate the age, sex, and race/ethnicity subpopulations. In Table 4, the populations for U.S.-born and foreign-born persons for 1990-1999 were obtained from *Quarterly Estimates of the United States Foreign-born and Native Resident Populations: April 1, 1990, to July 1, 1999* (www.census.gov/population/estimates/nation/ nativity/ fbtab001.txt). To calculate the rates for 2000 and 2001, population estimates reported in the U.S. Census Bureau Current Population Reports, P20-534, *The Foreign-born Population in the United States: March 2000*, were extrapolated to the April 2000 Census population and the July 1, 2001, population.

## **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 1999 and 2000 was obtained from the NCHS *National Vital Statistics Reports*, Vol. 49, No. 12, October 9, 2001. The number of deaths for 2001 was not available at the time of this publication.

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