

Federal Involvement in Tuberculosis Control and Research

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Primarily responsibility for designing and carrying out tuberculosis (TB) control services in the United States rests not with Federal officials, but with State public health departments and local health authorities. Governed by State laws that specify overall responsibilities regarding TB and the use of public health powers intended to prevent further transmission of the disease (124), State public health departments provide and coordinate a range of services. To varying degrees, these services generally include: surveillance; laboratory services, treatment, and followup; contact investigation; education; and consultation (93).

Private health care providers and a variety of organized groups (e.g., patient advocacy groups, public and professional groups, voluntary organizations, and community-based organizations) are also closely involved in these activities. In practice, individual TB control programs differ substantially from place to place, according to available resources, quality of the program management, available expertise, local prevalence of the disease, and characteristics of the affected population.

In the United States, the Federal Government is responsible for developing a national plan to control TB and for assisting in various ways to implement it. Although the Federal Government has long held responsibilities in regard to TB control (see box 7-A), the resurgence of TB has recently prompted Federal agencies and departments to expand their involvement, particularly in guidance and oversight of prevention and treatment activities, support of research and development, and assuring the availability of anti-TB drugs. In addition, the increasing size of the patient population has implications for reimbursement of TB services through government-sponsored health insurance programs like Medicaid and Medicare.



Box 7-A—The History of Tuberculosis Prevention and Control Within the U.S. Public Health Service

From the late 1800s to the 1940s, the primary method of tuberculosis (TB) control was the isolation of infected individuals in special sanatoriums until death or until the disease went into remission. In the early part of this century, TB control was largely a voluntary grass-roots movement at the State and local level. Local health departments set up TB programs at the urging of the Society for the Prevention of Tuberculosis, which had been established in 1904. With the advent of antibiotics in the 1940s, effective treatment for TB became possible. The U.S. Public Health Service's (PHS) Bureau of State Services became involved in the evaluation of anti-tuberculosis drugs such as streptomycin, para-amino salicylic acid, and isoniazid both in the United States and Europe. During the 1940s and 1950s, TB treatment still involved long stay in a sanatorium with additional treatment and lifelong followup after discharge.

In 1944 Congress passed the Public Health Service Act, which established the Division of Tuberculosis Control within PHS and authorized grants to States for tuberculosis control. By the end of World War II, PHS had organized TB support teams available to population centers with more than 100,000 residents to augment the supply of x-ray and case finding staff. By 1953, these teams had examined about 20 million people in 20 cities. Better living conditions and the availability of drugs to treat TB led to a decrease in the number of new cases found by the support teams. This decrease along with rising costs and growing concern about exposure to x-rays led PHS to discontinue the program.

As it became obvious by the 1960s that long-term isolation of patients with active disease was not necessary to protect the patient and the community, PHS began to recommend that States close their sanatoriums and treat patients mainly on an outpatient basis. Although this change represented significant potential savings to State and local governments, the closing of sanatoriums also placed new demands on local health departments to conduct followup of TB patients. In the early 1960s, health department case registries carried 75,000 to 100,000 TB patients requiring outpatient followup services. In addition, health departments also had to identify, test, and possibly treat an average of five individuals that each case of active TB may have infected. These new demands on local health departments necessitated assistance from PHS.

In 1959, TB experts met in Harriman, New York to take stock of the Nation's TB control efforts and to develop standards for evaluating control programs. This meeting came to be known as the Arden House

This chapter focuses on the current involvement of the Federal Government in public health efforts to control TB, research and development of new technologies for diagnosis and treatment of TB, regulation of TB treatment interventions, health services research, and reimbursement for TB services. The discussion is based mainly on information obtained by the Office of Technology Assessment (OTA) from each agency, institute, or organization. OTA received information that contained varying degrees of detail and synthesis regarding each group's involvement in TB-related work. Rather than attempting to provide a detailed account or evaluation of all Federal activities directly or indirectly related to TB, the discussion that follows highlights the major

current initiatives and programs concerning TB and the approximate funding allocated for them. The discussion provides recent spending information for the few agencies able to distinguish TB money from other funds.

PUBLIC HEALTH ACTIVITIES

The Centers for Disease Control and Prevention

The lead agency for TB control operations within the Federal Government is the Centers for Disease Control and Prevention (CDC). In fiscal year 1993 CDC'S budget for TB control activities totaled approximately \$79 million: \$34.3 million in project grants to State and local health departments in support of prevention and control

Conference. The group recommended eradication of TB mainly through drug treatment. A set of 11 secondary recommendations focused on making treatment feasible and efficient, led to the current approach to TB prevention and control—to treat active disease in order to cure the patient and prevent further spread of infection in order to prevent the development of active disease.

On November 1, 1960, the Tuberculosis Branch of the PHS's Bureau of State Services was organizationally transferred to the then Communicable Disease Center (CDC). In 1960, the Branch also initiated Federal TB project grants to State and local governments in response to the Surgeon General's Task Force on Tuberculosis. Funding for these grants reached a peak of \$20 million in 1968. In addition to providing funds, the CDC'S TB missions have been to provide national leadership in the development and implementation of effective strategies to interrupt the transmission of TB and ultimately eliminate the disease. CDC has established policies and guidelines for TB control programs in conjunction with American Thoracic Society. A important function of CDC has been to gather data on the disease to define the overall tuberculosis problem and examine more specific issues. CDC has provided consultative visits by headquarters staff to local programs and in some areas direct long-term assignments of CDC staff have been made to assist in program implementation. In addition, the agency provides training courses for TB workers.

During the late 1960s, categorical TB project grants were phased out in favor of General Public Health Formula Grants under section 314(d) of the Public Health Service Act (Ch. 373,58 Stat. 682). Because these new grants did not require that State and local governments use any of the funds for TB control, many health departments redistributed the funds to other purposes.

Uniform nationwide reporting of active TB cases to CDC began in 1953. For the next three decades, the United States saw a decline in active TB cases, from 84,304 reported in 1953 to a low of 22,255 cases in 1984. After 1985, however, the number of new cases began to increase again to 26,673 in 1992. Despite the overall increasing morbidity, in much of the country, TB had retreated into well-defined segments of the population (see chapter 3). Against this background and as a result of the occurrence of outbreaks of drug-resistant TB, CDC coordinated the 1988 "Strategic Plan for the Elimination of Tuberculosis in the United States" and the 1992 "National Action Plan to Combat Multidrug-Resistant Tuberculosis" described in chapter 7.

SOURCE: C. Bozzi, Assistant to the Director for Tuberculosis Coordination, Division of TB Elimination Centers for Disease Control and Prevention Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA, personal communication 1993.

services (including directly observed therapy (DOT) and educational activities); \$39.2 million in emergency funds appropriated separately by Congress for TB control programs in six States and seven cities most heavily affected by TB; and \$5.2 million for TB program operations at CDC. In addition to the \$79 million designated for TB, \$25.4 million designated for human immunodeficiency virus (HIV) activities were used for HIV-related TB activities (e.g., investigation of MDR-TB outbreaks and related issues; expansion of screening and prevention demonstration projects in drug treatment centers, correctional facilities, and other sites; and expansion of demonstration projects for the treatment and prevention of TB in HIV-infected or at-risk populations) (255,

330). Table 7-1 gives a breakdown of CDC TB spending in fiscal year 1993 according to the use to which the funds are put.

The total expenditure for fiscal year 1993 greatly exceeded previous years' budgets (see figure 7-1). For fiscal year 1994, the President requested that Congress appropriate \$129 million for TB control at the U.S. Department of Health and Human Services (U.S. DHHS); the \$50 million increase over 1993 is intended to support State programs in directly observed therapy and screening in high-risk populations, and to improve TB diagnosis, surveillance, prevention, and education (332).

The American Lung Association (ALA), a voluntary, national organization originally founded

Table 7-1 —U.S. Centers for Disease Control and Prevention Spending for Tuberculosis by Function, Fiscal Year 1993

	Dollars (\$ millions)	Percent of budget
Community-based control programs (screening, treatment, prevention, infection control)	\$36.9	35/0
Outreach and service linkage (implementation of directly observed therapy)	36.7	35
Research and demonstration	9.8	9
Surveillance, epidemiology and data systems	7.0	7
Laboratory services	4.8	5
Public education and information	4.4	4
Professional competence assurance (training for service providers, physicians, researchers, and laboratory personnel)	2.2	2
Leadership and administration (technical assistance to improve management of State and local TB control programs)	2.2	2
Community protection/regulatory programs	NA	NA
Total	\$104.0	100?40'

NA - not available.

a Comment percentages do not add up to 100 percent due to rounding error.

SOURCE: Office of Technology Assessment, 1993, based on data from C. Bozzi, Assistant to the Director for Tuberculosis Coordination, Division of Tuberculosis Elimination, Public Health Service, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Atlanta, GA, personal communication, July 9, 1993.

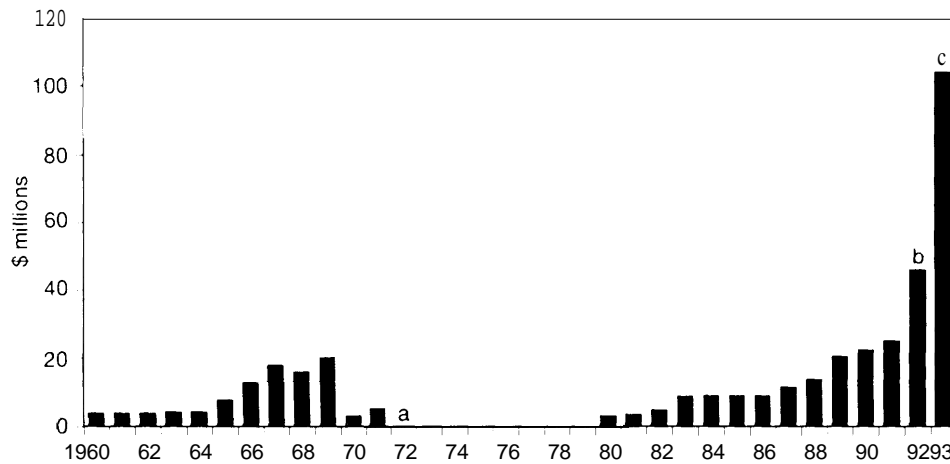
in 1904 to coordinate public and private TB control campaigns (262), recently recommended that CDC'S budget for TB control be increased to \$380 million in fiscal year 1994, stating that additional funds are needed to support DOT, training and educational activities, surveillance and epidemiologic studies, and evaluation of current programs (244).

ALA also recommended that continued funding to the States through CDC'S project grants be contingent on the adoption of an adequate State TB elimination plan (244). Other experts have suggested additional uses for CDC'S TB funds, including direct support of clinical services (as in New York City chest clinics of the 1970s) and the facilities in which they are housed, regional 'centers of excellence' specializing in the care of patients with TB, long-term care facilities and subsidized housing for TB patients, and bulk

purchasing of anti-TB drugs and infection control supplies (130).

The CDC'S Division of TB Elimination had its organizational beginnings in the 1940s. Box 7-A gives a history of U.S. Public Health Service (PHS) involvement in TB control. Federal TB activities and funding were drastically scaled back in the late 1960s as TB was perceived to be under control, but were restarted in the early 1980s (240). In the mid- 1980s, following indications that TB was no longer in decline and that a resurgence in cases was likely, CDC developed a comprehensive plan for TB control, entitled "A Strategic Plan for the Elimination of Tuberculosis in the United States. The plan was adopted in 1988, endorsed by then U.S. DHHS Secretary Louis Sullivan, and set as a national goal the elimination of TB by the year 2010 (i.e., reducing its incidence to less than one in a million).

Figure 7-1—Tuberculosis Funding, U.S. Centers for Disease Control and Prevention, Fiscal Years 1960-93



a Fiscal years 1972 through 1982 categorical grants ceased. Funds to States were block grants not specific for TB.

b Fiscal year 1992 includes \$26 million in HIV funds used for HIV-related TB activities.

c Fiscal year 1993 includes \$25 million in HIV funds used for HIV-related TB activities.

SOURCE: Office of Technology Assessment, 1993, based on data from the Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention.

The plan also set a target of 3.5 cases per 100,000 population by the year 2000 as an interim goal. To achieve this, the plan emphasized three concurrent efforts: more intensive use of existing prevention and control methods; the development and evaluation of new diagnostic, treatment, and prevention technologies; and the rapid transfer of knowledge, skills, and new technologies into clinical and public health practice (270,367).

Shortly thereafter, CDC, together with the American Thoracic Society and representatives from 22 national organizations, coordinated the National Tuberculosis Training Initiative, an educational effort geared toward medical and allied health professionals. The initiative's purpose was to make medical and public health professionals aware of the Strategic Plan, to improve the quality of care for individuals with tuberculous infection and active disease, and to improve medical education regarding TB (239). Through this effort, U.S. DHHS published the "Core Curriculum on Tuberculosis," summariz-

ing current information on TB and TB control (378).

In 1992, following the recent worsening of the problem as indicated by the series of MDR-TB outbreaks, CDC released another national plan designed to complement and enhance the Strategic Plan: the "National Action Plan to Combat Multidrug-Resistant Tuberculosis" (363). The Action Plan was developed by a task force assembled by CDC, composed of representatives from a number of Federal agencies, and consultants from various other public health groups. The task force's main focus was to define ways of intervening rapidly to prevent further transmission and generation of drug-resistant TB, as part of its ongoing efforts to control TB in general. The Action Plan identified a series of objectives in TB control and laid out a detailed plan of implementation involving an array of Government agencies and professional organizations with ongoing responsibilities in TB control and research. In general, the Action Plan defined a process to bring the current outbreaks under

Box 7-B—A Summary of the U.S. Centers for Disease Control and Prevention's Multidrug-Resistant Tuberculosis Action Plan

In response to the emergence of MDR-TB, a Federal task force was convened in December 1991 to develop a national action plan to combat the problem. The plan identifies a number of objectives to be undertaken at the national level. The objectives [as described by CDC staff in a recent article] are summarized [here]

Epidemiology and Surveillance—To better define the magnitude and nature of MDR-TB, national surveillance will be expanded to capture information on the incidence of drug-resistant TB. Epidemiologic studies will be used to identify where MDR-TB is being spread, what activities are associated with increases or decrease in transmission, and which preventive strategies are effective in community and in institutional settings. The impact of HIV infection on recent trends in TB disease and infection, including MDR-TB, will be assessed.

Laboratory Diagnosis—To improve the rapidity, sensitivity, and reliability of diagnostic methods for MDR-TB, widespread changes and improvements need to be implemented in clinical and public health laboratories. These changes include the use of the most sensitive and rapid laboratory diagnostic methods available, including the use of a primary susceptibility test panel of five drugs (INH, RIF, PZA, ethambutol, and streptomycin). New equipment, training courses, and information systems will be used in laboratories to achieve these objectives.

Patient Management—Activities need to be implemented to prevent patients with drug-susceptible TB from developing drug-resistant disease and to manage patients optimally who have developed drug-resistant disease. To achieve these goals, effective initial anti-tuberculosis therapy regimens and implementation of DOT [directly observed treatment] for all TB patients who would benefit from it regardless of their ability to pay for these services, will be promoted. Options for the long-term hospitalization of drug-resistant TB patients, when needed, will be explored. Efforts to facilitate access to diagnosis and treatment will be directed to those at high risk for both TB and nonadherence to therapy, such as persons who are homeless, mobile populations of migrant farm workers, refugees and immigrants from areas with a high prevalence of TB, and persons with substance abuse problems.

Screening and Preventive Therapy—To distinguish persons who are infected or at risk of developing MDR-TB to help prevent them from developing clinically active TB, widespread dissemination and

control, to prevent new ones, and to resume progress toward elimination of TB (see box 7-B summarizing key points of the MDR Action Plan).

CDC estimates that full implementation of those parts of the Action Plan for which it has responsibility would require \$380 million in annual spending (1993 dollars) above the \$104 million spent in fiscal year 1993. Estimates from other agencies are not available, but CDC has begun collecting such information following OTA'S queries.

In an effort to help OTA assess CDC'S priorities in implementing its part of the Action Plan should Congress not fully fund the Action Plan in

a single year, CDC supplied OTA with its estimates of how it would allocate funding increases of \$50 million, \$95 million, and the full \$380 million above fiscal year 1993 levels. CDC gave these funding breakdowns according to the same categories presented in table 7-1. CDC'S projections indicate that for these three potential funding levels, the proportion of funds allocated to each spending category would be essentially the same as that for actual fiscal year 1993 funding; partial or full funding would not change CDC'S relative priorities among these funding categories (38). No information on priorities within each spending category was available to OTA¹

¹ CDC has also identified 215 individual steps necessary to implement the Action Plan, assigning each a priority score of "1" (highest priority), "2", or "3" (lowest priority) (369). The vast majority of implementation steps were given a priority of "1" (76 percent) with most of the rest (23 percent) given the middle score of "2." Although these priorities underscore the sense of urgency of the Federal interagency group that prepared the Action Plan, they do not indicate how CDC and other agencies would proceed if funding did not permit full implementation of all steps identified as high priority.

implementation of recently published guidelines on management of persons exposed to MDR-TB will be promoted. Screening and preventive therapy (directly observed when necessary) among populations at risk for both TB and nonadherence to therapy will be implemented.

Infection and Outbreak Control—Given the **circumstances** of recent MDR-TB outbreaks in hospital and correctional institutions, the risk of transmission of MDR-TB to patients, workers, and others in institutional settings needs to be minimized. Implementation of current guidelines for reducing this risk is of the highest priority. Adequate screening and monitoring for TB infection among workers in settings where there is a substantial risk of TB transmission will be ensured.

Outbreaks represent a challenge to public health authorities in controlling TB. Various officials and organizations will collaborate to enhance the control of outbreaks of MDR-TB.

Program Evaluation—TB control programs need to be evaluated for effectiveness in managing patients and preventing the development of MDR-TB. Local epidemiologic data will be used for assessing the adequacy of the TB control programs.

Information Dissemination, Training, and Education—To disseminate information about MDR-TB and its prevention and control, high-risk populations, such as persons working in drug treatment centers, homeless shelters, HIV clinics, and correctional and other institutions with close living quarters, and their clients; refugees; and immigrants will be identified to be educated about TB. A system for the professional education of those involved in the prevention, control, diagnosis, and treatment of TB will be developed.

Research—Research is needed to identify better methods to combat MDR-TB. Increased knowledge of the basic genetics and biology of *M. tuberculosis* is necessary to understanding better the pathogenesis, immune response, and mechanisms of drug resistance of TB, so that improved diagnostic assays, drugs, and vaccines can be developed. A research subcommittee of the Public Health Service's National MDR-TB Task Force was recently formed to coordinate current and future TB research efforts among participating Federal agencies.

SOURCE: Excerpt from M.E. Villarino, L.J. Geiter, and P.M. Simone, "Multi-Drug Resistant Tuberculosis Challenge to Public Health efforts to Control Tuberculosis," *Public Health Reports* 107(6):623-624, 1992.

As part of its current TB control efforts, the CDC has also encouraged the formation of State and local TB elimination advisory committees. By the end of 1992, such committees have been formed in 28 areas resulting in TB elimination plans for 10 States and 4 cities (370).

In the past several years, the National Institute for Occupational Safety and Health (NIOSH), an agency within CDC, has conducted studies on occupational risks from respiratory exposures to TB, including health hazard evaluations in hospitals, health clinics, correctional facilities, laboratories, drug treatment centers, homeless shelters, and other sites. Also planned is surveillance for TB in workers; development of methods for detecting and measuring airborne particles containing tubercle bacilli; and evaluation of compliance with standard infection control guidelines in occupational settings (34,368). NIOSH recently

conducted a risk assessment on the use of personal respiratory protection in preventing transmission of TB in health care facilities (371) (see chapter 4). It has also recently begun additional research on the effectiveness of infection control interventions, including ventilation systems, ultraviolet light, and respirator efficiency (24).

Occupational Health and Safety Administration

The U.S. Department of Labor's Occupational Health and Safety Administration (OHSA) has regulatory and enforcement responsibilities for workplace health and safety. OHSA's recent TB-related activities include the issuance of guidelines to compliance safety and health officers on conducting inspections following a worker's

complaint of TB exposure in the workplace, outreach and training for labor, industry, academia, and professional groups, and 20 workplace inspections in response to employee complaints. OSHA is also a lead agency in implementing several steps in the National Action Plan to Combat MDR-TB (108). OSHA'S budget for TB-specific activities was approximately \$330,000 in fiscal year 1992 and \$339,000 in fiscal year 1993 (36).

U.S. Departments of Justice and State

Because Federal law bars immigration of individuals with communicable diseases, including active TB, while they are infectious (8 USC 1182, 1224, 1226), the U.S. Departments of Justice and State also play roles in TB control. Consular officers in U.S. embassies abroad require applicants for immigration visas to undergo chest x-rays and sputum smears (if the chest x-ray is abnormal). Those found to have active TB can usually proceed to the United States once treatment has rendered them noninfectious. At the port of entry, the U.S. Department of Justice's Immigration and Naturalization Service (INS) notifies a CDC quarantine officer who in turn informs State or local health officials in the area the immigrant plans to reside. Consular officers in U.S. embassies abroad can require medical examinations of applicants for nonimmigrant visas as well.

The INS funds detention facilities for individuals found to be in the United States illegally while they await immigration hearings or deportation. At nine of the facilities that the INS runs itself,² the PHS Office of Refugee Health provides tuberculin skin tests upon inmates' arrivals with followup diagnosis, treatment of active and latent cases, and notification of relevant State and local health departments for those released in the

United States (181). As of July 1, 1993, there were 5,658 persons under INS detention its own and contract facilities (47).

U.S. Department of Veterans Affairs

Through its nationwide system of hospitals, nursing homes, and outpatient clinics, the U.S. Department of Veterans Affairs (U.S. DVA) is responsible for a broad range of TB control services for veterans and their families. In general, the issues faced by these facilities regarding treatment and prevention of TB and the VA's responses to them parallel those outside the VA.

A recent survey found patients with drug-susceptible or drug-resistant TB, some of whom are also HIV-infected, in each of the four U.S. DVA regions of the country (258). In 1992, a cluster of MDR-TB cases was found at one VA medical center, which led to a review by infection control officials of current infection control practices and compliance with existing U.S. DVA guidelines and CDC recommendations for health care facilities (259).

The U.S. DVA reorganized its longstanding infection control program in 1990 under the direction of its Central Office Medical Service, which then issued revised hospital-based infection control guidelines based on recommendations from a number of expert groups. The Medical Service conducts annual infection control surveys, organizes an advisory group on infection control matters within the U.S. DVA, and participates in CDC'S national task force on MDR-TB (257). It also coordinates with State health departments in providing TB treatment services, reporting of cases of TB, investigating contacts of cases, and other activities (379). There is no separate budget within the U.S. DVA for TB activities.

²Some illegal immigrants are detained in facilities run by State governments, local governments, or private firms under contract for the INS. Information on TB services provided to these detainees was not available.

Indian Health Service

The Indian Health Service (IHS) works with State and local health departments to coordinate TB control services for American Indians and Alaska Natives (AI/AN). These services are delivered either through IHS facilities or State health departments. No IHS funds are designated specifically for TB services on a regular basis; however, IHS does provide TB services for special situations as needed (161).

In 1991, 345 cases of TB in individuals self-identified as AI/AN across 33 States were reported to CDC; 86 percent of these cases occurred in children under the age of 5. At least one cluster of TB cases has recently been reported among AI/AN populations—among the Choctaw tribe in Mississippi. In that case, Choctaw representatives requested and received a one-time appropriation of \$165,000 from the IHS to upgrade their TB control program. Since 1992, the Mississippi Board of Choctaw has assumed responsibility for developing and implementing its own TB control plan, although the State health department still supplies technical assistance to the tribe (161).

Federal Bureau of Prisons

The Health Services Division of the Federal Bureau of Prisons sets policy concerning TB control within Federal prisons nationwide. As of June 1993, this agency was responsible for just over 78,000 inmates in 71 institutions as well as another 6,000 individuals in less restrictive community-based facilities (186). There is no specific budget for TB services. Beginning in 1990, their policy specified that each prison must maintain a TB control program designed to identify infectious cases, isolate them, and begin effective treatment in accord with CDC guidelines. The basic components of the plan include: chest x-ray, medical history, and physical examination of all incoming inmates; tuberculin skin testing every 2 years; HIV testing for all inmates suspected or known to have active TB; reevaluation of all TB

cases at regular intervals; and provisions for all cases that cannot be treated adequately at a given prison site (185,346).

Despite these guidelines, however, experts suggested to OTA that many Federal correctional facilities may not fully comply with these guidelines due to a lack of resources or for other reasons (247,323). OTA found no evidence to determine the extent of compliance with the CDC guidelines among Federal correctional institutions (4,247).

US. Agency for International Development

Since being foreign-born is a risk factor for TB in the United States, attempts to control the disease elsewhere in the world may affect the extent of TB here. The U.S. Agency for International Development (U.S. AID), charged with administering the United States' foreign aid to less developed countries, supports TB services and research through several of its health-related programs. TB-related spending has grown in recent years and in 1992 included allocations of:

- \$7 million for bacillus Calmette-Gue'rin (BCG) vaccination of children through the Child Survival program;
- about \$850,000 for TB research and analysis, including support for the research and development of a rapid, simple test to diagnose TB appropriate for developing countries; and
- about \$500,000 for TB control programs.

Spending for TB control activities includes spending for centrally-administered programs as well as activities carried out by the U.S. Agency for International Development's field missions ranging from direct funding of national TB control programs to funding screening programs carried out by nongovernmental organizations. The agency HIV/AIDS programs also provide funding to the World Health Organization's Global Program on AIDS that carries out some TB activities related to the problem of dual infection with HIV and TB (196,197).

Health Resources and Services Administration

The Health Resources and Services Administration (HRSA) is an agency of the Public Health Service responsible for supporting health services to disadvantaged and underserved populations as well as improving the education, supply, and distribution of health professionals nationwide. Much of its activities are carried out in cooperation with State and local health departments and private organizations. Although the agency has had no TB-specific budget to-date, the President's budget for fiscal year 1994 includes a \$40 million request for such funds. In addition, many of its existing programs support TB activities. HRSA'S Bureau of Primary Health Care (BPHC) funds 800 clinics and other grantees who provide primary care including TB screening, diagnostic follow-up, and DOT for individuals at risk of contracting the disease. This includes grantees who receive funding through the Ryan White Comprehensive AIDS Resources Emergency Act (Public Law 101-381). BPHC also currently supports the development of TB educational materials and conferences for health care providers as well as the participation of its primary care programs in clinical trials for those dually infected with HIV and TB. HRSA'S Hansen Disease Center in Camille, Louisiana conducts TB drug development research with funds from the CDC and the National Institutes of Health (NIH). In fiscal year 1993, support from CDC and NIH for work at Carville totaled \$450,000 with an expected \$900,000 for fiscal year 1994 (264).

RESEARCH AND DEVELOPMENT

Although most of the current TB-related research and development is conducted with funds from the NIH, a number of other DHHS offices are also involved. For example, one of the

functions of the National Vaccine program Office (NVPO), which reports to the Assistant Secretary for Health (U.S. DHHS), is to coordinate research carried out through NIH, CDC, the Food and Drug Administration (FDA), and through the U.S. Department of Defense (U.S. DOD), and the Agency for International Development (U.S. AID) on the development and evaluation of vaccines against various diseases (333), including TB. NVPO designated \$1.3 million in fiscal year 1992 to support a number of research proposals focusing on the development of effective vaccines for the prevention of TB in immunocompetent and immunocompromised individuals (166). In fiscal year 1993, CDC supported an estimated \$9.8 million in TB research and demonstrations that included basic scientific inquiry, behavioral research, new diagnostic tools, infection control, and clinical research into vaccines and treatment (38). The FDA maintains its own research program to aid in the development and evaluation of drugs and other technologies that is charged with regulating.³ The Substance Abuse and Mental Health Services Administration (SAMHSA) supports some research relevant to the delivery of TB services.

National Institutes of Health

Funding for TB research at NIH has increased substantially in recent years: it went from approximately \$300,000 in fiscal year 1985 to \$4.3 million in fiscal year 1991, to \$15.3 million in fiscal year 1992, to \$35.9 million in fiscal year 1993 (37,260). The 1992 budget includes \$5.5 million designated for HIV research that was directed to HIV-related TB research; the 1993 budget includes \$14.1 million in such HIV money as well as another \$4.8 million in one-time funds transferred by the NIH director from her discretionary budget (261).⁴ An additional \$10.5 mil-

³ The FDA's regulatory responsibilities are described later in this chapter.

⁴ HIV funding relevant to TB is counted in NIH's estimates of both its TB funding and its HIV/AIDS spending.

lion was requested in the President's proposed fiscal year 1994 budget for TB research at NIH (332). NIH's TB research agenda covers a broad array of strategies (374):

- Basic research on the molecular biology of tubercle bacilli and immunologic responses to tuberculous infection considered essential for the development of improved treatments, vaccines, and diagnostic methods;
- Studies on the epidemiology and natural history of TB;
- Development of tools to diagnose tuberculous infection and active disease, and to determine drug susceptibility;
- New treatments for drug-susceptible and drug-resistant TB and new delivery methods for these drugs;
- Evaluation of ways to improve patient compliance with treatment;
- Clinical trials of preventive treatment in HIV-infected, purified protein derivative-positive individuals;
- Development of new vaccines to prevent TB;
- Training of new TB researchers (e.g., in career development awards) and improvements in medical education regarding TB;
- Educational efforts geared toward health care workers, patients, and the general public concerning prevention of TB.

In addition, NIH is spending \$2.3 million to convert one of its buildings into a specialized laboratory facility for researchers to conduct safe experiments using drug-resistant strains of tubercle bacilli. As part of its requested increase in fiscal year 1994, NIH (through the National Institute for Allergy and Infectious Diseases, (NIAID)) plans to fund one or more "TB Prevention and Control Research Units," multidisciplinary research centers with expertise and activities in epidemiology, basic science, and clinical interventions (260).

Seventeen of the relatively independent institutes and centers that constitute IWH report



NATIONAL INSTITUTES OF HEALTH

Aerial view of the NIH campus in Bethesda, Maryland. Seventeen of the institutes and centers that constitute NIH support TB-related research and development, although the bulk of this work is funded by the National Institute for Allergy and Infectious Disease.

ongoing TB research or training; NIAID receives the bulk of NIH's budget for TB (57 percent in fiscal year 1993) (376). Among the other 16 institutes and centers involved in TB research and training, those with the largest efforts are the National Center for Research Resources (NCRR), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute for Environmental Health Sciences, the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the National Center for Nursing Research (NCNR), and the National Institute for General Medical Sciences (NIGMS) (137,167,228,288,314,372,375)).

NIAID participated in the development of TB research strategies for the PHS National Action Plan. The agency estimates that funding for just those Action Plan activities that fall within NIAID's purview would cost \$45.6 million in fiscal year 1994, \$20.6 million above NIAID's estimated fiscal year 1993 spending for TB and \$10.1 million more than the President's requested increase in TB funding for fiscal year 1994 for all of NIH. In spring 1993, an NIH Executive Committee on Tuberculosis Research identified and prioritized new TB research opportunities for

all of NIH; complete funding of this research agenda would cost of \$102 million above fiscal year 1993 funding.⁵

REGULATION OF TECHNOLOGIES

In its role as regulator of medical drugs and devices, the FDA is responsible for ensuring the safety and effectiveness of the drugs, devices, and diagnostic agents to prevent, detect, and treat TB including BCG and other vaccines, and tuberculin skin tests. Although the agency has no budget specifically for TB-related activities, the FDA's role in TB control in recent years has focused on:

- alleviating the shortage of some anti-TB drugs;
- expediting the approval process for new drugs (e.g., by evaluating their effectiveness with surrogate measures such as early conversion to a negative sputum smear instead of cure rates following the full course of treatment.)
- developing guidelines for assessing the safety and efficacy of new diagnostic devices for rapid detection of TB (e.g. tests using polymerase chain reaction (PCR) technology) as well as devices used to help prevent the spread of M.tb. (e.g. germicidal lamps).

Prompted by reports in early 1991 of shortages of some anti-TB drugs and their ingredients, the FDA established a TB task force to examine factors contributing to the problem and to find ways of reestablishing stable supplies. For an interim period, a limited supply of streptomycin (SM) and para-aminosalicylic acid (PAS) was made available through CDC under an investigational new drug agreement for patients with MDR-TB. The FDA is currently working with pharmaceutical manufacturers to resolve problems in the manufacture and sale of anti-TB drugs in the United States and is now attempting to monitor supplies. The agency is also working with companies to encourage the development of implantable forms of anti-TB drugs and combina-

tion formulations (121). As mentioned earlier in this chapter, the FDA's regulatory role is complemented by a research program coordinated with the CDC and NIH to aid in the development and evaluation of new diagnostic tools, therapies, and vaccines (226).

HEALTH SERVICES RESEARCH

The U.S. DHH's Agency for Health Care Policy and Research (AHCPR) shares responsibility for funding research on the effectiveness, appropriateness, and cost of TB health care services and their delivery with CDC and some institutes at NIH. Although most of AHCPR's work is conducted through extramural research grants, it also conducts intramural research and facilitates the development, periodic review, and updating of clinical practice guidelines by panels of experts from outside the Federal government. The agency has had several activities to-date related to TB:

- Supporting the development of guidelines that will include recommendations on screening and prophylactic therapy for TB among HIV-infected people (32);
- Sponsoring educational workshops, such as a seminar for State judges on HIV/AIDS and TB to help them in their adjudication of cases that involve these diseases. Future workshops may be conducted for State legislators, other elected officials, and their staff (221,222);
- Funding ongoing research efforts on HIV/AIDS with an emphasis on studying comorbidities including TB; and
- Working with CDC to develop estimates of costs associated with TB (32).

Research at CDC, especially within its Division of TB Elimination, is increasingly focused on studies of the costs and effectiveness of treatment and other programs related to the control of TB. CDC'S increased efforts in this area

⁵This figure includes support for research projects that last for more than 1 year.

are the result of its expertise in TB and its close involvement with the State and local health departments that run TB control programs (191). NIH’s research portfolio also contains work relevant to the provision of effective TB health services, particularly behavioral research focusing on treatment compliance (314,375).

HOUSING

The U.S. Department of Housing and Urban Development has no programs specifically targeted to tuberculosis or people with tuberculosis. However, for a short period of time, it did send a representative to the meetings of the CDC-coordinated National MDR-TB Task Force (145).

REIMBURSEMENT FOR TB SERVICES Disability Programs Administered by the Social Security Administration

The Social Security Administration administers two programs that provide income to disabled individuals. The Social Security Disability Insurance (DI) program pays benefits to disabled individuals who have paid social security taxes and have achieved “insured status” as defined by law. Benefits depend on the amount of taxes paid over a person’s career. DI beneficiaries become eligible for Medicare after receiving DI payments for 2 years. The Supplemental Security Income (SS1) program pays benefits to disabled individuals with low-income. SS1 pays a standard amount to all beneficiaries and does not require that individuals have paid social security taxes, SS1 recipients also become eligible for Medicaid.

Both SS1 and DI use the same definition of disability-“an inability to engage in any substantial gainful activity by reason of any physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months” (42 USC Sec 423(d)(1)(A) for

DI and Sec 1382(a)(3)(A) for SS1). SSA evaluates disability applications in a sequential process to establish that the individual is not engaged in substantial, gainful activity due to an impairment that is listed among SSA’S *medical* impairments or that is at least as severe as a listed impairment. Applicants who do not meet this criteria can also be found to be disabled if they are unable, for at least a year, to do their previous type of work or other generally available work appropriate for their ages, educations, and previous work experiences (88,331).

SS1 or DI is not available for most TB patients without other disabling conditions because of the statutory requirement that the patient’s impairment last for at least twelve months. As described in earlier chapters, individuals with active, drug-susceptible TB and no other complicating conditions are usually infectious for only the first few weeks of treatment and are likely to be able to work afterwards. Patients with drug-resistant strains may be unable to work for a longer period of time, but their impairment may not necessarily be terminal or expected to last at least a year.⁶

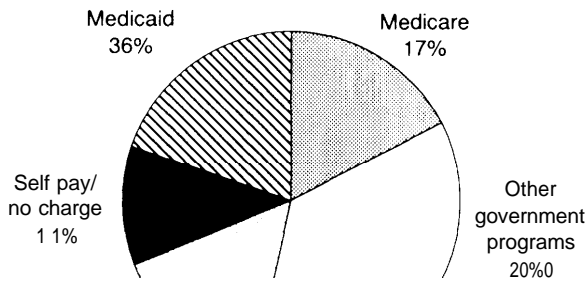
The most likely mechanism for a person with TB to qualify for DI or SS1 is to have another disabling condition, especially HIV. A diagnosis of TB in a person with HIV is considered disabling in itself according to the listing of impairments (Amendments to 20 CFR 404 *et seq.* published in 58 FR 36055, July 2, 1993). There is a separate listing for substance abuse that may also lead to disability benefits for some individuals with active TB (377).

The Role of Federal Health Insurance Programs

Although TB control falls largely to public health officials, the provision of medical services to individuals is a significant component of the

⁶For those TB patients whose disease does last at least 12 months, the SSA’s listings of medical impairments do affirm that their pulmonary infections are considered disabling (377).

Figure 7-2—Hospital Admissions With a Diagnosis of Tuberculosis in 16 States⁷ by Payer, 1990



Little, if any, systematic research has been done on the role of health insurance in financing care for TB Patients. However, indirect evidence suggests a significant Federal role, especially through Medicaid. A 1990 breakdown of all hospital admissions with tuberculosis as a diagnosis, in 16 States, according to payer (figure 7-2) shows that Medicaid was the single most likely payer (36 percent) with private health insurance paying for just 16 percent of admissions.⁷ In total, government pays for almost three-quarters of TB hospitalizations in these States. Although not representative of the entire country, the States examined do include several with the highest burdens of tuberculosis, notably New York and California (see chapter 3). Figure 7-3 shows that in New York State, Medicaid actually pays for a majority of TB hospitalizations (57 percent). Given that being poor and lacking access to regular health care are risk factors for TB (see chapter 3), the prominence of Medicaid, a program for low-income individuals and families, is not surprising.

What types of TB patients and services are covered under Medicare and Medicaid, the two major insurance programs with Federal funding? The remainder of this chapter addresses this question.⁸

MEDICAID⁹

Medicaid is funded jointly by the Federal and State governments and administered at the State level. By Federal mandate, it provides health insurance to certain groups of low-income individuals and families including all aged, blind, and disabled recipients of SS1, mothers and children

⁷ As a comparison for hospitalizations for all diagnoses nationwide in 1991, Medicaid was the expected payer only 13 percent of the time with private health insurance covering 38 percent of admissions. These data are from the 1991 National Hospital Discharge Survey (175).

⁸ The Federal Government also provides direct care to qualified veterans and active military **personnel** in its own health care facilities as well as health insurance to civilian dependents of active **military** personnel through the Civilian Health and Medical Program of the Uniformed Services program. These programs may provide or pay for its **beneficiaries** with tuberculosis, **although Medicare** and Medicaid represent the major Federal contribution in health services reimbursement.

⁹ While this report was in its final publishing stages, Congress adopted legislation giving States the option to use Medicaid funds to pay for TB services only for low-income individuals with either **tuberculous** infection or active disease who do not otherwise qualify for Medicaid (Public Law 103-66).

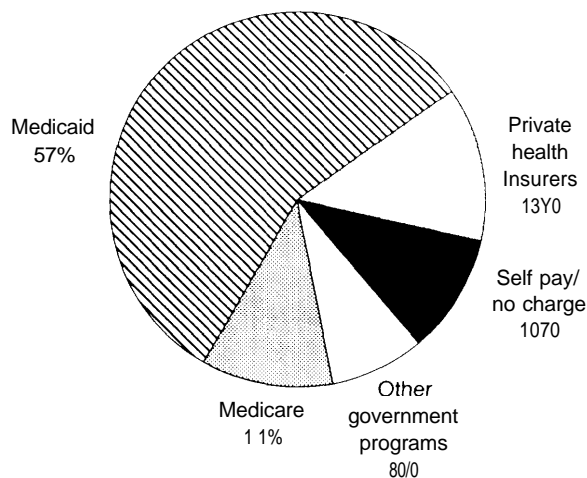
who receive Aid to Families with Dependent Children (AFDC), and other categories of poor women and children. States also have the option of covering ‘medically needy’ individuals whose high medical bills, in effect, make them poor or almost poor.

The Federal Government also requires that all categorically-eligible Medicaid beneficiaries (AFDC and SSI recipients) and some medically needy beneficiaries receive a minimum set of benefits that would cover inpatient, outpatient, laboratory, and other services. States are required to assure the availability of transportation to and from medical services and have the option of adding a variety of supplemental services to the minimum package. States receive matching Federal funds for the optional coverage they decide to provide as part of Medicaid (284,329).

While almost all inpatient, short-stay care associated with TB for Medicaid-eligible individuals would qualify for Medicaid reimbursement, concern over the eligibility of some long-term care and outpatient facilities providing TB services and a desire for flexibility in reimbursing various types of DOT has led the Health Care Financing Administration (HCFA), the Federal agency charged with administering the Federal Government’s regulation of Medicaid, to issue three pieces of correspondence to help guide the States (389).

In July 1992, New York State filed an amendment to their “State Medicaid plan” explicitly discussing the funding of DOT for Medicaid-eligible patients, the only State to have made such a change to its Medicaid program. The amendment establishes three reimbursement rates for DOT services designed to give flexibility in the provision and supervision of TB treatment; the reimbursement rate depends on the setting that care is provided and the amount of effort necessary to ensure completion of treatment. Reimbursement can include the cost of food vouchers, transportation tokens, and other incentives given

Figure 7-3—New York State Hospital Admissions With a Diagnosis of Tuberculosis, by Payer, 1990



SOURCE: Office of Technology Assessment, 1993, based on data derived from state hospital discharge abstracts covering 100 percent of acute short-stay hospitals and U.S. Department of Veterans Affairs hospitals. Data prepared by Codman Research Group, Inc., Lebanon, New Hampshire.

by health care providers to encourage compliance (168,282,283,284). As of April 1993, 22 health care institutions in New York City have agreed to provide Medicaid-reimbursed DOT with a total enrollment of approximately 250 patients. The State expects the first year of the program to cost Medicaid \$5.8 million in combined State and Federal funds (284,390).

HCFA estimates that \$75 million in Medicaid finds went for the care of patients with tuberculosis in 1991. This estimate comprises \$45 million in Federal funds and \$30 million in State funds (391).

MEDICARE

Medicare provides health insurance to individuals over age 65 who have had the appropriate taxes deducted from their paychecks during their careers and to individuals who have received DI disability benefits for at least 24 months (see section on disability).¹⁰ Both HIV, which can lead

¹⁰ Medicare also covers individuals receiving dialysis treatment for end-stage renal disease.

to disability, and old age are also risk factors for TB as discussed in chapter 3. HCFA estimates that in 1991, \$65 million in Medicare funds went for the treatment of TB (391).

Medicare consists of two types of insurance coverage. Part A covers short-term hospital stays after patients pay a deductible for each hospitalization. Hospitals are reimbursed under the diagnosis related group (DRG) system with a set amount for each hospital stay regardless of length. The actual reimbursement is based on the average historical cost of treating all patients with the same primary diagnosis. Part B covers outpatient services provided under a doctor's supervision in an office or ambulatory clinic in return for a monthly premium. Patients also pay an annual deductible and 20 percent of allowable charges.¹¹ Allowable charges are set by the Federal government.

For TB patients covered by Medicare, inpatient services provided in short-stay hospital and am-

bulatory services provided in an office or clinic under a doctor's supervision (most care provided while diagnosing active TB and treating it during its most acute phases) are almost all likely to be reimbursable. Most uncertainties about coverage center around DOT and the provision of care in specialized facilities. Although Medicare does contain some limited home health care benefits, the provision of DOT in the home would not be among them.¹² Similarly, Medicare pays for limited long-term care and skilled nursing services in certain types of federally approved facilities. To date, neither HCFA nor its regional contractors, usually private insurance companies that actually administer Medicare for the Federal Government, have undertaken any special efforts concerning Medicare coverage of TB services (389).

¹¹ A majority of elderly Medicare beneficiaries carry private health insurance designed to provide benefits not covered under Medicare and to help pay Medicare's deductibles and copayments (5).

¹² A recent Office of Technology Assessment report provides much more detail about current Medicare home health benefits (U.S. Congress, OTA, *Home Drug Infusion Therapy Under Medicare*, OTA-H-509, Washington DC: U.S. Government Printing Office, May 1992).