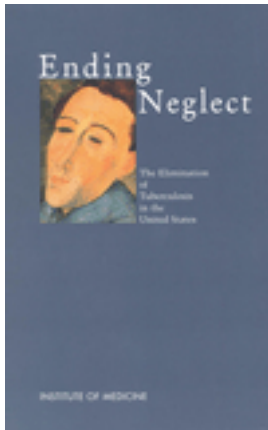


Free Executive Summary



Ending Neglect: The Elimination of Tuberculosis in the United States

Lawrence Geiter, Editor; Committee on the Elimination of Tuberculosis in the United States, Division of Health Promotion and Disease Prevention

ISBN: 0-309-07028-7, 292 pages, 6 x 9, hardback (2000)

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Tuberculosis emerged as an epidemic in the 1600s, began to decline as sanitation improved in the 19th century, and retreated further when effective therapy was developed in the 1950s. TB was virtually forgotten until a recent resurgence in the U.S. and around the world—ominously, in forms resistant to commonly used medicines. What must the nation do to eliminate TB? The distinguished committee from the Institute of Medicine offers recommendations in the key areas of epidemiology and prevention, diagnosis and treatment, funding and organization of public initiatives, and the U.S. role worldwide. The panel also focuses on how to mobilize policy makers and the public to effective action. The book provides important background on the pathology of tuberculosis, its history and status in the U.S., and the public and private response. The committee explains how the U.S. can act with both self-interest and humanitarianism in addressing the worldwide incidence of TB.

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Executive Summary

Institute of Medicine Study on the Elimination of
Tuberculosis in the United States

STATEMENT OF TASK

The study will review the current state of tuberculosis mortality, morbidity, and prevention/control efforts in the United States, with special emphasis on regional and other variations; assess special challenges and solutions for the high proportion of U.S. cases of TB [tuberculosis] in foreign-born persons; and review the current state of research and development in the United States on new diagnostics and therapeutics for TB prevention, control, and elimination; review the extent of multidrug-resistant tuberculosis and analyze factors that contribute to its development; and examine the role of the United States in international efforts at tuberculosis control. The committee will develop conclusions and recommendations regarding: a framework to guide a national campaign to eliminate TB in the United States; region-specific action steps required to work towards that goal; research needs and priorities for national TB elimination; information for health care providers and the public regarding the importance of vigilant and continued attention to TB control; health plan (fee-for-service and managed care) responsibilities for TB prevention and control; federal, state, and local public health policy maker's responsibilities and options regarding infrastructure needs; and strategies for U.S. contributions to worldwide TB prevention and control, leading to worldwide TB elimination.

Tuberculosis, an infectious disease caused by *Mycobacterium tuberculosis*, has plagued humanity since before recorded history and, globally, is still the leading infectious cause of death. As social and economic conditions began to improve in Europe and North America in the late 19th century, tuberculosis rates began to decline in the late 1800s and early 1900s and in the 1930s public health experts began to speculate about the possibility of elimination of this dread disease. Later, with the discovery of antimicrobial agents effective for the treatment of tuberculosis, the elimination of the disease seemed achievable. Plans for tuberculosis elimination were advanced, first to take advantage of the closing of no-longer-needed tuberculosis hospitals and sanatoriums to fund an aggressive drive against tuberculosis in the 1960s and then to take advantage of the retreat of tuberculosis into focal pockets in the United States and strive for elimination in the 1980s. None of these calls for elimination was heeded, and, to the contrary, categorical federal funding for tuberculosis was eliminated in 1972.

The price of the neglect reflected in the funding reductions was a resurgence of tuberculosis throughout the United States. This increase in tuberculosis incidence was greatest in places where the tuberculosis and human immunodeficiency virus epidemics overlapped and where new immigrants from countries with high rates of tuberculosis tended to settle. However, without question the major reason for the resurgence of tuberculosis was the deterioration of the public health infrastructure essential for the control of tuberculosis. It has been estimated that the monetary costs of losing control of tuberculosis were in excess of \$1 billion in New York City alone. Not only was the increase in the number of cases of tuberculosis great concern, but also of rising concern was the specter of multidrug-resistant tuberculosis, a form of the disease that requires treatment with less effective, toxic, and expensive drugs and that is often fatal.

In the past 6 to 7 years the decline in number of cases of tuberculosis has resumed, and all-time lows in both the number and incidence of cases have been achieved, clearly a laudable achievement. The question now confronting the United States is whether another cycle of neglect will be allowed to begin or whether, instead, decisive action will be taken to eliminate the disease. At a minimum, strategies for tuberculosis control will have to adapt to a declining incidence and the changing health care environment. For example, the private sector is becoming increasingly involved in both tuberculosis treatment and tuberculosis prevention, which will require effective programs of training and education for private sector clinicians, patients, and targeted segments of the general public. The increasing reliance on managed care will require changes in approaches to tuberculosis treatment but will also offer opportunities to ensure quality of care through effective contracts and clinical standards. Health departments will need to develop approaches to integrating tu-

berculosis control with other public health programs while maintaining the capacity and focus to ensure program effectiveness.

The changes outlined above will enable a continuation of the decline in the number and rates of tuberculosis; however, because they fall well short of the goal of elimination, the nation will continue to be susceptible to another resurgence when interest inevitably wanes or perturbations in epidemiological circumstances occur. To begin advancing toward the elimination of tuberculosis, aggressive new efforts must be implemented to identify those who are at the greatest risk of disease through targeted programs of tuberculin skin testing coupled with treatment for latent tuberculosis infection. The highest priority is the identification and treatment of infected contacts of individuals with infectious cases of active tuberculosis. In many parts of the country foreign-born individuals from countries with high rates of tuberculosis also make up a high-priority group; however, because the epidemiology of the disease varies from place to place within the United States, other high-risk groups must be identified locally. Prevention of tuberculosis in foreign-born immigrants from countries with high rates of tuberculosis presents a challenge. The proportion of U.S. cases among individuals in this group is steadily increasing, and soon more than half of all cases of tuberculosis in the United States will be among foreign-born individuals. To address the disease among some foreign-born individuals with tuberculosis, those applying for immigrant visas could be required to undergo tuberculin skin testing as part of the medical examination already required for immigrants to the United States and could be required to complete examination and treatment for tuberculosis or latent tuberculosis infection (when indicated) before receiving documents for permanent U.S. residency. This takes advantage of procedures already required at the time of immigration and identifies individuals during their period of highest risk for tuberculosis, the immigrant's first 5 years in the United States.

Unquestionably, such a policy will be difficult to implement. New resources will be required for health departments to review or conduct medical examinations for newly arrived immigrants and to ensure that treatment is appropriately prescribed and supervised. The Centers for Disease Control and Prevention (CDC) and the Immigration and Naturalization Service (INS) will also require new resources to provide the training and quality assurance necessary to conduct the overseas screening and to ensure the efficient flow of information to health departments. Approaches to implementation of this program should proceed in a stepwise fashion through a series of pilot studies, with each demonstrating effective implementation procedures. Despite the recognized difficulty, an analysis of the effect of this approach demonstrates that it is likely to have a substantial impact on the decline in the rate of tuberculosis in the United States. Not only will screening and treatment of foreign-

born individuals target an epidemiologically important group in the United States, but it also will develop and promote the infrastructure needed for aggressive programs of prevention for other high-risk populations already in the United States.

However, even these efforts will not lead to the elimination of tuberculosis. Elimination of tuberculosis will require continued research and the development of new tools. The past decade has seen increased resources for tuberculosis research. Recently, the complete genome of *M. tuberculosis* has been sequenced, providing a wealth of information and setting the stage for truly meaningful and important advances in tuberculosis prevention, diagnosis, and treatment. Globally, the focus has been on the development of a vaccine. However, for the United States the greater needs are for better tests for the diagnosis of latent tuberculosis infection and the identification of individuals who are at the greatest risk of developing active tuberculosis. Advances such as these, together with more effective treatment of latent infection, will lead to the elimination of tuberculosis in the United States.

Elimination of tuberculosis in the United States will also require that the global pandemic of tuberculosis be addressed effectively. As noted earlier, tuberculosis is a leading cause of death worldwide, even though it is a readily treatable and preventable disease. Moreover, the World Bank has identified treatment of tuberculosis as highly cost-effective. The United States must increase its engagement in the global effort to control tuberculosis through participation in multilateral efforts, such as the Stop TB Initiative, and through bilateral initiatives with countries where the rates of tuberculosis are high and that present special circumstances, such as Mexico, which shares a large land border with the United States.

The key to achieving tuberculosis elimination will be through social mobilization and maintaining the public interest and commitment necessary to provide sufficient resources for the effort. The tendency to shift attention and resources away from the elimination of tuberculosis will increase as the number of cases decreases. Only an aggressive effort aimed at building political commitment can prevent the elimination of funding for tuberculosis research and before the elimination of the disease, leading to yet another period of neglect.

The committee agrees with the current policy, advocated by the Advisory Council for the Elimination of Tuberculosis, of committing to the goal of eliminating tuberculosis in the United States, defined as a case rate of less than 1 per 1 million population per year. This plan was updated in a 10-year review published by the Council in 1999 in the *Morbidity and Mortality Weekly Report* (MMWR) and this report supports their conclusions.

The magnitude of this task is clear. Even if intensified tuberculosis

control efforts increase the annual rate of decline from the current 7.5 percent to a 10 percent rate of decline for the next 10 years new tools are developed during that time and those new tools result in a doubling of the annual rate of decline to 20 percent thereafter, it will still take until 2035 to reach the target for tuberculosis elimination. To achieve the goal of tuberculosis elimination in the United States the committee recommends steps that fall into five main categories:

1. Maintaining control of tuberculosis while adapting to a declining incidence of disease and changing systems of health care financing and management.
2. Speeding the decline of tuberculosis and advance toward the elimination of tuberculosis through increased efforts related to targeted tuberculin skin testing and treatment of latent infection.
3. Developing the tools needed for the ultimate elimination of tuberculosis, new diagnostic tests, particularly for diagnosis of infection, new treatments, and an effective vaccine.
4. Increasing U.S. engagement in global efforts to control elimination.
5. Mobilizing support for elimination and regularly measuring progress toward that goal.

MAINTAINING CONTROL

The control of tuberculosis requires the ability to identify and cure individuals with active tuberculosis. The current decline in the number of cases and rates of tuberculosis would indicate that most jurisdictions in the United States are achieving this objective, usually by using a patient-centered approach to therapy and ensuring that patients complete treatment. However, as the numbers of cases decline it will become increasingly difficult to maintain expertise in tuberculosis control and provide a focus within the public health system for the surveillance and management of infectious individuals. These challenges, however, are occurring at the same time that systems of health care financing are changing, including an increasing reliance on managed care organizations and private providers for the delivery of medical services. Those with tuberculosis are eligible for Medicaid, and many health departments are taking advantage of this to fund a variety of services, including directly observed therapy. In addition, tuberculin skin testing and treatment of latent infection are eligible for Medicaid reimbursement. Medicaid, Medicare, and other insurance plans could be important sources of funds for expanded tuberculosis prevention programs. An important aspect of Medicaid funding is that, as an entitlement, the funding provided grows with the number of patients served and is theoretically unlimited.

The loss of categorical funding for tuberculosis was a major factor in the decline in the tuberculosis control infrastructure and the subsequent resurgence of tuberculosis in the 1980s and 1990s. Categorical funding will ensure that support for tuberculosis control is not neglected again and can also be justified on the basis of the fact that tuberculosis is a serious, infectious disease spread through casual contact and requires a national approach for its control. However, as the number of cases declines, increased integration of tuberculosis with other public health activities will be required in some areas. Bureaucratic obstacles to shared resources (e.g., use of cofunding for personnel or facilities with funds from multiple programs) need to be identified and eliminated to allow the more efficient use of financial and other resources. It is also important to maintain funding to maintain activities at their current levels. Level funding for tuberculosis control programs can result in de facto cuts in funding because of the high rates of inflation associated with medical services and can put the current decline in the numbers of cases at risk.

(Note: The first digit in the recommendation number refers to the chapter in the report that contains the recommendation and supporting information.)

Recommendation 3.1 To permanently interrupt the transmission of tuberculosis and prevent the emergence of multidrug-resistant tuberculosis, the committee recommends that

- All states have health regulations that mandate completion of therapy (treatment to cure) for all patients with active tuberculosis.
- All treatment be administered in the context of patient-centered programs that are based on individual patient characteristics. Such programs must be the standard of care for patients with tuberculosis in all settings.

Recommendation 3.2 To ensure the most efficient application of existing resources, the committee recommends that

- New program standards be developed and used by CDC and state and local health departments to evaluate program performance.
- Standardized, flexible case management systems be developed to provide the information needed for the evaluation measurements. These systems should be integrated with existing case management systems and other automated public health data systems whenever possible.

Recommendation 3.3 To make further progress toward the elimination of tuberculosis in regions of the country experiencing low rates of disease, the committee recommends that

- Tuberculosis elimination activities be regionalized through a combination of federal and multistate initiatives to provide better access to and more efficient utilization of clinical, epidemiological, and other technical services.
- Protocols and action plans be developed jointly by CDC and the states for use by state and local health departments to enable planning for the availability of adequate resources.
- State and local health departments develop case management plans to ensure a uniform high quality of care for patients with tuberculosis and tuberculosis infection in their jurisdictions.

Recommendation 3.4 To maintain quality in tuberculosis care and control services in an era of increased use of managed care systems and privatization of services, the committee recommends that

- When it is determined that tuberculosis diagnosis and treatment services can be provided more efficiently outside of the public health department, the delivery of such services be governed by well-designed contracts that specify performance measures and responsibilities.
- Federal categorical funding for tuberculosis control be retained. Funding at the local level should provide sufficient dedicated resources for tuberculosis control but should be structured to provide maximum flexibility and efficiency.
- Both public and private health insurance programs be billed for tuberculosis diagnostic and treatment services whenever possible but tuberculosis services should never be denied due to a patient's inability to make a co-payment.

Recommendation 3.5 To promote a well-trained medical (in a broad sense) workforce and educated public, the committee recommends that

- The Strategic Plan for Tuberculosis Training and Education, which contains the blueprint that addresses the training and educational needs for tuberculosis control, be fully funded.
- Programs for the education of patients with tuberculosis be developed and funded.
- Funding be provided for government, academic, and nongovernmental agencies to work in collaboration with international partners to develop training and educational materials.

SPEEDING THE DECLINE

After ensuring the control of tuberculosis through the provision of adequate treatment of individuals with active tuberculosis, the second priority is targeted tuberculin skin testing and treatment of latent infection, which includes the identification and treatment of contacts. This measure serves to protect the health of the individual and will accelerate the decline in tuberculosis case rates. Previously, tuberculosis was believed to be largely transmitted through prolonged, close exposure, such as in the household. Recent experience has demonstrated, however, that there are many instances of *M. tuberculosis* transmission occurring outside the household, in a variety of environments. Therefore, the search for persons newly infected with *M. tuberculosis* (contact investigation) must be broadened.

The proportion of new tuberculosis cases in the United States among foreign-born individuals has been steadily increasing. The period of greatest risk of tuberculosis for individuals who immigrate to the United States from countries with high rates of tuberculosis is during their first 5 years in this country. Recent guidelines from CDC have emphasized the importance of identifying immigrants from high-incidence countries as soon as possible after their arrival in the United States and providing them with tuberculin skin testing and treatment for latent infection, when indicated. The addition of tuberculin skin testing to the medical evaluation for immigrant visa applicants from countries with high rates of tuberculosis and linking of evaluation and treatment for tuberculosis to receipt of permanent residency status could facilitate this process. The committee discussed this recommendation at great length and recognizes that this will entail a difficult and complicated process and will require significant additional resources for state and local health departments, CDC, and INS. Such a program may need to be implemented in a stepwise fashion, by using pilot programs that focus on the highest-risk populations, upgrading the capacities of local health departments and CDC and INS systems, and carefully evaluating the results. In addition, it will be important to collect data concerning the safety among recent immigrant populations of the new short-course regimens that may be the preferred treatment. The extraordinarily high risk of tuberculosis in newly arrived immigrants from high-incidence countries justifies this effort.

The majority of inmates of correctional facilities have demographic characteristics that put them at higher risk of having tuberculosis infection. The importance of preventing cases of tuberculosis in correctional facilities is magnified by the ease with which new infections can be transmitted, should an infectious case of tuberculosis occur in the close setting of a jail or prison.

Increased testing and treatment for contacts, newly arrived immigrants, and inmates of correctional facilities will have significant impacts but there will still be high-risk populations who must be identified locally. These include groups such as HIV-infected individuals, homeless people, intravenous drug abusers, and undocumented immigrants. Successful programs for targeted testing and treatment of latent infection have been designed for these populations and many involve close collaboration with the community-based organizations, neighborhood health centers, and private providers that already provide medical care to these individuals.

Recommendation 4.1 To limit the spread of tuberculosis from infectious patients to their contacts, the committee recommends that more effective methodologies for the identification of persons with recently acquired tuberculosis infection, especially persons exposed to patients with new cases of tuberculosis, be developed and efforts be increased to evaluate appropriately and treat latent infection in all persons who meet the criteria for treatment for such infections.

Recommendation 4.2 To prevent the development of tuberculosis among individuals with latent tuberculosis infection, the committee recommends that

- Tuberculin skin testing be required as part of the medical evaluation for immigrant visa applicants from countries with high rates of tuberculosis, a Class B4 immigration waiver designation be created for persons with normal chest radiographs and positive tuberculin skin tests, and all tuberculin-positive Class B immigrants be required to undergo an evaluation for tuberculosis and, when indicated, complete an approved course of treatment for latent infection before receiving a permanent residency card (“green card”). Implementation should be in a stepwise fashion and pilot programs should evaluate strategies and assess costs.

- Tuberculin testing be required of all inmates of correctional facilities and completion of an approved course of treatment, when indicated, be required, with referral to the appropriate public health agency for all inmates released before completion of treatment.

- Programs of targeted tuberculin skin testing and treatment of latent infection be increased for high-incidence groups, such as HIV-infected individuals, undocumented immigrants, homeless individuals, and intravenous drug abusers, as determined by local epidemiological circumstances.

DEVELOPING NEW TOOLS

Tuberculosis elimination is not possible with the tools that are available currently. Fortunately, an investment in the development of a tuberculosis research infrastructure and expertise during the past 7 years has the research community poised for progress in the development of new tools and strategies. The first priority area for research is development of an understanding of latent infection. The ability to identify individuals who are truly infected with *M. tuberculosis* and who are at risk for disease will tremendously simplify the process of tuberculosis elimination in the United States. An important area of research that has been lacking is behavioral and social science research targeted toward understanding and improving patient adherence with therapy. This is an increasingly complex and troublesome question as the characteristics of tuberculosis patients change and become ever more varied. The committee estimates that the National Institutes of Health (NIH), CDC, the U.S. Food and Drug Administration, and the U.S. Agency for International Development annual research budgets for tuberculosis will have to be increased to approximately \$280 million (approximately tripled). Moreover, industry and private foundations must substantially increase their investments in basic and applied research to achieve the recommendations presented above. To enable the most efficient use of the increased funds, the increase should be phased in and then maintained over a significant time period.

Recommendation 5.1 To advance the development of tuberculosis vaccines, the committee recommends that the plans outlined in the *Blueprint for Tuberculosis Vaccine Development*, published by NIH in 1998, be fully implemented.

Recommendation 5.2 To advance the development of diagnostic tests and new drugs for both latent infection and active disease, action plans should be developed and implemented. CDC should then exploit its expertise in population-based research to evaluate and define the role of promising products.

Recommendation 5.3 To promote better understanding of patient and provider nonadherence with tuberculosis treatment recommendations and guidelines, a plan for a behavioral and social science research agenda should be developed and implemented.

Recommendation 5.4 To encourage private-sector product development, the global market for tuberculosis diagnostic tests, drugs,

and vaccines should be better characterized and access to these markets for these new products should be facilitated.

Recommendation 5.5 To define the applicability of any new tools to the international arena and facilitate their development, the U.S. Agency for International Development (AID), NIH, and CDC should build upon international relationships and expertise to conduct research.

ENGAGING IN GLOBAL TUBERCULOSIS CONTROL

Tuberculosis is a leading cause of death worldwide, even though it is a readily treatable and preventable disease. Although an altruistic argument for promoting the global control of tuberculosis can easily be advanced, worldwide control of this disease is also in the nation's self-interest. The proportion of foreign-born patients with tuberculosis in the United States has been steadily increasing. In 1998, 41 percent of all patients with tuberculosis were foreign-born. It benefits the United States to help strengthen tuberculosis control programs globally, particularly in the countries that are the sources of the most tuberculosis cases imported into the United States. Tuberculosis will not be eliminated in the United States until the worldwide pandemic is brought under control.

Recommendation 6.1 To decrease the number of foreign-born individuals with tuberculosis in the United States, to minimize the spread and impact of multidrug-resistant tuberculosis, and to improve global health, the committee recommends that

- **The United States expand and strengthen its role in global tuberculosis control efforts, contributing to these efforts in a substantial manner through bilateral and multilateral international efforts.**
- **The United States contribute to global tuberculosis control efforts through targeted use of financial, technical, and human resources and research, all guided by a carefully considered strategic plan.**
- **The United States work in close coordination with other government and international agencies. In particular, the United States should continue its active role in and support of the Stop TB Initiative.**
- **AID, CDC, and NIH should jointly develop and publish strategic plans to guide U.S. involvement in global tuberculosis control efforts.**

MOBILIZING SUPPORT FOR ELIMINATION

The United States has a long history of social mobilization efforts in support of tuberculosis control. Social mobilization provides for the enlistment and coordination of efforts by myriad groups and individuals. Advocacy to influence policy makers and education of patients, health care providers, and the general public are critical activities.

An ad hoc World Health Organization committee identified the lack of political will on the part of national governments as a fundamental constraint to developing and sustaining effective tuberculosis control programs. Social mobilization is necessary to build and sustain political will in the United States and can lead to similar efforts internationally.

Recommendation 7.1 To build public support and sustain public interest and commitment to the elimination of tuberculosis, the committee recommends that CDC significantly increase resources for activities to secure and sustain public understanding and support for tuberculosis elimination efforts at the national, state, and local levels, including programs to increase knowledge among targeted groups of the general public.

Recommendation 7.2 To increase the effectiveness of mobilization efforts the committee recommends that the National Coalition for the Elimination of Tuberculosis continue to provide leadership and oversight and that CDC continue to work in collaboration with the coalition to secure the support and participation of nontraditional public health partners, ensure the development of state and local coalitions, and evaluate public understanding and support for tuberculosis elimination efforts with the assistance of public opinion research experts.

Recommendation 7.3 To assess the impacts of these recommendations and to measure progress toward accomplishing the elimination of tuberculosis, the committee recommends that, 3 years after the publication of this report and periodically thereafter, the Office of the Secretary of Health and Human Services conduct an evaluation of the actions taken in response to the recommendations in this report.

Ending Neglect

The Elimination of
Tuberculosis
in the
United States

Lawrence Geiter, *Editor*

Committee on the Elimination of Tuberculosis
in the United States

Division of Health Promotion and
Disease Prevention

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NATIONAL ACADEMY PRESS
Washington, D.C.

NATIONAL ACADEMY PRESS • 2101 Constitution Avenue, N.W. • Washington, DC 20418

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This project has been funded entirely with federal funds from the Centers for Disease Control and Prevention, under Contract No. 200-98-0012. The views presented are those of the Institute of Medicine Committee on the Elimination of Tuberculosis in the United States and are not necessarily those of the funding organization.

Library of Congress Cataloging-in-Publication Data

Institute of Medicine (U.S.). Committee on the Elimination of Tuberculosis in the United States. Ending neglect : the elimination of tuberculosis in the United States / Lawrence Geiter, editor; Committee on the Elimination of Tuberculosis in the United States, Division of Health Promotion and Disease Prevention, Institute of Medicine.

p. ; cm.

Includes bibliographical references and index.

ISBN 0-309-07028-7

1. Tuberculosis—United States. I. Geiter, Lawrence. II. Title.

[DNLM: 1. Tuberculosis, Pulmonary—prevention & control—United States
WF 300 I59e 2000]

RC313.A2 I55 2000

614.5'42'0973—dc21

00-056115

The full text of this report is available on line at www.nap.edu.

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Printed in the United States of America

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

Cover: Modigliani. Self-portrait, 1919. Oil on canvas. Museu de Arte Contemporanea da Universidade de Sao Paulo. Collection M and Madame Francisco-Matarazzo Sabrinho.

*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*

—Goethe



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Preface

In 1905, in his book *The Life of Reason*, the poet and philosopher George Santayana wrote “Those who do not remember the past are condemned to repeat it.” This statement is particularly apropos now as we attempt to develop a plan for the future elimination of tuberculosis in the United States, ever mindful of the lessons that can be gleaned from the historical record.

The incidence of tuberculosis in this country and in Europe began to decline in the late 19th and early 20th centuries with improving social and economic conditions. By the 1930s, the possibility of eliminating this leading infectious cause of death globally began to be pondered by public health experts. The introduction in the early 1950s of the first effective antimicrobial drugs for treatment of tuberculosis was followed in the 1960s by the closing of many tuberculosis hospitals and sanatoriums. The elimination of this dread disease seemed feasible at that time provided public interest and government expenditures commensurate with the task could be marshaled and sustained. This was not to be the case; rather, the declining incidence of tuberculosis in the United States induced complacency and neglect for this disease. Indeed, after several years of decreasing federal support, in 1972 categorical federal funding for tuberculosis control was eliminated entirely. It was not reinstated for 9 years, and then only at a very reduced level. In addition, the scientific community and funding agencies largely disregarded tuberculosis, deeming it of insufficient importance to warrant a high research priority. As a consequence of this lack of funding and research interest, scientific publications in this field decreased by almost 50 percent between 1968 and 1980. The price of

this neglect has been the resurgence of tuberculosis in the United States in the late 1980s and early 1990s, with major costs in suffering, death, and economic losses. Reversal of the ensuing increased case rates, many involving patients whose infecting microorganisms were multidrug resistant, was accomplished only with great difficulty and required energetic tuberculosis control measures and markedly increased public expenditures.

We are now at a critical juncture. On the one hand, control of tuberculosis in the United States has been regained and we are at an all-time low in the number of new cases (18,361 in 1998). On the other hand, we are particularly vulnerable again to the complacency and neglect that comes with declining numbers of cases. Now is the time to commit to the abolition of the recurrent cycles of neglect followed by resurgence that have been the history of tuberculosis in the latter half of the past century.

In 1989, almost simultaneous with an unexpected upsurge in the incidence of tuberculosis in the United States, the Centers for Disease Control and Prevention (CDC) and the Advisory Council for the Elimination of Tuberculosis (ACET) developed a strategic national plan to reduce the incidence of tuberculosis to 3.5 cases per 100,000 persons by the year 2000, and by 2010, to less than 1 case per 1 million population. However, in place of the steady (about 7 percent per year) decline of cases prior to 1985, between 1985 and 1992 cases of tuberculosis increased from 22,210 to 26,673 per year. Since the latter date, the incidence of tuberculosis in the United States has resumed its former rate of decline (again about 7 percent annually) to 18,361 cases in 1998, or 6.8 cases per 100,000 population. At this rate of decline it would take 60 more years to reach the stated 1989 CDC/ACET goal for 2010 (1 case per 1 million population) unless changes were made in the methods used for the control of tuberculosis.

This Institute of Medicine report, *Ending Neglect: The Elimination of Tuberculosis in the United States*, undertaken under sponsorship from the CDC, reviews the lessons learned from the neglect of tuberculosis between the late 1960s and the early 1990s and reaffirms committing to the goal of eliminating tuberculosis in the United States, defined as a case rate of less than 1 case per 1 million population per year. Clearly, to meet this goal aggressive and decisive actions beyond what is now in effect will be required. The report details the following recommendations in full, but a few are listed here:

- **Maintaining control of tuberculosis while adjusting control measures to declining incidence of disease and changing systems of health care management.** This will be integral to interrupting transmission of tuberculosis and, most important, to preventing the emergence of multidrug-resistant tuberculosis. Among measures to ensure this, all

states should mandate completion of therapy for all patients with active tuberculosis. In addition, to advance toward elimination of tuberculosis in areas of the country with already low rates of tuberculosis, activities toward elimination should be regionalized through both federal and multistate initiatives to improve access to and more efficient utilization of clinical, epidemiological, case management, and laboratory services. Federal categorical funding for tuberculosis control should be retained, providing dedicated resources for this purpose while allowing maximum flexibility and efficiency in its implementation.

- **Accelerating the rate of decline of tuberculosis (aimed at elimination) by increasing efforts at targeted tuberculin testing and treatment of latent infection.** This would involve development of more effective methodologies to identify persons with recently acquired tuberculosis infection and increased efforts to evaluate and treat latent infection in persons at high risk of subsequent progression to active disease. Tuberculin skin testing should be required in the medical evaluation of immigrants applying for visas from countries with high rates of tuberculosis. Those found to be tuberculin positive should be required to undergo an evaluation for tuberculosis, and, when appropriate, complete an approved course of treatment for latent infection before receiving their permanent residency card. Similar tuberculin testing should be required of all inmates of correctional institutions and, when indicated, completion of an appropriate course of treatment. Programs of targeted tuberculin skin testing and treatment of latent infection should be intensified for other high-incidence populations such as homeless individuals, undocumented immigrants, and intravenous drug abusers, as indicated by local epidemiological considerations.

- **Developing new tools necessary for the ultimate elimination of tuberculosis, including new diagnostic tests for latent infection, new treatments and an effective vaccine.**

- **Increasing involvement of the United States in global tuberculosis control, recognizing the fact that tuberculosis is not constrained by national boundaries and that increasing proportions of new cases in this country are developing in individuals born in countries with high incidences of tuberculosis.**

- **Mobilizing and sustaining public support and commitment for elimination of tuberculosis and regularly measuring progress toward that goal.**

This committee comprised 13 individuals with expertise in tuberculosis (clinical aspects, epidemiology, mycobacteriological research, prevention and control, and health education), ethics, public health policy and infectious disease eradication, state correctional health services, interna-

tional health and general infectious disease. In response to public comment on committee composition that noted an absence of experts on public health tuberculosis laboratories, a special report on this subject was commissioned and is included in this report (Appendix D). The committee met five times, and these included public sessions at four of the meetings. In particular, the final public session was held to provide for full and open discussion on issues raised regarding tuberculin testing (and prophylactic therapy when appropriate) of immigrants to the United States from countries with high incidence rates of tuberculosis. This discussion benefited from the involvement of experts in ethics, immigration law, and public policy as well as representatives from the Immigration and Naturalization Service, CDC, and the Department of State.

In addition, committee members conducted site visits to a variety of sites (state and local health departments, CDC, public hospitals, homeless facilities, and facilities for nonadherent infectious patients placed under legal orders to complete therapy), selected to represent a full range of the problems and issues in current tuberculosis control. These sites included ones in Atlanta, San Diego, Seattle/King County and Tacoma/Pierce County in Washington, Boston, Washington, D.C., and Augusta and Portland in Maine (Appendix C).

The report is organized in the following fashion. Chapter 1 covers the fundamentals of tuberculosis, including its transmission, pathogenesis, diagnosis, treatment, and control. Chapter 2 reviews the history of tuberculosis in the United States, analyzes the implications of disease elimination, and discusses the ethical issues in moving toward elimination. Chapter 3 considers many of the challenges of tuberculosis programs to prevent a resurgence of tuberculosis in this country as the number of cases declines: maintaining high skill levels and quality of care, needs for performance standards, developing necessary information systems for evaluating case management and disease control, and the increasing use of managed care and the potential for regionalization of control and diagnostic efforts. Chapter 4 makes the case for accelerating the rate of decline of tuberculosis through use of targeted tuberculin skin testing programs and treatment of latent infection; improving methodologies for contact tracing, examination and treatment; changing the medical examination of visa applicants from high-incidence countries to include tuberculin testing and treatment, where appropriate, in those that are tuberculin positive. This change from established procedure evoked the most discussion and greatest attention from the committee. The approaches discussed in this chapter should speed up the current rate of decline of tuberculosis and advance the eventual elimination of this disease in the United States. Chapter 5 describes the current status of tuberculosis research and pinpoints the research needs, both short term (newer methodologies for the

diagnosis and treatment of latent tuberculosis) and longer term (vaccine development), that need to be fulfilled to make the elimination of tuberculosis a reality. Chapter 6 identifies the need for an enhanced role of the United States in global tuberculosis control, both from the point of view of self-interest and humanitarian considerations. Chapter 7 covers the important role of public advocacy efforts to develop and sustain the political commitment needed to make elimination of tuberculosis a reality.

The committee would like to thank the numerous experts from various governmental agencies, academic institutions, professional organizations, and groups working with immigrants, migrant workers, and the homeless who made presentations at its meetings, thus ensuring consideration of a broad set of views in the development of its recommendations (Appendix B). The committee is particularly grateful to Lawrence Geiter, Ph.D., the IOM study director, for his untiring efforts in working our discussions and contributions into a coherent, thorough, and well-reasoned report within a year of our first meeting, with the assistance of his staff, Donna Almario, Elizabeth Epstein, and Patricia Spaulding. We wish to thank Robert Fullilove, Ed.D., liaison to the IOM Board on Health Promotion and Disease Prevention, who attended and participated in our meetings and discussions, and George Comstock, Dr.P.H., who was originally a committee member until forced to withdraw because of an illness in his family. We also wish to thank Kenneth I. Shine, M.D., president of IOM; Kathleen Stratton, acting director of the Division of Health Promotion and Disease Prevention; and Rose Martinez, director of the Division of Health Promotion and Disease Prevention, for their support and insights.

Morton N. Swartz, M.D., *Chair*

Acknowledgments

The committee wishes to express its appreciation to the many individuals who contributed to the completion of this project. We especially want to thank our consultant, Robert C. Good, Ph.D., whose paper appears as Appendix D, and the many workshop presenters who provided the committee with a wealth of information (see Appendix B).

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We wish to thank the following individuals for their participation in the review of this report:

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While the individuals listed above have provided constructive comments and suggestions, it must be emphasized that responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Ending Neglect

