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SYNOPSIS

THE PAST DECADE has witnessed an unprecedented upturn in tuberculosis morbidity and outbreaks of difficult-to-treat and highly lethal multidrug-resistant tuberculosis. In the early 1990s, a national consensus developed among public health officials to define more comprehensively the problem, and in January 1993, expanded tuberculosis surveillance was implemented nationwide.

Carefully selected epidemiologic and case management variables were added to the Report of Verified Case of Tuberculosis form. Information is collected on the health status and treatment of patients, including human immunodeficiency virus status, drug susceptibility test results, and the initial drug regimen. Completion of therapy and use of directly observed therapy are also monitored.

The new surveillance system allows a comparison of the quality of care of patients in the public and private sectors. Additional epidemiologic variables include membership in high-risk groups (the homeless, residents of correctional or long-term care facilities, migrant workers, health care workers, and correctional employees) and substance abuse (injecting drug use, non-injecting drug use, and excess alcohol use).

The additional information derived from expanded tuberculosis surveillance is crucial to optimal patient management, policy development, resource allocation, as well as program planning, implementation, and evaluation at Federal, State, and local levels.



The Need



for Epidemic Intelligence

The past decade has witnessed dramatic transformations in the epidemiology of tuberculosis (TB) in the United States. As recently as 1984, the United States enjoyed a 7% annual decline in reported cases, continuing a long-term trend first documented nationwide in 1953 when there were 84,304 reported cases^{1,2}. The national prevention objective for 1990—an annual reported incidence of eight cases per 100,000 population—appeared easily reachable³.

In the spring of 1985, however, the nation began to experience excess TB morbidity⁴. After reaching an all-time low of 22,201 cases in 1985, reported cases rose 20% to 26,673 in 1992 (a rate of 10.5 per 100,000), resulting in an estimated 52,000 excess cases from 1985 to 1992⁵. Although the reasons for this excess morbidity are not fully known, the available evidence suggests that human immunodeficiency virus (HIV) infection, TB in the foreign born, and increased transmission are, in large part, responsible⁵⁻¹¹.

A second alarming phenomenon was the emergence of multidrug-resistant tuberculosis (MDR TB), involving patients with isolates of *Mycobacterium tuberculosis* that are resistant to the two most powerful antituberculosis drugs, isoniazid and rifampin¹²⁻¹⁴. From 1990 to 1992, the Centers for Disease Control and Prevention (CDC) investigated eight hospital outbreaks and one State correctional system outbreak of this difficult-to-treat and highly lethal illness¹³⁻¹⁴. More than 90% of these patients were HIV-infected, and fatality rates were as

high as 70–90%¹⁴. In addition to excess morbidity and MDR TB, the published literature suggested numerous groups with a high incidence of TB ^{7,15–22}.

Given these changes in the recent epidemiology of TB, public health officials nationwide saw the need to expand TB surveillance¹². In January 1993, CDC added new variables to the form used by State and local TB programs to report TB cases⁵. A summary of the original and expanded surveillance variables is shown in the box.

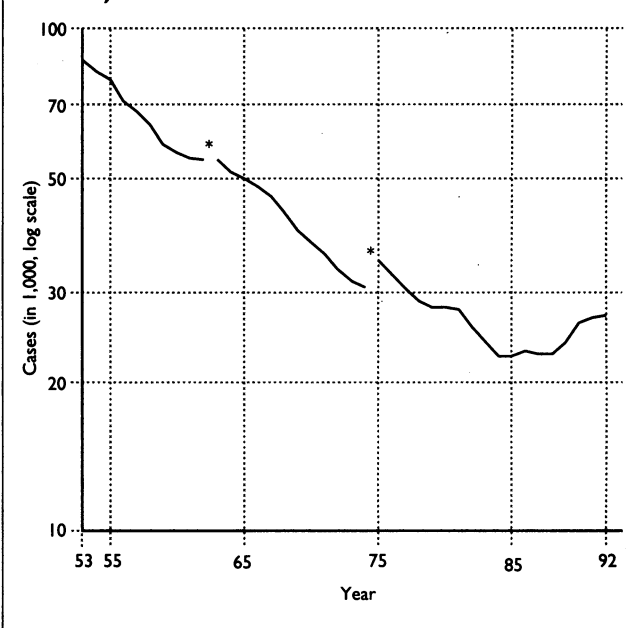
Expanded Surveillance Variables

The HIV status of a TB patient is a critical piece of information for optimal clinical management of TB, HIV infection, and other HIV-related conditions^{7,12,23,24}. Knowledge of HIV status allows the clinician to provide counseling, antiretroviral therapy, and prophylaxis for other infections^{23,24}. It also alerts the TB clinician to look for other HIV-related infections and adverse drug reactions, especially cutaneous reactions ^{7,9,23–25}. HIV infection is the most potent risk factor yet identified for the development of TB in persons with prior tuberculous infection^{26–28}. The routine collection of HIV status on each reported TB patient is needed to determine the extent to which HIV infection contributes to excess TB morbidity and MDR TB, (that is, the proportion of total patients and MDR TB patients with HIV infection).

The new surveillance system captures initial drug susceptibility results on culture-positive patients. The information allows monitoring of the epidemiology of drug resistance and assists in detecting outbreaks of MDR TB so that appropriate interventions can be implemented¹². Initial drug susceptibility results are necessary to determine the extent to which drug resistance is being transmitted, that is, occurring in persons with no prior history of TB therapy^{29–30}. Comparison of initial and final drug susceptibility results of isolates from patients who fail to respond to therapy measures the extent to which patients acquire drug resistance during therapy^{29–32}.

The two major reasons for drug-resistant TB are (a) failure of health care providers to treat patients initially with an adequate drug regimen and (b) failure of patients to take prescribed medication^{29–34}. Information on the initial drug regimen indicates the extent to which health care providers are using treatment regimens recommended by the American Thoracic Society, CDC, the American Academy of Pediatrics, and the Infectious Disease Society of America^{13,22,35}. In the current era of increased drug resistance, treatment guidelines recommend initial four-drug regimens of isoniazid, rifampin, pyrazinamide, and ethambutol or streptomycin until drug susceptibility studies are available, unless there is little possibility of primary resistance to isoniazid. Past experience has shown that changing the prescribing habits of some practitioners may take years³⁶. Information on the initial drug regimen prescribed coupled with information on initial drug susceptibility results allows a judgment about the adequacy of therapy and corrective action on individual cases by public health officials and health care providers, if

Figure 1. Reported tuberculosis cases, United States, 1953–1992



*Change in case definition

After reaching an all-time low of 22,201 cases in 1985, tuberculosis rose 20% to 26,673 in 1992.

the regimen is judged to be inadequate or suboptimal.

Several identifiable behaviors place a patient at increased risk for failing to take prescribed medications^{37,38}. These include injecting drug use, non-injecting drug use, and excess alcohol use^{38–46}. Patients with substance abuse problems need assistance in adhering to antituberculosis therapy as well as referral for substance abuse treatment.

To ensure completion of therapy, the use of directly observed therapy (DOT) in which a health care worker supervises the taking of medicine by the patient is a very important tool^{13,22,33,35,47–50}. DOT should be considered for all patients because of the difficulty in predicting which patients will adhere to a prescribed treatment regimen^{13,22,33}. Nationwide monitoring of the extent to which DOT is used—particularly among persons with known high risk behaviors or drug-resistant disease—is extremely important. Current treatment recommendations state that the use of DOT should be increased in an area if the percentage of patients that complete therapy within 12 months is less than 90%¹³.

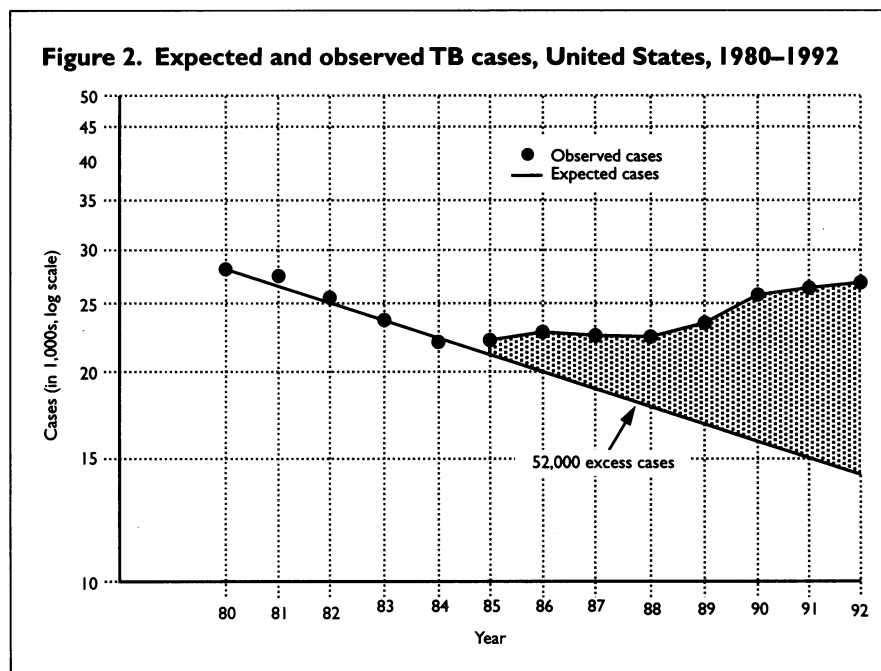
Information on sputum culture conversion is collected to determine how quickly patients respond to therapy and to identify patients not responding to therapy due to an inadequate regimen or patient nonadherence³⁵.

The proportion of patients who complete therapy is a critical indicator of TB program effectiveness^{12,51–52}. In 1992, the most recent year for which national aggregate data are available, 77% of patients completed a recommended course of therapy within 12 months, and 15% were still on therapy after 12 months⁵¹. Expanded surveillance now permits

detailed analysis, including an assessment of the actual duration of therapy (by measuring the interval from date therapy started to date therapy stopped) and whether that duration is appropriate for any given patient. Reason therapy stopped quantifies the proportion of patients who successfully complete a recommended course of therapy, are lost to followup, die or move during therapy, or do not complete therapy because of nonadherence.

Information on type of health care provider (that is, public sector, private sector, or both) helps assess the quality of care in each sector, (for example, by determining the pro-

obtained a Federal assurance of confidentiality for expanded TB surveillance, in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). Information contained on the expanded case report form that would permit identification of any person has been collected with a guarantee that it will be held in strict confidence, will be used only for surveillance purposes, and will not be disclosed or released without the consent of the person. TB case reports should be treated with the same strict confidentiality and data security precautions as currently exist in Federal, State, and local HIV/AIDS programs.



From 1985 to 1992, reported tuberculosis cases in the United States exceeded the expected number of cases by 52,000, based on trends from 1980 to 1984.

portion of patients that receive adequate drug regimens and complete therapy). Such information is important for determining the need for education and support services for each type of provider. For example, in one study, the application of new treatment recommendations by health care providers in the private sector lagged substantially behind that of the public sector³⁶.

TB programs also collect information on whether persons belong to groups with a high incidence of TB, including homeless persons, residents of correctional facilities, residents of long-term care facilities, and migratory agricultural workers or migrant workers^{15–20}. Health care workers and correctional employees are two occupational groups at risk of exposure to TB and among whom fatal cases of MDR TB have occurred as a result of work-related exposure^{14,16–19,21}.

Confidentiality. As with the HIV/AIDS reporting system²⁸, CDC receives no personal identifiers on reported TB patients. Because of the sensitive nature of HIV status, CDC

Surveillance software. CDC has developed software for expanded surveillance. Information on TB cases is entered onto a personal computer. The software program offers password protection and data encryption to protect confidentiality, edit programs to ensure the completeness and accuracy of information, and a verification feature to determine if a case meets the established case definition for TB⁵³. Information from reporting areas is encrypted, downloaded to a floppy diskette, and mailed to CDC on a monthly basis.

Optimal patient management. Optimal patient management of TB patients includes the development of an individualized treatment plan, provision of a “creative array”⁵⁴ of services to care for the patient, and adherence-promoting strategies to ensure completion of therapy^{12,13,33–34,38,47–50,54–56}. Some TB patients need services such as HIV early

intervention, shelter for the homeless, and treatment for substance abuse. Although the expanded surveillance system does not monitor the provision of these services, it does allow TB programs at State and local levels to quantify the number of TB patients who are HIV infected, homeless, or substance abusers and need special services as part of their individualized treatment plans. The data collected can help State and local jurisdictions estimate the resources needed to provide such services. Expanded surveillance does monitor the provision of directly observed therapy.

Conclusion

Surveillance has been defined as “the ongoing systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link in the surveillance chain is the application of these data

Original and Expanded Tuberculosis Surveillance Variables

<i>Epidemiologic variables</i>	<i>Case management variables</i>
Date of birth (age)	Site(s) of disease
Sex	Tuberculin skin test results
Race	Chest radiograph results
Ethnic origin	Smear/culture results
Country of origin	Vital status (alive or dead)
Date of arrival in U. S.	Previous diagnosis of TB
State	
County of residence	
City of residence	
Zip code of residence	
Date of case report	
Date case counted	
HIV status ¹	Initial drug regimen ¹
Homeless within past year ¹	Drug susceptibility testing:
Residence at diagnosis:	Initial results ¹
Correctional facility ¹	Final results ¹
Long-term care facility ¹	Sputum culture conversion ¹
Substance use in past year:	Date therapy started ¹
Injecting drug use ¹	Date therapy stopped ¹
Non-injecting drug use ¹	Reason therapy stopped ¹
Excess alcohol use ¹	Directly observed therapy ¹
Occupation:	Type of health-care provider ¹
Health care worker ¹	
Correctional employee ¹	
Migrant worker ¹	
Other occupation ¹	
Not employed last 24 months ¹	

¹Added to individual case reports beginning 1993

to prevention and control⁷⁵. Data from the expanded surveillance system, with recommendations, is shared with State and local health officials, physicians, nurses, and other health care workers who collect and use the data. The information should lead to improved patient management, more appropriate policy recommendations, more rational allocation of resources, and better program planning and implementation. Collecting data on carefully selected epidemiologic and case management variables enhances the ability of Federal, State, and local health officials to evaluate programs and better target resources for the prevention and control of TB.

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Copies of the expanded Report of Verified Case of Tuberculosis form are available from State and local tuberculosis control programs or from the Division of Tuberculosis Elimination.

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