A Call for Action on the

Tuberculosis Elimination Plan for the United States

StopTB USA

Tuberculosis Elimination Plan Committee

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Disclaimer:

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the organizations of the consultants or writers.

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Table of Contents

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I. Executive Summary

A. Reasons for Issuing this Call for Action in 2010

In 2000, the Institute of Medicine (IOM) published a report, *Ending Neglect: The Elimination of Tuberculosis in the United States,* detailing the history of efforts to control and eliminate tuberculosis in the United States and recommending a plan to eliminate tuberculosis in the United States by 2035. In 2007, based upon the recommendations from its retreat, the National Coalition for the Elimination of Tuberculosis (NCET) has transitioned to Stop TB USA. The name change reflects the need to be more readily identified as the point of contact for the Stop TB Partnership at the World Health Organization. In late 2007, Stop TB USA assembled a Tuberculosis Elimination Plan Committee to assess the progress since the release of the IOM report and to formulate recommendations to update the IOM plan. This report assesses how and why the IOM's tuberculosis elimination plan has not been fully implemented and provides updated action plans to move forward on its recommendations to accelerate progress toward tuberculosis elimination in the United States.

1. Slowing Decline in Rates of Tuberculosis Disease

Nine years after the IOM report, its recommendations have not been fully implemented, and the annual decline in tuberculosis incidence rates has slowed to only 3.8% per year since 2003.

If this trend continues, it will take 97 years to achieve tuberculosis elimination, defined as a rate of less than one case of tuberculosis per million persons. This is clearly a goal well below the horizon from a human perspective in 2010.

TB Disease, Latent TB Infection: Definitions, Transmission, and Statistics

Tuberculosis is a life-threatening illness caused by a group of bacteria called *Mycobacterium tuberculosis* complex. The commonly used public health term *tuberculosis case* is used to describe a newly reported diagnosis of tuberculosis. The statistic for noting the frequency of tuberculosis in a population is the *tuberculosis case rate,* defined as the number of tuberculosis cases per year in an area divided by the number of people living in that area multiplied by 100,000. The tuberculosis case rate is also referred to as the *tuberculosis incidence rate*.

M. tuberculosis is transmitted from a person with tuberculosis of the lungs (pulmonary tuberculosis) through the air to other people who may become infected.

Infection with *M. tuberculosis* is called *latent tuberculosis infection* because there are no symptoms or signs of tuberculosis disease. Latent tuberculosis infection can be diagnosed with a tuberculin skin test or specific blood tests (interferon gamma release assays or IGRAs).

Latent tuberculosis infection carries a 10 percent lifetime risk of tuberculosis disease with about half of the cases occurring within the first two years after infection. Infants, human immunodeficiency virus (HIV)-infected persons, and those with suppressed immune systems are at much higher risk for developing tuberculosis from latent tuberculosis infection.

Placed in the context of affected persons today, only 300 newly reported cases of tuberculosis would have been expected in the entire US population of 300 million if tuberculosis elimination had been achieved. Instead, 12,904 cases of tuberculosis were reported in 2008, a decrease of only 2.9% from the 13,288 reported in 2007.

2. Health Disparities in Rates of Tuberculosis Disease

A major health disparity exists for tuberculosis. In 2008 only 17% of the cases of tuberculosis in the United States were reported in the majority non-Hispanic white population. Compared to reported tuberculosis case rates among non-Hispanic whites, the rates are 5.5-fold higher among American Indians, 7.4-fold higher among Hispanics, 8.0-fold higher among blacks, and 22.9-fold higher among Asians.

3. Serious Health and Economic Impacts of Tuberculosis Disease

Information on the frequency of tuberculosis is available and believed to be fairly accurate because cases of tuberculosis are reportable to state health departments and forwarded to the Centers for Disease Control and Prevention (CDC). For each of the 12,904 persons reported with tuberculosis in 2008, the continuing presence of tuberculosis in the United States may have resulted in preventable death, life-threatening illness, disability, and/or loss of productivity, particularly in minority populations. Tuberculosis remains a deadly disease with over 1,200 of the persons reported as cases in 2006 (the most current year with complete follow-up) having died either before diagnosis or before completing treatment.[1] Among survivors, the health impact remains significant. Over half of the survivors of pulmonary (lung) tuberculosis are left with significant lung impairment.[2]

Tuberculosis disease also has a strong economic impact. Prolonged short-term disability due to illness and isolation for public health protection impacts patient and family income. In addition, treating each patient for tuberculosis is expensive with outpatient directly observed treatment costs of $4,000. About 50% of patients are hospitalized at a cost per patient of $19,000. (Both cost estimates are in 2004 dollars.)[3] Many of these costs are absorbed by the public health sector because patients with tuberculosis often lack health insurance, and the clinical expertise in tuberculosis of many private physicians is limited.

Detecting tuberculosis is also expensive. For each patient with confirmed tuberculosis, ten or more people are often evaluated for suspected tuberculosis but determined not to have tuberculosis. A study of laboratory diagnostic tests in Tarrant County, Texas, found that 148 cultures for mycobacteria were done across the community for each confirmed case of tuberculosis in 2002, translating into an estimated laboratory cost of $16,830 for each confirmed tuberculosis case reported by the health department. Health departments evaluate and treat at least as many suspected but not reportable tuberculosis cases as those that meet the reporting requirements, and the health department costs range from $2,180 to $3,525 for each patient treated initially for suspected tuberculosis but later determined to have another diagnosis. These costs do not include hospitalizations that are not covered by public health departments.[4]

Improvements in tuberculosis diagnostic tests could reduce the cost, inconvenience, and/or side effects that result from delays in making or excluding the diagnosis of tuberculosis.

With the emergence of multidrug-resistant and extensively drug-resistant strains, tuberculosis has become much more expensive and difficult to diagnose and treat. In the United States, the average estimated hospitalization cost for treating a patient with extensively drug-resistant tuberculosis is $600,000, and that does not include costs of outpatient care and related public health department interventions.[5] The global spread of drug-resistant tuberculosis strains—particularly in human immunodeficiency virus (HIV) co-infected populations living in countries with high tuberculosis burdens but poorly functioning tuberculosis control programs—poses a growing threat to US residents.

4. Few Modern Tools for Tuberculosis Diagnosis, Treatment, and Prevention

Further, due to decades of stagnation in research and development, few modern tools have been introduced for the diagnosis, treatment, and prevention of the disease.

The bacilli Calmette-Guérin (BCG) vaccine is the only existing vaccine against tuberculosis and is widely used. However, BCG has had no apparent impact on reversing the growing global tuberculosis pandemic. New, more effective vaccines are urgently needed.

For more accurate and timely detection of latent tuberculosis infection, two blood tests are currently licensed in the United States. However, insufficient funding for operational research has led to delays in implementation of these tests, and many public health programs have been unable to cover the additional cost of these tests.

To more rapidly diagnose tuberculosis disease, there is the nucleic acid amplification (NAA) test. Other promising newer diagnostic methods are able to detect multidrug-resistant tuberculosis within just days. However, implementation of these tests remains limited because of inadequate operational research, the official approval processes, cost issues, and/or laboratory expertise.[6]

New treatment regimens for tuberculosis disease and latent tuberculosis infection are needed to shorten and simplify treatment, be compatible with antiretrovirals and other commonly-used medicines, and address drug resistance.

5. Erosion of Public Health Infrastructure and Loss of Expertise

In the United States, public health provides key elements of tuberculosis control that are not available in the private sector. Two key, recent surveys conducted by the National Tuberculosis Controllers Association (NTCA) and National Tuberculosis Nurse Coalition (NTNC) indicated erosion of tuberculosis control infrastructure and impending loss of expertise. These surveys verify the need to augment and invest in domestic tuberculosis programs.

The NTCA survey focused on resources for tuberculosis control activities from 2006 through 2008. Respondents reported that the most common barrier to reaching the national objectives for tuberculosis control was underfunding of public health systems (81%). Estimates from each program on needed funding ranged from $13,000-$99,000 for eight programs (33%), $100,000-$399,000 for eight programs (33%), $400,000-$1.5 million for six programs (25%), to $2-2.2 million for two programs (8%).

The NTNC survey noted an impending loss of nursing tuberculosis case management expertise as 33% and 74% of current tuberculosis case managers anticipate retirement within 5 and 10 years, respectively. This loss of key infrastructure comes at a time when tuberculosis nursing case managers report increasing case complexity due to drug resistance (multidrug-resistant and extensively drug-resistant tuberculosis), comorbid conditions, and greater linguistic and cultural diversity of patients with tuberculosis in their communities.

6. Tuberculosis Elimination—A Worthy and Achievable Goal

Despite this dire assessment of current progress, the elimination of tuberculosis in the United States, first proposed in 1989 and reaffirmed by the IOM in 2000, is a worthy and achievable goal if we accept the challenge.

The authors of the IOM's *Ending Neglect* report concluded that the 2010 tuberculosis elimination goal could not be achieved, owing in part to the 1985 through 1992 resurgence of tuberculosis in the United States as well as to the global impact of the tuberculosis and HIV pandemics. The IOM report suggested that the elimination of tuberculosis might be feasible by 2035 if a number of recommendations for accelerating the decline in tuberculosis cases were implemented. Given the trends since 2003, the decline in tuberculosis case rates will have to be dramatically increased if tuberculosis elimination is to be achieved by 2035.

However, the benefits are well worth the effort. Compared to maintaining the current rate of decline, eliminating tuberculosis by 2035 would result in

- 253,000 fewer tuberculosis cases
- 15,200 fewer tuberculosis-related deaths
- $1.3 billion less in treatment costs in 2006 dollars[7]

Each case of tuberculosis represents a profound impact on a person, a family, a workplace, and a community. Preventing the ongoing accumulation of deaths, disability, healthcare costs, and loss of family income from tuberculosis will require full participation by policy makers, the public health sector, medical practitioners, professional societies, community-based organizations, and voluntary organizations to implement the recommendations made in 2000 by the IOM in *Ending Neglect.*

B. Purpose of this Call for Action

The Stop TB USA Tuberculosis Elimination Plan Committee has drafted this update and based it upon the following documents that explain national guidelines and strategies that will need to be implemented to eliminate tuberculosis in the United States:

- Centers for Disease Control and Prevention. A strategic plan for the elimination of tuberculosis in the United States. *MMWR* 1989;38:269–272. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00001375.htm
- Centers for Disease Control and Prevention. Tuberculosis elimination revisited: obstacles, opportunities, and a renewed commitment—Advisory Council for the Elimination of Tuberculosis (ACET). *MMWR* 1999;48 (No. RR-09):1–13. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4809a1.htm
- Institute of Medicine. *Ending Neglect: The Elimination of Tuberculosis in the United States.* Washington, DC: National Academy Press; 2000.
- Centers for Disease Control and Prevention. Progressing toward tuberculosis elimination in low-incidence areas of the United States. *MMWR* 2002;51 (No. RR-5):1–16. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5105.pdf
- American Thoracic Society, Centers for Disease Control and Prevention, Infectious Diseases Society of America. Controlling tuberculosis in the United States: recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. *MMWR* 2005;54 (No. RR-12):1–81. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5412a1.htm
- Centers for Disease Control and Prevention. Plan to combat extensively drug-resistant tuberculosis: recommendations of the Federal Tuberculosis Task Force. *MMWR* 2009;58 (No. RR-03):1-43. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5803a1.htm

The aim of this plan is not to rewrite the IOM plan for eliminating tuberculosis: the IOM plan and its recommendations are still valid. The purpose of this plan is to call for stakeholder involvement and to serve as a foundation for making specific action plans to implement the IOM recommendations. The purpose of this call for action is to engage policy makers in all levels of government, the public health sector, medical practitioners, professional societies, community-based organizations, and voluntary organizations in the effort to eliminate tuberculosis in the United States.

C. Progress Assessment Summary

In its 2000 report, *Ending Neglect*, the IOM recommended that five specific goals be targeted in order to eliminate tuberculosis in the United States. Table 1 summarizes the current status of progress toward these goals.

TABLE 1

Success in Meeting Institute of Medicine Goals

Institute of Medicine Goal	Success	Comments
Maintain control of tuberculosis while adjusting to declining tuberculosis case numbers and rates	Yes	There has been continuing decline in tuberculosis case numbers and rates since 1993
Accelerate the rate of decline of tuberculosis cases and rates by increasing efforts at targeted testing and treatment of latent tuberculosis infection	No	The decline in tuberculosis is slowing, not accelerating. The treatment of latent tuberculosis infection remains largely limited to public health departments and has not been expanded by other medical care providers to the level required for tuberculosis elimination
Develop the new diagnostic, treatment, and prevention tools that will be necessary for the ultimate elimination of tuberculosis	Yes / No	Research on new tools has expanded significantly since 2000, but product development pipelines are still meager compared with research and development activity seen in other disease areas. Additionally, operational research needed to bring about widespread implementation by public health departments, other healthcare facilities, and laboratories is dwindling
Increase the involvement of the United States in global tuberculosis control	Yes	Yearly US Agency for International Development funding for global tuberculosis control has increased from $72 million to $162 million from 2002 to 2008. Tuberculosis-human immunodeficiency virus (HIV) funding accounts for 4% of the President's Emergency Plan for Acquired Immunodeficiency Syndrome (AIDS) Relief total program budget
Mobilize and sustain public support for elimination; measure progress toward the goal	Yes / No	There are ongoing efforts to mobilize public and political support, but success is only modest

The continued decline in case rates provides evidence that tuberculosis remains under control, but the acceleration of tuberculosis elimination that the IOM anticipated with the implementation of Goals 2 through 5 (Table 1) has not occurred. Treatment of latent tuberculosis infection is a tuberculosis prevention strategy that is critical to eliminate tuberculosis. However, expansion of the treatment of latent tuberculosis infection has not occurred and remains limited in public health departments where it is considered low priority when resources are scarce. Expansion of treatment for latent tuberculosis infection has been severely limited due to the lack of an effective, safe, and affordable short-course treatment regimen. Detailed information on the progress made toward the IOM goals is provided in Chapter II: "Eliminating TB in the United States," pages 20-35.

The 2008 tuberculosis case rates, the reported number of persons diagnosed with active tuberculosis per 100,000 persons per year, are shown in Table 2 (next page) for the overall total US population. The rate of 4.2 cases per 100,000 population is equivalent to 42 per million population, 42-fold higher than one per million, the definition of tuberculosis elimination. Also shown are the average annual percentage changes in tuberculosis case rates from 2003 through 2008 for the total US population and by birthplace and race/ethnicity.

Projecting these trends forward, it would take until 2107—97 years from 2010—to achieve the tuberculosis elimination goal of one case of tuberculosis per million for the entire US population. A major contribution to this estimate is the higher rate and slower annual decrease among foreign-born persons, a population projected to require 141 years for tuberculosis elimination.

TABLE 2

Projected Years for Tuberculosis Elimination: Based on 2000–2008 Rates per 100,000 per Year

	2008 Rate	% Change	Projected Year (Number of Years from 2010)
US Total	4.2	-3.8	2107 (97)
US-born	2.0	-5.9	2059 (49)
Foreign-born	20.3	-3.7	2151 (141)
Non-Hispanic White	1.1	-5.4	2052 (42)
Non-Hispanic Black	8.8	-5.5	2090 (80)
Non-Hispanic Asian	25.6	-5.9	2094 (84)
Hispanic	8.1	-3.4	2139 (129)

Source: R. Pratt, T. Navin, M. Chen, J. Becerra, CDC.

Racial and ethnic minority populations (blacks, Asians, and Hispanics) continue to be disproportionately affected by tuberculosis in the United States. Tuberculosis elimination among the various racial and ethnic minority populations is projected to take 80 to 129 years. The rates and delayed years of projected tuberculosis elimination for ethnic and racial groups also reflect the proportion of tuberculosis cases that occur among foreign-born persons within these groups. Foreign-born persons, who most likely arrived in the United States with latent tuberculosis infection that progressed to tuberculosis, accounted for 95% and 76% of cases among Asian and Hispanic residents respectively in 2008. Foreign-born persons made up 32% of tuberculosis cases reported among black persons, an increase from 5% in 1993.

Much of the ongoing cost, disability, and premature mortality that are predicted to continue for the next 97 years may be preventable if we implement the IOM recommendations. Tuberculosis disparately affects racial and ethnic minorities, yet every American remains at potential risk for tuberculosis due to the global burden of tuberculosis, including drug-resistant strains of tuberculosis that require treatment for up to two years. The following recommendations for action will benefit every American as well as our global neighbors who have an urgent need for the same new tools that we seek for the diagnosis, treatment, and prevention of tuberculosis.

D. Recommendations for Action

The Tuberculosis Elimination Plan Committee has developed a set of general recommendations for action on national, state, and/or local levels in all US communities and populations. Separate recommendations have been formulated for speeding up the development and implementation of tuberculosis diagnostics, drugs, and vaccines. Other recommendations have been developed for specific US-born and foreign-born populations to address the risk factors and/or interventions that are either unique or more important for those persons. In addition, the challenges of providing tuberculosis services in states with low tuberculosis case burdens have been a subject of discussion and research, and this document provides updated plans for action to accelerate tuberculosis elimination in areas with low incidences of tuberculosis.

1. General Recommendations for Action

The general recommendations reflect important roles that must be assumed by federal, state, county, and municipal agencies as well as other local and national organizations if tuberculosis is to be eliminated.

TABLE 3

General Recommendations for Action to Accelerate Tuberculosis Elimination in the United States

1. The Division of Tuberculosis Elimination of the Centers for Disease Control and Prevention should receive increased funding to fulfill its responsibilities in accelerating tuberculosis elimination. Essential elements include oversight, guideline development, updating model tuberculosis control laws, consultation, financial assistance, and technical support
2. The Division of Tuberculosis Elimination should receive additional funding in order to accelerate the research studies needed to evaluate and implement better tools for the diagnosis and treatment of latent tuberculosis infection
3. Municipal, county, and state officials should ensure the provision of timely access to high-quality, expert public health services for the diagnosis, treatment, and prevention of tuberculosis cases and outbreaks among their residents. Patient-centered, public health-based programs that respect the cultural and ethnic understanding, needs, and priorities of high-risk populations must be developed. Effective and just tuberculosis control laws and regulations should be maintained
4. Private and public healthcare providers, community health centers, hospitals, academic medical centers, professional medical organizations, correctional care facilities, and long-term care facilities should engage in providing quality diagnostic and treatment services for persons with tuberculosis and in the treatment of latent tuberculosis infection to prevent future tuberculosis cases
5. Community leaders and community-based organizations serving persons at increased risk of tuberculosis must engage in overcoming challenges faced by their constituents in eliminating the threat of tuberculosis for them, their families, and their communities
6. National, state, and local voluntary and professional organizations supporting the elimination of respiratory and infectious diseases should assist Stop TB USA in obtaining the infrastructure funding needed to mobilize its members and partners in generating the political will to implement the 2000 Institute of Medicine recommendations for tuberculosis elimination

2. New Tools

Tuberculosis control in the United States has been maintained over the past two decades by placing emphasis on the detection and treatment of tuberculosis and on the evaluation and treatment of contacts (persons exposed to infectious tuberculosis). These top-priority activities must be done well, and new diagnostic tools and treatments for active tuberculosis must be developed. But, as pointed out in the IOM report, accelerating our progress toward eliminating tuberculosis requires additional resources and tools to expand the treatment of latent tuberculosis infection. Tuberculosis elimination requires much more rapid development, evaluation, and implementation of new tools to accelerate the decline in the rate of cases of tuberculosis, particularly with the recent trends of stagnation in these case rates.

TABLE 4

Action Plans to Accelerate New Tools Development

1. Global tuberculosis research and development investment must increase nearly fivefold, from approximately $450 million per year to $2 billion per year, in order to meet the goals set by the Stop TB Partnership Global Plan 2006-2015. Support must cover the full pipeline of research activities. Funding must support critical work being conducted by US agencies as well as by universities, product development partnerships, and other not-for-profit entities. Donations from private philanthropy and increased investments from the private sector also are crucial
    - To address scientific gaps, accelerate development and ensure a robust pipeline of new candidate agents for diagnosis, prevention, and treatment, the National Institutes of Health should maintain and grow support for basic and discovery research and product development
    - The Centers for Disease Control and Prevention's Division of Tuberculosis Elimination has historically, and must continue to play, an important role in tuberculosis clinical research and field studies to ensure that promising tools can be further developed and introduced
    - The US Agency for International Development (USAID) is a significant supporter of clinical evaluation and introduction of new tools for use in developing countries and currently provides a small amount of funding for tuberculosis drug research. USAID is authorized to expand its current tuberculosis research and development funding and initiate new funding for vaccine development. It is important that appropriations support this enhanced authority
    - Governments, foundations, and the private sector must accurately track and transparently report tuberculosis research and development investments to ensure that funding gaps are addressed
2. Advocacy efforts to educate policy makers about the critical role of government funding for tuberculosis research and in the development of new diagnostics, drugs, and vaccines must be intensified and new constituents engaged
3. To address scientific barriers, basic research must be intensified to facilitate research and development of new tools

3. US-born Populations

Compared to foreign-born persons with tuberculosis, US-born persons with tuberculosis are more likely to have been homeless, to have reported abuse of alcohol or other substances, to be diagnosed in correctional care or long-term care facilities, and to have HIV infection. These observations are particularly important for persons belonging to minority populations and lead to specific actions needed to accelerate tuberculosis elimination in US-born populations.

TABLE 5

Action Plans for Tuberculosis Elimination among the US-born

Local, State, and Federal Government

1. Local, state, and federal government should:

- Adequately fund community-based testing and treatment for latent tuberculosis infection, focusing specifically on persons who are homeless, marginally housed, alcohol or drug abusers, or co-infected with human immunodeficiency virus (HIV) and on persons who have diabetes and other medical risk factors for disease progression
- Develop tuberculosis control programs in correctional facilities that function at the same level as external health department programs to improve screening and surveillance capacity, contact investigation, and case management and discharge planning of inmates who are moved frequently among different facilities, have high recidivism rates, or leave institutions before treatment is completed
- Increase resources to support early diagnosis of tuberculosis through screening for tuberculosis at sites where persons at risk for tuberculosis congregate, especially sites with high crowding and limited ventilation. Encourage the implementation of mandatory tuberculosis screening of all homeless persons in shelters, day drop-in centers, and other congregate sites to prevent outbreaks and spread of tuberculosis
- Provide the resources needed to implement geographic information system mapping and *M. tuberculosis* isolate genotyping in order to identify specific locations where tuberculosis transmission occurs, communicate this risk to community members, and gain support for targeted tuberculosis control efforts
- Partner with key community members and providers to promote education, create cohesive interventions, and develop policies and strategies that address the unique tuberculosis problems of each community and locality
- Increase tuberculosis education of staff in shelters, housing services, substance abuse treatment sites, and correctional facilities. Ensure that medical providers are trained to recognize tuberculosis risk factors in the patients they serve, including US-born patients

Community Partners

2. Medical providers and institutions that provide health services for high-risk US-born persons should incorporate programs to provide targeted testing and treatment for latent tuberculosis infection into their routine medical services, seeking assistance as needed from local and state tuberculosis control programs

3. Correctional institutions, homeless shelters, and substance abuse treatment facilities, where high-risk US-born persons tend to congregate, should implement mandatory tuberculosis screening to detect cases, prevent outbreaks, and limit the spread of tuberculosis

4. Community-based organizations that provide support and advocacy for high-risk US-born populations should educate their constituencies and the public about the hazards of tuberculosis in their target populations and the risks to the general community and should advocate for funding of public programs to protect against the disease

4. Foreign-born Populations

As noted in the 2000 IOM report, the burden of tuberculosis among foreign-born persons results from latent tuberculosis infection that progresses to tuberculosis after arrival in the United States, so eliminating tuberculosis requires expanded treatment of latent tuberculosis infection. There are also unique linguistic and cultural issues that must be addressed in providing quality tuberculosis services to many foreign-born persons.

TABLE 6

Action Plans for Tuberculosis Elimination among the Foreign-born

Federal Government

1. The Division of Tuberculosis Elimination should evaluate the feasibility of testing all immigrant applicants being screened overseas for latent tuberculosis infection (currently limited to children aged 2 to 14 years) including the use of the new tools of blood testing with interferon gamma release assays with the goal of treating latent tuberculosis infection with an effective, safe, short-course regimen
2. The US government must ensure that receiving jurisdictions are promptly notified of incoming refugees and Class B immigrants along with complete medical records from overseas tuberculosis screening so that local tuberculosis programs can complete follow-up in a timely manner. Mechanisms must be developed to track migration of new arrivals with diagnoses of latent tuberculosis infection to optimize chances for treatment completion and to allow for maintenance of medical record information
3. The US government must maintain and increase its commitment to global tuberculosis control and elimination, including the support for implementation and enhancement of existing effective control and prevention strategies and the development of new tools for diagnosis, treatment, and prevention of tuberculosis

Local and State Government

4. Local and state government should:
   - Collaborate with Centers for Disease Control and Prevention and overseas panel physicians in evaluating and ensuring the effectiveness of the overseas screening process of immigrants and refugees now that sputum cultures for tuberculosis have been added to the screening process
   - Ensure the follow-up of immigrants who have undergone overseas tuberculosis screening and testing for latent tuberculosis infection
   - Collaborate with agencies and organizations (such as US Immigration and Customs Enforcement [ICE]; federal, state, and local public health authorities; transnational referral programs; foreign consulates; and foreign national tuberculosis programs) to ensure continuity of care for ICE detainees with confirmed or suspected active tuberculosis who may be repatriated before completion of tuberculosis treatment
   - Work with civil surgeons, community health centers, and medical practitioners serving foreign-born populations and with institutions and employers that sponsor foreign-born

students, to raise the awareness of tuberculosis in high-risk foreign-born persons, reduce delays in diagnosis, and broaden the scope of targeted testing and treatment programs for latent tuberculosis infection. Services that can be provided by health departments include facilitating laboratory testing, providing medications, providing community and provider education and expert clinical consultation and referral services, and evaluating the effectiveness of community-based programs

Community Partners

5. Community health centers should make the diagnosis and treatment of latent tuberculosis infection a priority activity. This will require collaboration with public health agencies to provide a full range of tuberculosis prevention services for new immigrants and other high-risk populations (such as migrant workers) regardless of ability to pay, visa status, or movement among local health jurisdictions
6. Civil surgeons performing visa status adjustments for immigrants in their communities must ensure that their evaluations include effective tuberculosis screening according to current standards. Greater emphasis, combined with additional resources, must be placed on treatment of latent tuberculosis infection among immigrants diagnosed with latent tuberculosis infection during these examinations
7. Institutions and employers who sponsor students and workers from moderate- or high-burden tuberculosis countries, who under current policy are not required to undergo tuberculosis screening before entry to the United States, should establish tuberculosis screening programs for their constituents. Such programs should incorporate treatment for those diagnosed with latent tuberculosis infection
8. Medical practitioners who provide care to foreign-born persons should educate their patients about symptoms of tuberculosis and should incorporate tuberculosis screening, targeted testing, and treatment of latent tuberculosis infection into ongoing medical services to high-risk patients

5. Tuberculosis Low-incidence Areas

The challenges of progressing toward tuberculosis elimination in areas with low-incidence rates of tuberculosis are described in the 2002 report of the Advisory Council for the Elimination of Tuberculosis (ACET). The report recommends evaluating the feasibility of interstate regionalization by creating collaborative consortiums to ensure that high-quality, essential (core) elements of tuberculosis control are maintained. There are now two models that have been developed and implemented for regionalization of tuberculosis prevention and control. The first model is the New England Tuberculosis Consortium, a collaboration among the six New England tuberculosis programs and the CDC. These six states share a similar epidemiology pattern, common borders, and a history of past collaborative efforts. The New England Tuberculosis Consortium has built a regional leadership team that shares expertise and resources in an organized and supportive fashion.

The second model is described in the *Proposed Approach to Tuberculosis Control and Elimination in the Low-Incidence Region of Idaho, Montana, Utah and Wyoming,* which is available online at http://www.nationaltbcenter.ucsf.edu/research/patce.cfm. In this

model developed through a Tuberculosis Epidemiologic Studies Consortium project funded by the CDC, four western states with a team of CDC staff, national tuberculosis experts, and the Francis J. Curry National Tuberculosis Center staff worked to identify and address the challenges of controlling tuberculosis in low-incidence areas by implementing and evaluating a series of public health interventions to meet those challenges.

Three important findings were noted in both models. First, tuberculosis control program staff members and resources in low-incidence states cannot simply merge across the state boundaries to create a larger multistate program. Second, tuberculosis control services within each state can be enhanced when tuberculosis program staff collaborate in a multistate regional tuberculosis elimination effort. Third, limited—but necessary—additional federal resources, including personnel assigned to the region, must be provided to maintain effective regional collaboration.

A successful tuberculosis elimination campaign will lead to more tuberculosis low-incidence areas, and the lessons learned in the New England and the western state regions will be applicable to more areas of the United States. Core tuberculosis control services must be maintained, not eliminated, as the number of tuberculosis cases declines in order to avoid a resurgence in the disease, as occurred in the mid-1980s.

TABLE 7

Action Plans for Tuberculosis Elimination in Low-incidence Areas

Local, State, and Federal Government

1. Local, state, and federal government should:

- Stop the loss of core tuberculosis control capacity: Provide and sustain resources at local, state, and federal public health levels to maintain core tuberculosis control program functions in low-incidence regions as outlined in the “Progressing Toward Tuberculosis Elimination in Low-Incidence Areas of the United States” (*MMWR* 2002;51[No.RR-5]:1–16)
- Make progressing toward tuberculosis elimination in low-incidence areas a national priority

Federal Government

2. The Centers for Disease Control and Prevention should undertake the following roles and responsibilities:

- Continue to assess regional capacity and provide funding for expansion of regional tuberculosis control efforts in low-incidence states
- Provide additional support for the Division of Tuberculosis Elimination Field Services and Evaluation Branch to increase assignments of field-based medical officers and public health advisors to provide technical assistance and support for tuberculosis control and elimination efforts

- Ensure that federal funding to low-incidence states allows for innovative new strategies to improve tuberculosis elimination efforts
- Continue to sponsor operational research and to provide technical assistance for tuberculosis surveillance and program evaluation focused on the unique needs in low-incidence areas
- Collaborate with state health departments in low-incidence regions to ensure that all patients have access to the expertise, case management, and specialized treatment (including surgery) necessary for patients with treating multidrug-resistant tuberculosis
- Collaborate with state health departments in low-incidence areas to replicate and support successful models for providing regional access to facilities for prolonged health care and/or isolation when needed
- Assist in the investigation and control of outbreaks in collaboration with local and state health departments and other federal agencies
- Provide sufficient support to the regional training and medical consultation centers (RTMCCs) for field-based training and for medical consultation based on the needs of low-incidence areas
- Continue to periodically assess the status of tuberculosis control laws and regulations and propose model tuberculosis laws as needed

3. The US Department of Health and Human Services should support the Indian Health Service in tuberculosis control and elimination activities including:

- Assessing the local population-specific needs for services and strategies for tuberculosis elimination
- Collaborating with tribal, local, and/or state governments in the provision of services and developing surge capacity to address potential outbreaks

4. Health Resources and Services Administration (HRSA) should take the following actions for HRSA-supported community health centers:

- Commit to the goal of tuberculosis elimination for HRSA clinic populations
- Include tuberculosis risk assessments, screening, and prevention services in developing electronic medical record systems
- Include both targeted testing and completion of treatment for latent tuberculosis infection as priority clinical outcome measures
- Take a leading role in translating new tools for diagnosis, treatment, and prevention of tuberculosis into primary care practice

State and Local Government

5. State and local government should:

- Create a plan and/or participate in the creation of a regional multistate tuberculosis elimination plan that prioritizes activities of public health programs in low-incidence areas based on an assessment of resources, tuberculosis control goals, and input from community organizations and advocacy groups
- Develop and participate in regional programs to provide educational and training opportunities that meet the unique needs of public health staff in low-incidence areas for

whom providing quality tuberculosis services must compete with other assignments. Where feasible, design training and education activities to minimize travel, combine tuberculosis activities with other trainings or conferences, and use long-distance, web-based approaches

- Ensure the timely availability of high-quality laboratory services within low-incidence jurisdictions. In states where there is not enough need or where resources are inadequate for highly specialized tests, the state public health laboratory should arrange that certain tests be done at contract laboratories or regional public health laboratories and carefully monitor performance of these external laboratories
- Prevent the development of drug-resistant tuberculosis cases by ensuring the provision of case management with directly observed therapy for patients with active tuberculosis even in low-incidence, remote locations. This should include exploring novel approaches such as using trained, contracted, or volunteer community members to provide directly observed therapy or the assignment of public health teams or community health teams to remote locations
- Provide access to facilities and sufficient resources that allow for prolonged care through the completion of treatment for patients with complex needs including multidrug- and extensively drug-resistant tuberculosis

Community Partners

6. In low-incidence areas, non-governmental partners can play a particularly important role in tuberculosis elimination efforts because government agencies often have minimal infrastructure for disease control programs

- Tuberculosis-related education should prioritize general medical practitioners and emergency department providers because patients usually first seek medical attention in those sectors
- General and specialty medical associations should include tuberculosis among their educational programs for their constituents
- Organizations that provide advocacy and support for groups at high risk of tuberculosis should educate their constituencies about the importance of tuberculosis and should maintain close liaison with public health agencies
- Employers of workers from high-risk populations should ensure the ready access to medical care for their workers
- Organizations that provide emergency services, including overnight shelter, should consult with public health agencies to assess the risk of tuberculosis and establish appropriate control measures
- Directors of congregate living situations (such as correctional facilities and long-term care settings) should work with tuberculosis programs to prevent transmission within these facilities
- Colleges and universities that sponsor foreign students should consult with public agencies to assess the risk of tuberculosis among their students and establish appropriate control measures

E. Unexpected Decrease in Tuberculosis Cases Reported in the United States in 2009

Preliminary Report of an Unexpected Decrease in Tuberculosis Cases Reported in the United States in 2009: Implications for this *Call for Action*

Just prior to the publication of this *Call for Action,* the CDC released a preliminary notice in the *Morbidity and Mortality Weekly Report (MMWR)* on March 19, 2010, that a total of 11,540 tuberculosis cases were reported in the United States for a rate of 3.8 cases per 100,000 persons. This represents a 10.6% decrease in reported tuberculosis cases and an 11.4% decrease in the case rate compared to 2008. This is the greatest single year decrease in the case rate on record since 1953. Tuberculosis rates decreased substantially in 2009 among both foreign-born and US-born persons, though foreign-born persons and racial/ethnic minorities continued to bear a disproportionate burden of tuberculosis. Since this represents a far greater one-year decrease in case rate than the average 3.8% decline from 2000 through 2008 described earlier in this chapter, the Stop TB USA Tuberculosis Elimination Plan Committee would like to briefly discuss the implications of this new data for *A Call for Action on the Tuberculosis Elimination Plan for the United States.*

First, a full understanding of the causes of this remarkable change will require collection of additional information and analysis of its implications for the national goal of tuberculosis elimination. The potential contributors to this decline could include improved tuberculosis control but could also reflect surveillance reporting changes instituted in 2009, population demographic shifts, and under-diagnosis or under-reporting of cases. As noted in the *MMWR* report, the CDC and the National Tuberculosis Controllers Association are studying the possible explanations for the unexpectedly large drop in tuberculosis cases and rates.

Second, if this decrease in tuberculosis cases and rates is due to a true reduction in the occurrence of tuberculosis, this decrease does not diminish the importance of the recommendations in this document. An even greater acceleration of the rate of decline in tuberculosis cases will be needed if we are to eliminate tuberculosis by the year 2035 and avoid 253,000 preventable tuberculosis cases and the associated deaths, disability, and loss of family income. A decrease of over 10% per year, followed by 20% per year was called for by the IOM ten years ago.[12] Having finally achieved this first step is a call for action, not merely a call for celebration.

For more information, the *MMWR* report, "Decrease in Reported Tuberculosis Cases --- United States, 2009," is available at:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5910a2.htm.

F. Conclusion: The Call for Action

We are beginning to see the winds of change, but what we really need is a storm. It is imperative that we transform the way we diagnose, treat, prevent, and control TB—through biomedical research and public health measures—to the same extent that we have done and will continue to do with HIV/AIDS. [8]

—**ANTHONY FAUCI**, MD, Director
National Institute of Allergy and Infectious Diseases

Stop TB USA issues a call for action to all partners and stakeholders in the plan to eliminate the scourge of tuberculosis from the United States by 2035. To more rapidly progress toward eliminating tuberculosis in the United States, we call for the following five start-up steps to fully implement the IOM recommendations and the Stop TB USA action plans:

1. Commit to implementing the IOM recommendations in *Ending Neglect* and conduct a periodic review on the progress toward elimination
2. Develop new timelines and interim goals for tuberculosis elimination
3. With the assistance of national, state, and local voluntary and professional organizations, obtain the infrastructure funding to enable Stop TB USA to collaborate with CDC and engage its members and partners in generating the political will to implement the IOM recommendations in *Ending Neglect* and the action plans in this update
4. Address the federal funding gap by obtaining an independent assessment of how effectively the increased funding levels authorized in the Comprehensive Tuberculosis Elimination Act of 2007 could accelerate the development and implementation of new tools for diagnosis, treatment, and prevention of tuberculosis
5. Engage at federal, state, and local levels policy makers, the public health sector, medical practitioners, professional societies, community-based organizations, and voluntary organizations to commit to TB elimination

Each of these five steps will be needed for implementation of the general action plans (Table 3, page 10), action plans for new tools development (Table 4, page 11), and action plans for populations who are US-born, foreign-born, and living in areas with low tuberculosis case rates (Tables 5 through 7, pages 11-17). For more information on these steps, refer to Chapter II: "Eliminating TB in the United States," pages 32-35.

II. Eliminating Tuberculosis in the United States

A. Twenty-Year History

In 1984 Dr. James O. Mason, Director of the US Centers for Disease Control and Prevention (CDC), challenged the public health community to develop a strategy to eliminate tuberculosis from the United States. The US Health and Human Services Advisory Council for the Elimination of Tuberculosis (ACET) was established in 1987 by the Secretary of the US Department of Health and Human Services to provide recommendations for eliminating tuberculosis as a public health problem in the United States.[9]

1. Advisory Council for the Elimination of Tuberculosis Report, 1989

In 1989, the ACET report called for the elimination of tuberculosis in the United States by the year 2010, defining tuberculosis elimination as a case rate of less than one case of tuberculosis per million persons.[9] A year 2000 interim target of achieving a case rate of 3.5 per 100,000 was also established. When the report was published in 1989, the US case rate for tuberculosis was 9.5 per 100,000. The ACET report claimed that tuberculosis elimination was a realistic goal for three reasons: tuberculosis was retreating into geographically and demographically defined high-risk populations; biotechnology had the potential for generating better tools for diagnosis, treatment, and prevention; and advances in computer, telecommunications, and other technologies could enhance implementation of new tools.

A three-step plan of action to achieve tuberculosis elimination was proposed:

1. More effective use of existing prevention and control methods, especially in high-risk populations defined as human immunodeficiency virus (HIV)-infected persons, racial and ethnic minorities, the foreign-born, and the elderly
2. Development and evaluation of new technologies for tuberculosis treatment, diagnosis, and prevention
3. Rapid assessment and transfer of newly developed technologies into clinical and public health practice

2. Resurgence of Tuberculosis, 1985–1992

Ironically at the time of the preparation of the ACET report, there were early indications the United States was experiencing the first resurgence of tuberculosis known since national case reporting was instituted in 1953. The annual tuberculosis case rate had remained stagnant between 9.2 and 9.5 cases per 100,000 per year for the five-year period 1985 through 1989. The resurgence—related to the expansion of HIV infection, hospital transmission of *Mycobacterium tuberculosis*, multidrug-resistant tuberculosis,

disassembly of categorical public health tuberculosis programs at state and local levels, and increasing immigration from countries with a high incidence of tuberculosis—extended through 1992. The resurgence took a heavy toll in terms of tuberculosis-related illness and death, including healthcare workers, and also forced a large amount of additional resources to be returned to tuberculosis control.[10] After the public health capacity was rebuilt, a resumption of the downward trend in tuberculosis morbidity in the United States in 1993 led to a renewed interest in tuberculosis elimination. In 1999, ACET reassessed its 1989 plan and made updated recommendations for tuberculosis elimination.[11]

In its reassessment, ACET concluded that the success against resurgent tuberculosis should reinforce the nation's confidence that:

- Tuberculosis can be controlled and ultimately eliminated in the United States with expanded partnerships and the development of new tools for diagnosis, treatment, and prevention of tuberculosis
- Tuberculosis elimination will have widespread economic, public health, and social benefits
- Committing to decisive action against tuberculosis in the United States would fulfill an obligation to persons throughout the world who have this preventable and curable disease

3. Institute of Medicine Report, 2000

As an outgrowth of the renewed interest in tuberculosis elimination, an independent study was conducted by the Institute of Medicine (IOM) and published in 2000.[12] That report, *Ending Neglect: The Elimination of Tuberculosis in the United States,* affirmed a commitment to ACET's 1989 goal of eliminating tuberculosis in the United States and offered five recommendations:

1. Maintain control of tuberculosis while adjusting to declining incidence and changing systems of healthcare management
2. Accelerate the rate of decline of tuberculosis by increasing efforts at targeted testing and treatment for latent tuberculosis infection
3. Develop new tools necessary for the ultimate elimination of tuberculosis: new diagnostic tests, treatments, and more effective vaccines
4. Increase the involvement of the Unites States in global tuberculosis control
5. Mobilize and sustain public support for elimination and measure progress toward the goal

The IOM report projected tuberculosis elimination by 2035 *if* the first and second of these recommendations lead to a 10% initial annual rate of decline in tuberculosis incidence that is followed a decade later by an accelerated 20% annual decline brought on by the implementation of new tools. The IOM also noted the cyclical nature of the nation's response to tuberculosis and warned against allowing the occurrence of another "cycle of neglect." The national response to decreasing rates of tuberculosis

prior to the 1980s was to decrease public health resources for tuberculosis control. In order to reverse the erosion of the tuberculosis control infrastructure that preceded and caused the resurgence of 1985 through 1992, major increases in annual funding to the CDC for local TB control were required from 1992 through 1994. As the national, state, and local tuberculosis control programs were rebuilt, the tuberculosis case rate for the United States decreased from 10.4 in 1992 to 5.8 per 100,000 persons per year by 2000, but this rate was well above the interim goal of 3.5 proposed by ACET in 1989.

4. Costs of Implementing Recommendations, 2002

In its 2002 report, *TB Elimination: The Federal Funding Gap* (available at http://edisk.fandm.edu/dick.fluck/TBWhitePaper02.pdf), over 50 medical professional, healthcare, and service organizations supported a National Coalition for the Elimination of Tuberculosis (NCET) recommendation for a 3.8-fold increase in the annual budget of the Division of Tuberculosis Elimination from roughly $140 million to $528 million. NCET based this recommendation on two reasons. First, federal funding for tuberculosis control from 1993 through 2000 had experienced significant cuts once seemingly level funding was adjusted for inflation. Second, major increases in funding for the Division of Tuberculosis Elimination at the CDC would be needed for tuberculosis elimination to succeed, including intensification of tuberculosis elimination efforts and research to bring new tools into use. Populations to be targeted for intensified effort included persons at higher risk for tuberculosis, including foreign-born persons living in the United States, persons living along the US-Mexico border, and minority populations experiencing tuberculosis health disparities, particularly in the southeastern United States. Increased funding was recommended to accelerate the Division's tuberculosis research agenda, including the CDC's Tuberculosis Epidemiologic Studies Consortium's applied research and the Tuberculosis Trials Consortium's studies to evaluate new tuberculosis treatments.

5. Challenges in Low-incidence Areas, 2002

The challenges of progressing toward tuberculosis elimination in areas with low-incidence rates of tuberculosis were described in ACET's 2002 report, "Progressing Toward Tuberculosis Elimination in Low-Incidence Areas of the United States." The report focused on the 22 states that faced the challenge of maintaining an effective tuberculosis control program with 50 or fewer tuberculosis cases per year and an annual tuberculosis rate of less than 3.5 cases per 100,000 persons per year. The report recommended evaluating the feasibility of interstate regionalization of tuberculosis services as proposed previously by the IOM. One of the initial projects of the Division of Tuberculosis Elimination's Tuberculosis Epidemiologic Studies Consortium was to evaluate the implementation of regional approaches to enhance tuberculosis control and elimination in the low-incidence region comprised of Idaho, Montana, Utah, and Wyoming.

6. Tuberculosis Control Guidelines, 2005

Building on the issues raised in the IOM report, the 2005 guidelines on tuberculosis control issued by the American Thoracic Society (ATS), Infectious Diseases Society of America (IDSA), and the CDC[13] concluded that "the traditional model of tuberculosis control, in which planning and execution reside almost exclusively with the public health sector, is no longer the optimal approach during a sustained drive toward the elimination of tuberculosis." That report affirmed the essential role of the public health sector in planning, coordinating, and evaluating the tuberculosis control effort but, in addition, proposed roles and responsibilities for a full range of stakeholders whose participation was deemed to be essential.

7. Comprehensive Tuberculosis Elimination Act (P.L. 110-392)

The Comprehensive Tuberculosis Elimination Act of 2007 was signed into law in late 2008, authorizing up to $210 million per year in funding for the CDC's Division of Tuberculosis Elimination. If followed by full appropriation of funding, this roughly 50% increase in the funding for the Division will help to reverse the 40% effective loss of funding due to inflation over the previous 15 years. Based upon the 2002 NCET report, additional increases will be needed to develop, evaluate, and implement the new tools that will be required to eliminate tuberculosis from the United States.

B. Epidemiological Progress and Trends

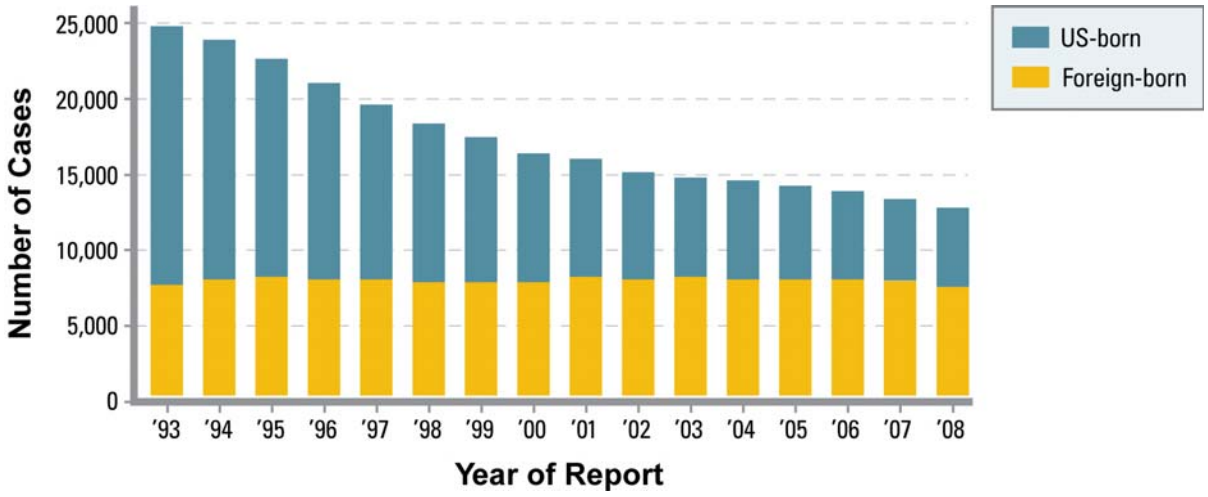
In 2008, reported cases of tuberculosis decreased to 12,904 for an annual incidence rate of 4.2 cases per 100,000 persons, the lowest recorded number and rate since national reporting began in 1953. Since the tuberculosis resurgence in 1985 to 1992, there has been an uninterrupted 52% decline in tuberculosis incidence in the United States. However, the rate of that decline is slowing, from an average 6.6% decrease in cases per year from 1993 to 2002, to an average 3.4% decline from 2003 to 2008. This change coincided in 2002 with the observation that, for the first year in US history, foreign-born persons accounted for the majority (51%) of reported tuberculosis cases, a proportion that has increased to 59% of tuberculosis cases reported in 2008.[14]

1. Tuberculosis in Foreign-born Populations

As shown in Figure 1, the decrease in reported cases of tuberculosis in the United States has occurred primarily among the US-born population with a 70% drop from 17,422 cases in 1993 to 5,283 cases in 2008; whereas, the number of reported tuberculosis cases in foreign-born populations has increased 2% from 7,403 to 7,563 in 2008. Case rates for US-born persons decreased to 2.0 cases per 100,000 persons in 2008 (a 73% decrease from 1993), while the rate among foreign-born persons decreased only 40% to 20.3 cases per 100,000 persons.

FIGURE 1

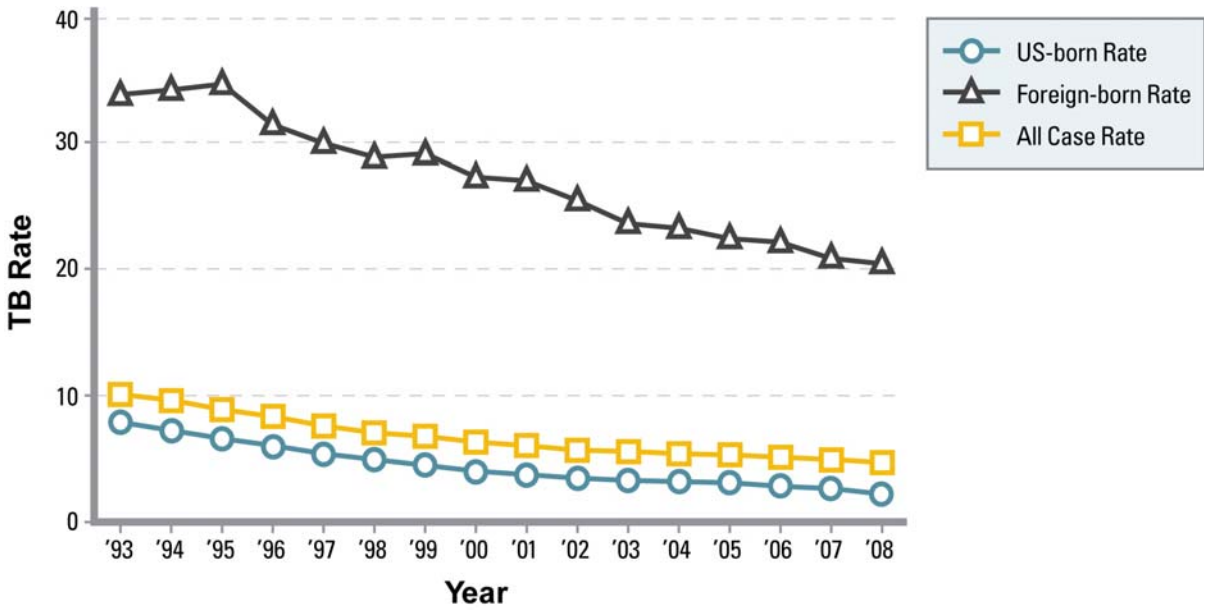
Number of US Tuberculosis Cases Reported in US-born and Foreign-born Persons, 1993-2008



The trends for the annual tuberculosis rates for the United States and the separate populations of US- and foreign-born persons (Figure 2) demonstrate a decrease in slope after 2002, representing a slowing of the decline in tuberculosis case rates for the overall US population and the US-born sub-population. Rates were 10.2-fold higher among foreign-born compared to US-born persons in 2008, accounting for a projected delay until year 2151 for tuberculosis elimination in foreign-born persons compared to year 2059 for those born in the United States (Table 2, page 8).

FIGURE 2

Tuberculosis Case Rates (Cases per 100,000 Population) for US-born and Foreign-born Persons, United States, 1993-2008



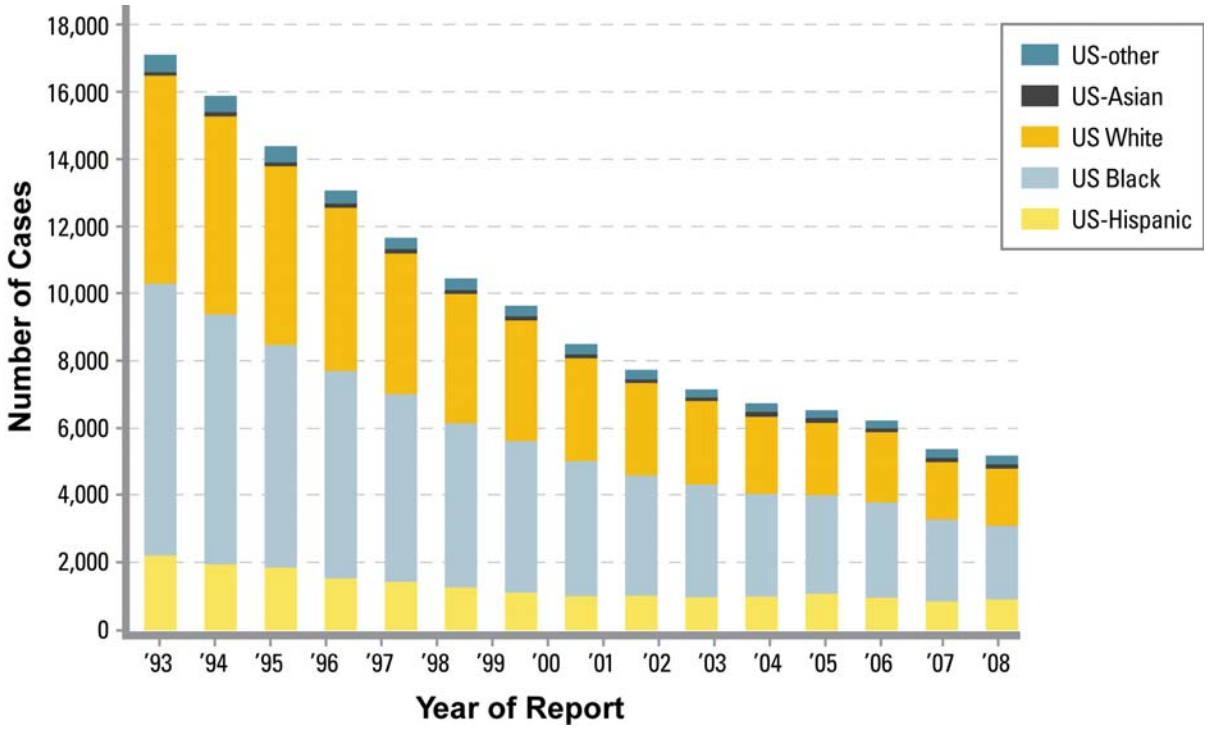
If we maintain the annual percent change in case rates seen from 2003 through 2008, it will take an estimated 97 years from 2010 to reach the tuberculosis elimination goal of one case per million for the entire US population (Table 2, page 8). A major contribution to this estimate is the higher rate and slower annual decrease among foreign-born persons, for whom tuberculosis elimination is projected to require 141 years.

2. Persisting Disparity of Tuberculosis

Accurate population estimates are not currently available for race and ethnicity stratified by birthplace. However, trends in the number of reported cases of tuberculosis among US-born persons by race and ethnicity (Figure 3) indicate a persisting disparity of tuberculosis among US-born blacks with no evidence of improvement and a persistence of approximately 1,000 cases per year among Hispanics.

FIGURE 3

Number of Tuberculosis Cases Reported in US-born Persons by Race and Ethnicity, 1993-2008



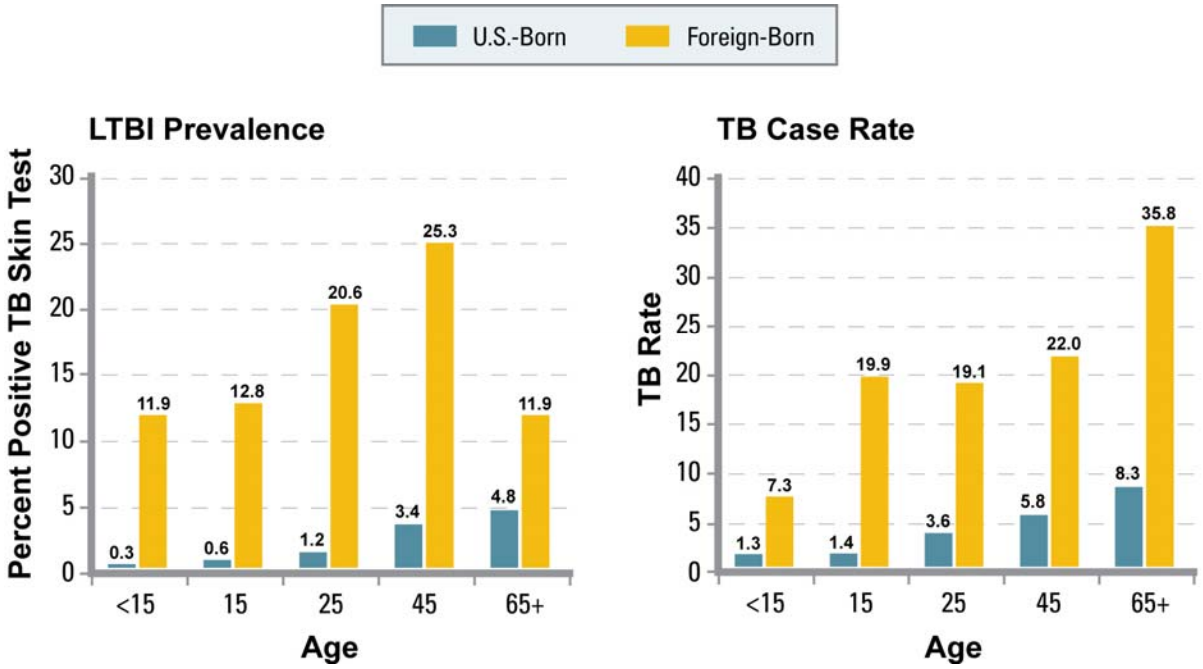
The determinants of risk of tuberculosis, however, are not limited to birthplace and race or ethnicity. Certain other readily-identified subgroups of the US population have been consistently found to experience rates of tuberculosis much higher than the population as a whole.[13] These include persons with tuberculosis risk factors of lower socioeconomic status, homelessness, incarceration, abuse of alcohol and/or other substances, HIV infection, and certain underlying medical conditions.

3. Latent Tuberculosis Infection

These differences in tuberculosis incidence associated with birthplace, race, ethnicity, and socioeconomic factors are also reflected in population rates of latent tuberculosis infection among US residents. A recently published survey from the CDC[15] indicated that the prevalence of latent tuberculosis infection (defined as the percentage of persons with a positive tuberculin skin test) in the US population in 1999 and 2000 was 4.2%, with much greater prevalence rates of infection among immigrants and persons in poverty. Prevalence rates were 18.7% in immigrants compared to 1.8% in US-born persons. Among those living below the poverty level, 6.1% were infected compared to 3.3% of those not living in poverty.

FIGURE 4

US-born and Foreign-born Prevalence of Latent Tuberculosis Infection (LTBI) and Case Rates (Cases per 100,000 Population) by Age, 1999–2000



The age-specific data show striking parallels in risk of tuberculosis and latent tuberculosis infection among US residents by birthplace (US versus non-US; Figure 4) that, combined with the marked differences in tuberculosis rates among segments of the US-born population, strongly suggest that the barriers to tuberculosis elimination may differ for the populations of US-born and foreign-born persons in the United States. A successful tuberculosis elimination plan for the United States requires approaches to address the unique challenges posed in different populations and to identify the partners who need to be engaged for the effort to succeed.

C. Progress Assessment

1. Success in Meeting Institute of Medicine Goals

One way to assess recent progress toward tuberculosis elimination in the United States is to evaluate success in implementing the five specific goals proposed by the IOM in its 2000 report.[12] Table 1 (page 6) summarizes the current status of progress on the IOM recommendations.

Whereas tuberculosis remains under control (IOM Goal 1), as evidenced by continued declining case rates, the annual rate of decline is slowing, not accelerating. Why is the United States not achieving IOM Goal 2, the acceleration of the decline in tuberculosis? A recent report found that in the Netherlands a similar gradual annual decline in tuberculosis incidence was due to the natural replacement of older population members, who have high rates of latent tuberculosis infection and risk of progression to tuberculosis disease, by younger residents with successively lower rates of latent tuberculosis infection, resulting from less exposure to tuberculosis at younger ages.[16] In the United States, the very low rates of latent tuberculosis infection in younger persons are seen only in the native-born population, but rates are much higher in those born abroad and parallel the higher rates of tuberculosis by age group as seen in Figure 4 (page 27).

Treatment of latent tuberculosis infection is a tuberculosis prevention strategy that is critical to eliminate tuberculosis. The ATS/CDC report on targeted testing and treatment of latent tuberculosis infection,[17] as well as the IOM report Goal 2, called for expansion of treatment of latent tuberculosis infection into the private medical sector as a means to increasing access to this preventive intervention against tuberculosis. However, a survey conducted by the CDC Tuberculosis Epidemiologic Studies Consortium found that in 2002, over 90% of all latent tuberculosis infection treatment was administered in public health clinics, including those serving immigrants and refugees, and in corrections facilities.[18]

Expansion of the treatment of latent tuberculosis infection has not occurred and remains limited in public health departments where it is considered low priority when resources are scarce. In addition, the completion rate for the standard nine-month course of isoniazid for latent tuberculosis infection is often less than 50% to 60%. The lack of an effective, safe, and affordable short-course regimen that would improve treatment completion rates has severely limited expansion of treatment for latent tuberculosis infection.

The failure to achieve IOM Goal 3—to develop and implement new tools for the diagnosis, treatment, and prevention of tuberculosis—continues to pose a major impediment to tuberculosis elimination. The call for new tools was made by ACET in the initial tuberculosis elimination plan in 1989, repeated by ACET in 1999, and stated as necessary in the 2000 IOM report in order to double the rate of decline in tuberculosis cases by the year 2010. Investment in research and development for new

tools for tuberculosis has been deemed "woefully inadequate," especially when compared to research and development expenditures for HIV.[19]

Unfortunately, two decades into the tuberculosis elimination effort, few new tools have been developed, and none yet has been widely implemented. There have been no substantive changes in the standard drug regimen for active tuberculosis since the 1980s. The Federal Tuberculosis Task Force noted the major problems now faced by clinicians and public health officials in addressing the needs of tuberculosis patients infected with multidrug- resistant (MDR) and extensively drug-resistant (XDR) strains of *Mycobacterium tuberculosis*.[20] To prevent latent tuberculosis infection from progressing to active tuberculosis, the nine-month isoniazid treatment, introduced in the 1960s, remains the treatment regimen of choice, and no approved treatments are available for persons infected with MDR or XDR strains. A new generation of tests for latent tuberculosis infection, interferon gamma release assays, has been licensed, but due to limited clinical evaluation there continues to be controversy concerning their proper role in clinical practice.[21] The Division of Tuberculosis Elimination at the CDC has committed about $9 million per year to fund the Tuberculosis Trials Consortium. This consortium, funded with domestic dollars, conducts international clinical trials of new treatment tools that will benefit patients in the United States and improve the outcomes of tuberculosis treatment globally in high-burden countries.

Considerable progress has been made on IOM Goal 4, increasing involvement by the United States in global tuberculosis control. The President's Emergency Plan for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID) represent major initiatives in addressing the global burden of tuberculosis. The Division of Tuberculosis Elimination devotes most of its roughly $140 million annual budget to domestic tuberculosis elimination efforts but plays a major role in a number of countries in implementing the PEPFAR and USAID initiatives. Although this global effort represents good progress on Goal 4, the federal global tuberculosis efforts through PEPFAR and USAID should be better coordinated and balanced with domestic tuberculosis control and elimination efforts. Although the burden of tuberculosis cases globally overwhelms the numbers in the United States, tuberculosis elimination will require increases in both domestic as well as global funding.

Finally, a critical element in concerted public health action is broad public consensus on the importance of the endeavor. According to the IOM report, "social mobilization is necessary to build and sustain political will (for tuberculosis elimination) in the United States and can lead to similar efforts internationally."[12] The United States has a long history of social mobilization, the enlistment and coordination of various individuals and groups, in support of tuberculosis control efforts. However, today tuberculosis is not generally viewed as a problem in the United States,[12] and there has been only limited success over the last ten years in meeting IOM Goal 5. NCET, the predecessor of Stop TB USA, made a concerted effort to advocate for tuberculosis elimination, but this effort was not successful in developing the political will needed in order to accelerate the development and implementation of the new tools needed for diagnosis, treatment, and prevention of tuberculosis.

2. Robustness of Government Funding

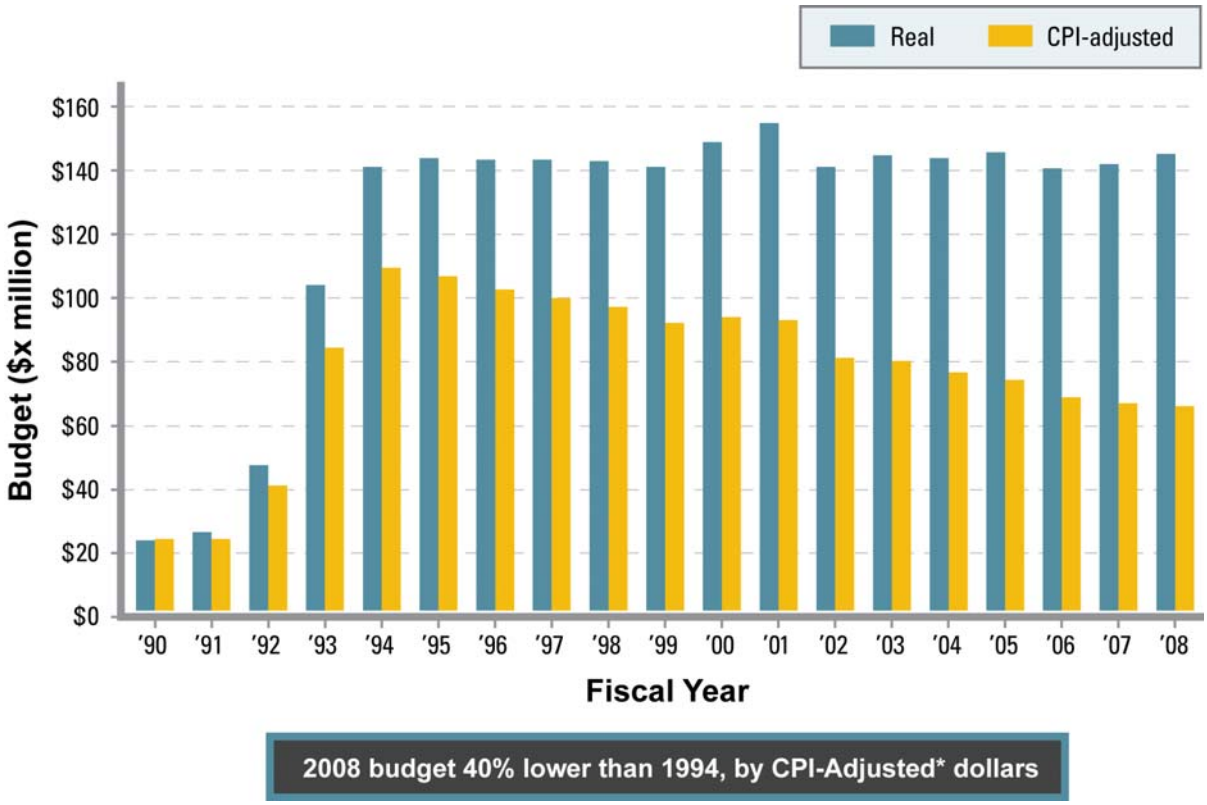
Another measurement of progress toward tuberculosis elimination is the robustness of financing from public and private sources. Despite the recommended increase in the annual budget of the Division of Tuberculosis Elimination to the $528 million recommended in the 2002 NCET report, *TB Elimination: The Federal Funding Gap,* effective funding levels of the Division have decreased 40% since 1994 due to the combination of flat-funding despite inflation, budget cuts, and rescissions (Figure 5, page 31).

The Federal Tuberculosis Task Force Plan in Response to the Institute of Medicine Report, Ending Neglect: The Elimination of Tuberculosis in the United States 2003[22] concluded that the five recommendations of the IOM report "cannot be implemented with current funding." As a result of cuts in federal funding to states for tuberculosis control, targeted testing and treatment programs for latent tuberculosis infection are being reduced or eliminated, and there is evidence that preventable cases of active tuberculosis are rising.

The 2002 ACET report, "Progressing Toward Tuberculosis Elimination in Low-Incidence Areas of the United States" cited loss of expert personnel and resources among reasons why there has not been more progress.[23] That report asserted that local and state health departments have the most important role in controlling tuberculosis, but it also cited evidence of deficient funding for tuberculosis control, not to mention tuberculosis elimination efforts, throughout states and localities in the United States. In addition, there is a predicted loss of skilled, experienced staff. A Health Resources and Services Administration report from 2005 cited an impending crisis in the public health workforce as older workers across a broad range of disciplines retire, requiring increased funds for training if they are to be replaced.[24]

FIGURE 5

Annual CDC Tuberculosis Budget, FY 1990–FY 2008



CPI = Consumer Price Index.

3. Overall Assessment of Progress Toward Tuberculosis Elimination

The United States is not moving purposefully toward the elimination of tuberculosis. Epidemiological data indicate that interim elimination targets have not been met, that the rate of decrease in tuberculosis incidence is slowing, and that, if the current trend continues, tuberculosis elimination in the United States will require nearly 100 years.

Reasons for lack of progress toward elimination, presented above and expanded upon in subsequent sections of this report, include:

- The ongoing global tuberculosis epidemic, including HIV/tuberculosis co-infection, which continues to impact tuberculosis incidence in the United States
- A 40% erosion, rather than the recommended over 3.8-fold increase, in resources for tuberculosis control

- Insufficient effort to speed the decline of tuberculosis by targeting persons with latent tuberculosis infection and high risk of progressing to active tuberculosis (IOM Goal 2)
- Insufficient funding for research and development for new tools for diagnosis, treatment, and prevention (IOM Goal 3)
- Lack of public understanding and support at the national, state, and local levels for tuberculosis elimination in order to make it a high national priority (IOM Goal 5)
- Lack of the development of, consensus on, and advocacy for specific strategies for tuberculosis control in high-risk groups
- Continued lack of successful advocacy for tuberculosis elimination

D. The Call for Action to Eliminate Tuberculosis from the United States

Stop TB USA issues a call for action to all partners and stakeholders in the plan to eliminate the scourge of tuberculosis from the United States by 2035. To more rapidly progress toward eliminating tuberculosis in the United States, the Stop TB USA TB Elimination Plan Writing Committee has identified general and specific action plans (Tables 3-7, pages 9-17) and now issues a call for action on five start-up steps that are critical to fully implement the IOM recommendations and the Stop TB USA action plans:

1. Commit to implementing the IOM recommendations in *Ending Neglect* and conduct a periodic review on the progress toward elimination
2. Develop new timelines and interim goals for tuberculosis elimination
3. With the assistance of national, state, and local voluntary and professional organizations, obtain the infrastructure funding to enable Stop TB USA to collaborate with CDC and engage its members and partners in generating the political will to implement the IOM recommendations in *Ending Neglect* and the action plans in this update
4. Address the federal funding gap by obtaining an independent assessment of how effectively the increased funding levels authorized in the Comprehensive Tuberculosis Elimination Act of 2007 could accelerate the development and implementation of new tools for diagnosis, treatment, and prevention of tuberculosis
5. Engage at federal, state, and local levels policy makers, the public health sector, medical practitioners, professional societies, community-based organizations, and voluntary organizations to commit to TB elimination

1. Implementation of the Institute of Medicine Recommendations

The Tuberculosis Elimination Plan Committee endorses the IOM's year 2000 recommendations in *Ending Neglect* in which the IOM defined five major goals to achieve in the tuberculosis elimination campaign for the United States (Table 1, page 6). The tuberculosis elimination effort is failing, not for want of the right goals or specific recommendations, but rather because the IOM recommendations needed to achieve those goals have not been fully implemented. For example, to eliminate tuberculosis, it is critical that the IOM recommendation to accelerate the development of new tools is followed. Tuberculosis may be controlled but not eliminated in our lifetimes, or even within the lifetimes of our children, if we are forced to rely upon the outdated tools in current use. Tuberculosis elimination will require an unprecedented effort to ensure that core tuberculosis control functions are maintained and to finally bring into use the new tools called for in 2000 by IOM and two decades ago by ACET.

2. Development of New Timelines and Interim Goals

In addition, the Committee recommends that a new timeline be developed for the goal for tuberculosis elimination in the United States, along with new interim targets. These new interim targets must be realistically achievable with broader application of existing tuberculosis elimination tools as well as with the implementation of new tools and strategies that could be more rapidly implemented with the authorized increase in federal funding.

Periodic evaluations of progress will need to be conducted. The IOM (Recommendation 7.3) requested that the Office of the Secretary of Health and Human Services conduct periodic evaluations of actions taken in response to the recommendations made in 2000, but it is not clear that this recommendation was followed. We recommend that Stop TB USA conduct periodic evaluations of the action taken on the recommendations in this report and provide reports to ACET that will be forwarded to the Secretary of the Office of the Department of Health and Human Services. The first report should be within two years (2012) and at two-year intervals thereafter.

3. Obtaining Infrastructure Funding for Stop TB USA to Enable Collaboration with Centers for Disease Control and Prevention

The CDC should collaborate with the members and partners of Stop TB USA in implementing specific action plans for accelerating TB elimination including:

- Consensus-building, advocacy, and mobilization
- Acceleration of the development and implementation of new tools for diagnosis, prevention, and treatment
- Implementation of strategies to reach high-risk segments of the US population

The IOM recommended that the NCET provide the leadership and oversight for coordinating the engagement of these partners and stakeholders and ensuring effective collaboration with the CDC. NCET, now identified as Stop TB USA, lacks the resources needed to meet this challenge. National, state, and local voluntary and professional

organizations supporting the control and elimination of respiratory and infectious diseases will need to assist Stop TB USA in obtaining the infrastructure funding needed to engage all its members and partners in generating the political will to implement the 2000 recommendations and the updated action plans in this document, a challenge in any fiscal climate, and even more so in recessionary times.

4. Closing of the Federal Funding Gap

Opportunities to Address the Federal Funding Gap

Although endorsing the IOM's year 2000 recommendations in *Ending Neglect,* the Tuberculosis Elimination Plan Committee concludes that even the IOM's revised timeline of 2035 cannot be met due to inadequate funding. Federal funding has not increased to the level recommended by the IOM as necessary to accelerate the elimination of tuberculosis.

There are encouraging developments—but as yet unfulfilled promises—toward addressing this major funding gap. The Comprehensive Tuberculosis Elimination Act of 2007 increased the federal funding authorized for CDC's Division of Tuberculosis Elimination to $210 million for 2008 and then to $243 million per year over the next three years. However, the actual funding appropriated for the Division remained essentially flat at just over $144 million for 2008. All members and partners of Stop TB USA need to mobilize to build the political will to increase the Division's funding to the full appropriated levels.

Assessment by the Federal Tuberculosis Task Force of the Benefits of the Recommended Increase in Funding for New Tools for Tuberculosis Elimination

As discussed above, new tools are needed for the diagnosis, treatment, and prevention of tuberculosis. These tools are a critical component of the tuberculosis elimination plan for the United States as proposed in 1989 and updated by the IOM in 2000. Addressing the need for new tools requires a coordinated federal intervention, a role uniquely suited for the Federal Tuberculosis Task Force.

The Federal Tuberculosis Task Force outlined the need for new tools development and implementation in the 2009 plan for extensively drug-resistant tuberculosis. We call for an independent review to assess the potential impact on the development and implementation of new tools that could be expected by increasing funding to the levels authorized in the Comprehensive Tuberculosis Elimination Act of 2007. We request that this assessment be completed within four months of this report in order to use this assessment in proposing new interim goals in the tuberculosis elimination campaign. Increased new tools funding must include basic science research, the focus of the National Institutes of Health, as well as operational research, the focus of the CDC.

5. Engagement of a Broad Range of Stakeholders

The control and eventual elimination of tuberculosis in the United States is not just a federal responsibility. There must be a renewed and expanded commitment to the goal

of tuberculosis elimination in the United States by municipal, county, and state as well as federal policy makers if adequate resources, including funding, are provided.

Much greater social mobilization is required to implement the measures needed to eliminate tuberculosis. In order to create this social mobilization, Stop TB USA, other stakeholders, and partners (including professional and voluntary organizations) must increase and maintain public awareness of the ongoing threat posed by tuberculosis.

The success of this effort requires that stakeholders and partners join with Stop TB USA in endorsing the revised goal and interim targets as well as the implementation of general recommendations for the nation as a whole and those specific to populations at higher risk. The 2005 tuberculosis control guidelines provided detailed roles and responsibilities for the partners who must be involved for tuberculosis elimination to be successful.[13] For more discussion on stakeholders and potential partners involved in tuberculosis, refer to Chapter VII: "Mobilizing Partners in the Fight against Tuberculosis," pages 76-82.

TO CONCLUDE AND MOVE FORWARD: As seen in the progress assessment, the IOM recommendations have not been fully implemented, and the goal of eliminating tuberculosis in the United States by 2035 remains beyond reach with our current approach. Stakeholders across the country must join the effort to develop and implement new, creative measures to accelerate the elimination of tuberculosis.

III. New Tools

There is a critical unmet need globally as well as within the United States for better tools to diagnose, treat, and prevent tuberculosis. Despite promising advances in research for new diagnostics, drugs, and vaccines, significantly increased funding is needed in order to accelerate the development, evaluation, and implementation of these new tools. A thorough analysis of tuberculosis research activities and funding trends for 2005 through 2008, recently updated and published by the Treatment Action Group (TAG), indicates a significant shortfall in funding for tuberculosis research and development based on the funding needs identified by the *Global Plan to Stop TB 2006 – 2015* and by TAG. At the current pace, only $2.05 billion will have been spent on tuberculosis research and development between 2006 and 2015, less than a quarter of the $9 billion recommended by the Global Plan and just one tenth of the $20 billion recommended by TAG.

TAG also compiles yearly *Pipeline Reports* detailing the global status of diagnostic, treatment, and prevention research developments for tuberculosis as well as human immunodeficiency virus (HIV) and hepatitis. These *Pipeline Reports* and the *Critical Analysis of Funding Trends* are available online at http://www.treatmentactiongroup.org.

A. Update on Progress in New Tools Development

1. Diagnostics

There are currently two blood tests licensed in the United States for the detection of latent tuberculosis infection that hold promise for improving the accuracy and timeliness of diagnosis. These tests, called interferon gamma release assays (IGRAs), appear to overcome many of the well-known problems with the Mantoux tuberculin skin test. The tuberculin skin test requires that a healthcare provider inject fluid into the skin of the forearm and examine the arm 48 to 72 hours later for thickening or induration of the skin. Administration of this test requires training to measure small differences in the skin where the fluid was injected and can be falsely positive in some, but not all, persons who have had the bacilli Calmette-Guérin (BCG) vaccination for tuberculosis.

Insufficient clinical research funding has delayed the implementation of the IGRA tests as public health officials and clinicians await the results of testing in high-risk populations such as children and persons with impaired immune systems. The implementation of IGRA tests has also been limited because the far higher cost of blood tests, compared to the tuberculin skin test, poses a major limitation in public health settings that are experiencing budget cuts.

The currently available diagnostic tests for active tuberculosis and for detection of drug-resistant strains in the United States include liquid culture methods that diagnose most tuberculosis cases within two weeks and provide drug susceptibility test results within an additional one to two weeks. Another method for detecting the genetic material of tuberculosis in a sputum sample, which can produce results one or more weeks faster than liquid culture, is the licensed test called nucleic acid amplification (NAA). The implementation of NAA testing, however, particularly in public health settings, has been delayed due to the additional expense added by the cost of cultures that are still required in order to test for drug susceptibility. There are also promising newer diagnostic methods that are able to detect multidrug-resistant tuberculosis within just days, but implementation of these tests remains limited because of inadequate operational research, the official approval processes, cost issues, and/or laboratory expertise.[25]

2. Drugs

Today's first-line drugs for the treatment of tuberculosis were developed and brought to the market more than 40 years ago, after which, research and development ground to a halt due to a lack of commercial incentive to invest in new therapies. Due to the complexity of the tuberculosis bacterium, tuberculosis disease requires that it be treated with multiple drugs at the same time. The current treatment regimen, a combination of four drugs administered daily for six to nine months, is cumbersome, potentially toxic, and places an extraordinary burden on patients and healthcare providers alike. Incomplete and improper treatment has led to the growth of multidrug-resistant strains of tuberculosis (MDR TB) that are much more difficult and costly to treat. The threat of antibiotic resistance has been further intensified by the emergence of extensively drug-resistant tuberculosis (XDR TB), which, in some cases, can be virtually untreatable due to the lack of effective anti-tuberculosis drugs. The current treatment regimen is also limited by the fact that the cornerstone of first-line treatment, rifampin, is incompatible with certain commonly-used antiretroviral therapies for human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS). Ideal new regimens will significantly shorten and simplify treatment, be compatible with antiretrovirals and other commonly-used medicines, and address drug resistance.

After near-total stagnation of the global pipeline for anti-tuberculosis drugs, the founding of the Global Alliance for TB Drug Development in 2000 and the recent entry of several pharmaceutical companies into the tuberculosis drug research and development arena is encouraging. Currently there are seven drug candidates in clinical development for tuberculosis and dozens more in earlier stages of development. However, attrition rates are high for drug development, and only a small number of compounds discovered will ever reach registration. Since tuberculosis will always require multiple drugs in a combination treatment, a revolutionary breakthrough in tuberculosis treatment hinges on the ability to register several new drugs. Although significant advancements have been made, the global pipeline of anti-tuberculosis drugs is not nearly large enough to ensure that this occurs. Recent research showed the

impressive benefit of adding a new drug, TMC207, to the regimen that patients were receiving for MDR TB.[26] This finding provides some hope that new regimens may be available, at least for MDR TB, much sooner than anticipated.

Significant funding gaps exist to support clinical trials, the most expensive stage of drug development. A single Phase III clinical trial can cost more than $100 million, according to the Stop TB Partnership Working Group on New TB Drugs. Furthermore, as multiple drug candidates enter clinical testing, the need for trial sites with the capability to conduct pivotal registration-standard clinical trials becomes acute. Currently, this infrastructure is severely lacking in developing countries, where larger patient numbers ensure timely enrollment into clinical trials. If adequate resources and capacity are available, the first new anti-tuberculosis drugs may be available in three to five years. The recent announcement that the National Institutes of Health (NIH) increased tuberculosis clinical research funding is clearly a welcome development.[8] At the same time, it will be necessary to maintain and increase investments in drug discovery to ensure a robust pipeline of future anti-tuberculosis drugs.

3. Vaccines

The BCG vaccine, created in 1921, is the only existing vaccine against tuberculosis. Unfortunately, it is only partially effective. It provides some protection against severe forms of pediatric tuberculosis but is unreliable against pulmonary tuberculosis, which is the infectious form of tuberculosis and which accounts for most of the tuberculosis disease burden worldwide. Despite being widely used, BCG has had no apparent impact on reversing the growing global tuberculosis pandemic. New, more effective vaccines are urgently needed to protect against all forms of tuberculosis—including MDR and XDR TB—and to prevent tuberculosis in children, adolescents, and adults, including in people infected with HIV. New vaccines would also help to decrease tuberculosis incidence overall and prevent further spread of the disease.

BCG is not used routinely in the United States where most infants are not exposed to tuberculosis, and it has never been a component of the US tuberculosis control program. The greatest direct benefit of a better tuberculosis vaccine would be realized in populations living in countries with high tuberculosis burdens, which would also benefit the United States by reducing the incidence of active tuberculosis in people who travel to the United States. The United States and other industrialized countries would indirectly benefit as well. For example, reducing tuberculosis would reinforce multibillion dollar US programs to combat HIV/AIDS, as patients already receiving antiretroviral treatment are still succumbing to undiagnosed and untreated tuberculosis.

Vaccines under development have the potential to prevent tuberculosis in any of several ways: by preventing infection, primary disease, latency, or reactivation of latent tuberculosis. Several potentially better tuberculosis vaccines have entered early-stage clinical trials to determine safety and immunogenicity, and the first Phase IIb “proof-of-concept” trial of a new preventive tuberculosis vaccine in infants in over 80 years was initiated in 2009. Numerous additional candidates are in preclinical development.

The Aeras Global TB Vaccine Foundation and other investigators from around the globe are sponsoring research on these tuberculosis vaccine candidates, but additional funding will be needed for further studies and to advance the most promising candidates through Phase III efficacy and licensure trials. These later stage trials require a large number of participants and long follow-up periods and are very expensive. Aeras estimates that a Phase III trial of one candidate vaccine could cost $120 million.

TAG suggests that, in the most optimistic scenario, the first new tuberculosis vaccine would be available in 2015.

4. Scientific Barriers

Major scientific hurdles and gaps remain in our understanding of tuberculosis, and these challenges need to be quickly met if new and better tools are to be developed for the elimination of both drug-sensitive and drug-resistant tuberculosis.[20] The identification of new diagnostics, drugs, and vaccines that will radically transform tuberculosis control and treatment will require a better understanding of bacterial latency, persistence, metabolism, and the host immune response to infection. Research and development will be hastened by the development of better animal models, identification of novel drug targets and predictive biomarkers, and discovery of new imaging and drug and vaccine delivery technologies. The improved preparedness of clinical trials sites will ensure that new tools are evaluated and delivered to patients without delays. Further, basic research on vaccine candidates as well as greater investigation of the mechanisms of action and pharmacokinetic/pharmacodynamic parameters of current drugs will lead to significant improvement in existing development approaches and, ultimately, to optimized prevention and treatment strategies.

5. Financial Barriers

To support this crucial work, the Global Plan to Stop TB estimates $9 billion in funding is required in the next decade for research and development of new tuberculosis diagnostics, drugs, and vaccines. With the inclusion of basic science and operational research, the November 2009 TAG report suggests that tuberculosis research and development funding investments need to increase to $2 billion per year, from the Global Plan's original target of $900 million per year.[27]

In 2008, the latest year for which data are available, overall funding investments for global tuberculosis research and development held nearly steady at $510 million, increasing only 8% from $474 million in 2007. This investment, measured against the Global Plan's 2008 target for new tools research funding, still falls short significantly by nearly $400 million, according to TAG's report. The funding gap for tuberculosis diagnostic, drug, and vaccine research, based on the Global Plan's proposed costs for each in 2008, were $13 million, $268 million, and $186 million respectively.

Investments from both the public and philanthropic sectors have been decelerating, especially in areas of operational research. Although public sector funding remains the

largest proportion of overall investments, the 2008 contributions decreased slightly to 52.3%, a 4.1% decrease from 2007. The NIH, one of the world's largest health research investors, has decreased its investment in tuberculosis research by 10% from 2005 through 2008.

Philanthropies, principally the Bill and Melinda Gates Foundation, substantially boosted their contributions, increasing the sector's proportion of total investment from 29.2% to 33.6%. Reported private sector investments held steady at 14.1% of total investments in 2008.

Despite slight increases in the investments for research and development of new diagnostics, drugs, and vaccines in 2008, the investment for basic and operational research has decreased. The overall trend is toward the deceleration of investment, further intensifying the already significant funding gap for tuberculosis research and development.

Insufficient advocacy for mobilizing resources continues to limit the advancement of the tuberculosis research and development agenda. While other health areas have focused heavily on developing improved cures, there is little understanding of the need for new tuberculosis diagnostics, drugs, and vaccines among health and advocacy groups in the United States. While investigators themselves have been a strong voice of support for increased investment in tuberculosis research, the issue has not been widely taken up by non-scientific or community-based groups or by the general scientific and academic communities. Without greater understanding about the limitations of current tools and research, it is unlikely that public and private donors will recognize the urgency for greater investment in biomedical research for tuberculosis. Researchers and other stakeholders will need to build awareness and a broader base of support in the community in order to intensify advocacy efforts.

B. Action Plans to Accelerate New Tools Development

For a summary of action plans for the development and implementation of new tools, refer to Table 4: Action Plans to Accelerate New Tools Development, pages 10-11.

1. Tuberculosis Research and Development Investment

Tuberculosis research and development investment must increase fourfold, from approximately $500 million per year to $2 billion per year in order to meet the ambitious research and development goals set by the Global Plan. Support must cover the full spectrum of research activities: basic research to understand the relationship between the bacillus and the host; discovery research to identify possible candidates; preclinical and clinical testing to evaluate the safety and efficacy of new diagnostics, drugs, and vaccines; and operational research to optimize the use of currently available products. Funding must support critical work being conducted by US agencies as well as by universities, product development partnerships, and other not-for-profit entities.

Donations from private philanthropy and increased investments from the private sector also are crucial for the successful development of new diagnostics, drugs, and vaccines.

The NIH must assume a greater role in tuberculosis research and development. To address scientific gaps, accelerate development and ensure a robust pipeline of new candidates, the NIH should maintain and grow support for basic and discovery research and product development. A promising development is the 2007 NIH announcement of expanding research initiatives to address MDR and XDR TB.[28]

The Centers for Disease Control and Prevention's (CDC's) Division of Tuberculosis Elimination has historically, and must continue to play, an important role in tuberculosis clinical research and field studies to ensure that promising tools can be further developed and introduced.

The US Agency for International Development (USAID) is a significant supporter of clinical evaluation and introduction of new diagnostics, drugs, and vaccines for use in developing countries and currently provides a small amount of funding for tuberculosis drug research. Under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act passed in 2008, USAID is authorized to expand its current tuberculosis research and development funding and initiate new funding for vaccine development. It is important that appropriations support this enhanced authority.

Tuberculosis research and development require substantial coordination of scientific and operational activities at many levels, both globally and nationally. Governments, foundations, and the private sector must accurately track and transparently report tuberculosis research and development investments to ensure that funding gaps are addressed.

2. Advocacy

Advocacy efforts to educate policy makers about the critical role of government funding for tuberculosis research and in the development of new diagnostics, drugs, and vaccines must be intensified. Stop TB USA, partners, and stakeholders must engage new constituents in the tuberculosis research advocacy movement, particularly community-based organizations, non-governmental organizations, and other health advocacy groups.

3. Basic Research and Methods

To address scientific barriers, basic research must be intensified and methods must be established to facilitate research and development across all new tools. These improvements will strengthen the pipeline of new concepts entering research, accelerate development, and improve the diagnosis, treatment, and prevention of tuberculosis.

TO CONCLUDE AND MOVE FORWARD: Better tools to diagnose, treat, and prevent tuberculosis are urgently needed. Developing and bringing these new tools into clinical practice requires an investment of significantly increased funding.

IV. Tuberculosis among US-born Populations

Communities continue to experience outbreaks and chains of tuberculosis transmission within US-born populations, especially those associated with human immunodeficiency virus (HIV) infection, incarceration, homelessness, and limited access to health care. The elimination of tuberculosis within US-born populations will not be successful without implementation of effective measures to accelerate tuberculosis elimination in these groups.

A. Trends and Challenges

1. Epidemiology and Demographics

The convergence of high rates of HIV and substance abuse with the crowding of homelessness, marginal housing, and incarceration creates ideal scenarios for ongoing transmission and high rates of tuberculosis.

Molecular epidemiology, the use of genetic typing of *M. tuberculosis* strains in studies of how tuberculosis is spread, confirms significantly higher rates of tuberculosis among US-born populations due to recent spread and infection (rather than from latent infection that occurred many years ago) when compared to the foreign-born.[29] Among persons with tuberculosis, those born in the United States and with low socioeconomic backgrounds are even more likely to have developed their tuberculosis due to recent transmission and outbreaks.[30]

High HIV rates among the urban poor amplify transmission, causing larger and prolonged outbreaks of tuberculosis.[31] HIV infection, the biggest risk factor for tuberculosis, continues to play a dominant role among US-born cases, especially among substance users, the homeless, African Americans, correctional facility inmates, and alcohol abusers.[32] As shown in Table 8 (next page) for US tuberculosis cases in 2006, HIV infection was reported in 16% of US-born non-Hispanic blacks and 7% of US-born Hispanics compared to 5% or less for other US-born racial/ethnic groups and foreign-born persons.

In addition to HIV infection, US-born persons with reported tuberculosis are more likely to have the compounding medical and social issues of homelessness, alcohol, and/or other drug abuse and to have been diagnosed in a correctional care facility or long-term care facility.[33] Homelessness within the year before diagnosis was reported in 11% of US-born persons with tuberculosis, and 57% of all homeless US-born cases were reported among blacks. Among HIV-positive, US-born tuberculosis cases, African Americans accounted for 79%.

TABLE 8

Percent of Tuberculosis Cases with Specific Risk Factors: Total Foreign-born Population Compared to Racial and Ethnic Groups among the US-born Population (2006)

Population	Homeless (%)	Jail, Prison (%)	Long-term care (%)	Alcohol and/or Drug Abuse (%)	HIV+ (%)
Total Foreign-born	2	3	1	9	5
US-born					
Asian/Pacific Islanders	2	1	1	6	1
Non-Hispanic White	11	4	6	25	5
American Indian, Other	27	5	4	43	4
Hispanic	7	5	2	17	7
Non-Hispanic Black	11	6	3	32	16

HIV = human immunodeficiency virus.
Source: R. Pratt, T. Navin, M. Chen, J. Becerra, CDC.

2. Loss of Funds and Personnel Dedicated to Tuberculosis Control

The decline in categorical funding for over a decade has led to significant decreases in personnel and resources for individual and community outreach, incentives and enablers needed for case management, aggressive contact investigations, and completion of treatment.

Since the spike in funding in the early 1990s, health department programs for preventing tuberculosis by targeted testing and treatment of latent tuberculosis infection in US-born communities have been dismantled because of the need to maintain core functions of active tuberculosis treatment and contact investigation. The lack of resources devoted to targeted testing and treatment of latent tuberculosis infection to prevent tuberculosis cases makes elimination of tuberculosis among the US-born impossible.

Most cases of tuberculosis are detected when persons seek medical care for the symptoms of the disease. Because US-born persons with tuberculosis come from populations who are least likely to access health care, delays in seeking and/or accessing health care lead to delays in diagnosis, contributing to ongoing airborne spread of the disease in their communities.[34]

3. Resource-Intensive Contact Investigations

Once disease is detected, contact investigation in these populations is complex, resource intensive, and more challenging because of the highly mobile nature and competing priorities of people within these groups. Social mistrust and stigma of tuberculosis make these people difficult to reach and further hamper efforts to adequately identify and evaluate all contacts.

Without improvements in health department programs aimed at finding, evaluating, and treating contacts (persons exposed) to infectious tuberculosis cases, transmission of tuberculosis will continue to occur from recently infected persons who develop tuberculosis. Contact investigations among populations of marginally housed persons in shelters, low-cost hotels, and drug treatment facilities are resource intensive and often require on-site services, including education (of residents, patients, and staff), mobile radiology, phlebotomy, sputum collection, and incentives and enablers for follow-up. Communication and partnering with community programs are necessary and require skilled staff. Because of the cost and complexity of these investigations, programs often reserve investigations to only the cases considered most contagious or after an outbreak has already been detected.

4. Complexity of Addressing Health Disparities

With the current funding downturn, the hiring and training of skillful staff to work with the difficult-to-reach is currently limited and unaffordable. The complexity of working with persons who have multiple medical, social, and mental problems requires a highly skilled workforce that is willing to provide outreach in potentially dangerous environments. It is challenging for the patients who are trying to make ends meet or worrying about their next meal to have to take medication for latent tuberculosis infection for a minimum of six to nine months. Knowledge of existing services for non-tuberculosis issues and access to these services are often critical in stabilizing patients who are on treatment or in the process of a work-up for tuberculosis.

The activities that are critical to the success of working with US-born populations at risk for tuberculosis are labor and resource intensive. The cost of care is substantially higher than for other at-risk populations but is necessary to protect the public. Resource demands can surge dramatically and unpredictably: one outbreak in a correctional facility or homeless shelter can create significant challenges for a health department and facility staff already stretched to capacity—a common scenario with the current level of infrastructure for tuberculosis control in the United States.

5. Tuberculosis in Correctional Facilities

Correctional facilities hold over 2.2 million people, including persons frequently affected by substance abuse, homelessness, HIV infection, lower socioeconomic status, and limited access to medical care. Overcrowding has become commonplace in these facilities.

The link between tuberculosis and correctional care facilities, particularly among African Americans, is often not recognized and represents a missed opportunity for tuberculosis control and prevention. According to the US Department of Justice Bureau of Justice Statistics, at year end 2006 there were 3,042 black male sentenced prisoners per 100,000 black males in the United States, compared to 1,261 Hispanic male sentenced prisoners per 100,000 Hispanic males and 487 white male sentenced prisoners per 100,000 white males.[35]

Common challenges in state and county correctional facilities include insufficient resources for screening and staff surge capacity during outbreaks. The problem is particularly acute in smaller county jails, where inmates often stay briefly while awaiting release or transfer to other correctional facilities.

B. Action Plans to Accelerate Tuberculosis Elimination among US-born Populations

Although the roots of the disparities may remain despite our efforts, tuberculosis control programs in the United States are models of providing high-quality and equitable care to all patients. With the right resources, tuberculosis programs can lessen and eventually eliminate the uneven burden of disease among the US-born. Engaging difficult-to-reach US-born populations with tuberculosis will require aggressive community- and patient-centered approaches to screening and prevention. Community-based tuberculosis services and prevention in high-risk communities and facilities where tuberculosis exposure perpetuates disease are needed to eliminate ongoing transmission among the US-born. Further erosion of the core infrastructure and rationed services will only serve to raise the risk of transmission and jeopardize the hard-won current containment of tuberculosis.

For a summary of action plans for eliminating tuberculosis in US-born populations, refer to Table 5: Action Plans for Tuberculosis Elimination among the US-born, pages 11-12.

1. Community-Based Tuberculosis Activities

In the Action Plans for Eliminating Tuberculosis among the US-born, it is recommended that funding be augmented and restored for community-based targeted testing and latent tuberculosis infection treatment focusing specifically on persons who are homeless, marginally housed, or co-infected with HIV and on persons who have diabetes and other medical risk factors for disease progression (local, state, and federal government item 1, bullet 1).

The lack of access to screening and targeted testing of at-risk US-born persons perpetuates delayed diagnosis of contagious tuberculosis, reactivation, and transmission in high-risk settings such as shelters, jails, low-cost housing, community drop-in centers, and substance abuse treatment facilities.

Funding for treatment of latent tuberculosis infection of homeless contacts and persons with HIV or medical risk factors for progression to active tuberculosis must be increased in order for health departments and other medical providers to make this key prevention activity a priority. Outreach, incentives, and enablers are needed to engage difficult-to-reach populations in prevention activities, namely treatment of latent tuberculosis infection. To combat the high rates of nonadherence, directly observed therapy for latent tuberculosis infection treatment has been shown to be effective[36] and is needed if tuberculosis elimination is the goal.

Community-based programs, new technology, and training are essential for screening, targeted testing, and treatment. Community-based programs that provide on-site screening and directly observed therapy for both active tuberculosis and latent tuberculosis infection are needed to bridge the gap of access to care. Implementation of new technology, such as blood-based tuberculosis testing to improve adherence to screening, should be prioritized for the difficult-to-reach since it requires only one clinic visit to get a result, instead of the two clinic visits needed for tuberculin skin test results. Tuberculosis control staff working with these populations must be well trained, highly motivated, and able to create strong relationships with community members.

The importance of community input, education, leadership, and coalition building cannot be understated in these activities. These efforts will require significant resources in order to be successful in case management, completion of treatment for tuberculosis, contact investigation, and targeted testing and treatment of latent tuberculosis infection.

Because of the high risk of transmission in them, congregate settings present valuable opportunities for screening and tuberculosis case detection. It is recommended to enhance tuberculosis control programs at correctional facilities to the same level as external health department programs in order to improve screening and surveillance capacity, contact investigation, and case management of inmates who are moved frequently to different facilities, have high recidivism rates, or leave institutions before treatment is completed (local, state, and federal government item 1, bullet 2).

Special focus should be placed on screening and tuberculosis case detection in shelters, correctional facilities, residential substance abuse programs, and community day drop-in centers where risk of transmission is high. It is common for at-risk persons to cycle through some or all of these sites and facilities in a single year.[37] Hence, requiring tuberculosis screening in these settings and fully implementing existing guidelines for these groups is an important strategy in creating access to the difficult-to-reach. It is recommended that local health departments should have the resources to limit transmission through early case detection and screening at sites with high crowding and limited ventilation. Mandatory tuberculosis screening should be implemented of all homeless in shelters, day drop-in centers, and other congregate sites to prevent outbreaks and spread of tuberculosis (local, state, and federal government item 1, bullet 3).

Preventing tuberculosis transmission in these congregate settings is challenging because of the frequent movement of persons within and between settings and programs. In these facilities, and especially in correctional facilities, development of databases for tuberculosis surveillance is needed and critical to serve these populations and collaborate with local public health authorities.[38] Better disease surveillance and medical databases to track inmates and transfer vital information among facilities are badly needed to improve efficiency and care. It is recommended that local health departments should enhance surveillance activities using geographic information system mapping and genetic typing (genotypying) of strains of *M. tuberculosis* to identify specific local areas of ongoing transmission in order to target efforts and communicate with the public (local, state, and federal government item 1, bullet 4).

Finally, training and education specific to tuberculosis are needed to address contact investigation, collaboration between correctional facilities and public health units, and case management and discharge planning for inmates with tuberculosis disease and high-priority latent tuberculosis-infected inmates.

SUCCESSFUL PARTNERSHIPS:

Forth Worth Community Partnership for TB Detection and Prevention

In the western part of the Dallas-Fort Worth metropolitan area in Tarrant County, Texas, community organizations partnered with the local public health department to implement location-based tuberculosis screening.[39]

Despite years of free voluntary tuberculosis screening, communities in three Tarrant County zip codes with high rates of unemployment, homelessness, and substance abuse suffered persistent high rates of tuberculosis transmission.

After being presented with the epidemiologic data, community organizations partnered with the local public health department to make annual tuberculosis screening mandatory for persons to continue receiving a variety of services. Screening was expanded from homeless shelters to be location-based at other community organizations providing services, including mental health facilities, temporary labor services, Veterans Administration job training and living facilities, dialysis centers, churches, community service centers, a human immunodeficiency virus (HIV) congregate living facility, and living facilities sponsored by faith-based organizations. Screened persons were given county-issued screening cards that were required to receive services at the partner organizations.

Before these new programs, screening detected only 5% of active tuberculosis cases among shelter residents. The remaining cases were diagnosed in hospitals. In September 2002, location-based screening detected 20 cases of active tuberculosis among the first 702 persons screened. The prevalence of active tuberculosis was 2.9% in the first screening, and 1.9% in the first year, a rate exceeded in the United States only during outbreaks in homeless shelters or in evaluation of contacts to active tuberculosis cases. Early results are promising: the prevalence of active tuberculosis dropped from 1.9% in the first 12 months to 0.5% in the last 16 months reported.

2. Awareness of Tuberculosis among Healthcare and Service Providers

It is recommended that local health departments should increase tuberculosis education of community workers in shelters, housing services, and substance abuse treatment sites; correctional staff; and providers serving high-incidence US-born populations in order to address the lack of awareness that tuberculosis is a health disparity among the populations they serve (local, state, and federal government item 1, bullet 6).

Lack of awareness among healthcare providers about tuberculosis and associated health disparities often has led to delayed diagnosis and prolonged transmission in the community. Studies have demonstrated delays in diagnosis of tuberculosis due to other primary diagnoses, such as asthma, HIV infection, and community-acquired pneumonia. It is crucial for community providers to know who gets tuberculosis in their community, how to make the diagnosis, and how to rapidly report tuberculosis to state or local health departments.

3. Advocacy and Mobilization

On a local level, it is recommended that local health departments partner with key community members and providers to promote education, create cohesive interventions, and develop policies and strategies that address the unique tuberculosis problems of each community and the locality (local, state, and federal government item 1, bullet 5). On local, state, and national levels, as mentioned above, it is recommended that governments should restore and augment funding for community-based targeted testing and latent tuberculosis infection treatment (local, state, and federal government item 1, bullet 1).

SUCCESSFUL PARTNERSHIPS:

Stop Tuberculosis in the African American Community Summit

The Division of Tuberculosis Elimination and RTI International co-sponsored the Stop Tuberculosis in the African American Community Summit in May 2006 to engage partners in collaborative efforts to address the impact of the tuberculosis disparity in the African American community. The goals of this meeting were to raise awareness about the problem of tuberculosis in the African American community, create links, and build networks that will lead to ongoing activities and strategies to decrease tuberculosis in the African American community. The Summit brought together community and religious leaders, healthcare providers, public health leaders, policy and decision makers, state and local health department staff, communications professionals, academicians, and others who committed to undertaking specific goals and action items.

Current funding opportunities for tuberculosis control have focused largely on the global rather than domestic efforts to eliminate tuberculosis. High-level officials and Congress are not aware that tuberculosis among the US-born is an issue of disparities

and inequity, with rates of tuberculosis in poor inner city communities that rival those in the developing world. Additionally, communities most heavily affected by tuberculosis often have little political clout and few advocates when other social issues seem more pressing. Poor Americans with tuberculosis are also unlikely advocates because of the added stigma to their already difficult lives. Raising public awareness among local, state, and national politicians and lawmakers of the daily domestic outbreaks and ongoing transmission in US-born populations is critical in increasing domestic funding for tuberculosis control and elimination.

TO CONCLUDE AND MOVE FORWARD: A major barrier to tuberculosis elimination in the United States is the health disparity for tuberculosis among US-born minority populations, who now account for 87% of tuberculosis cases in the US-born population. Tuberculosis persists in the minority populations due to the failure to prevent tuberculosis outbreaks that often occur in congregate settings, such as: crowded, inadequate housing; homeless shelters; correctional care settings; and substance treatment programs. Higher rates of HIV infection among these minority populations compound the problem.

Addressing the ongoing challenge of tuberculosis among difficult-to-reach US-born groups will require advocacy and mobilization, education, and community- and patient-centered approaches to screening and prevention that focus on community-based tuberculosis services and prevention in high-risk communities and facilities where tuberculosis exposure perpetuates disease.

V. Tuberculosis among Foreign-born Populations

Despite the 70% decrease in the number of tuberculosis cases among US-born persons over the past 15 years, no progress has been made in reducing the number of tuberculosis cases reported among foreign-born persons each year (Figure 1, page 24). The persistence of over 7,500 tuberculosis cases each year with the associated disability and death among foreign-born persons in the United States is due to three factors: demographic trends in the United States, high rates of latent tuberculosis infection in the foreign-born population, and cultural-linguistic and socioeconomic challenges to implementing tuberculosis control measures. The solution to tuberculosis elimination among foreign-born US residents and the nation lies in addressing these three factors as well as investing in tuberculosis control and elimination globally, especially in those regions of the world where tuberculosis control and elimination is threatened by the spread of drug-resistant strains of *Mycobacterium tuberculosis*.

A. Trends and Challenges

1. Demographic Trends among Foreign-born US Residents

The number of new immigrants, defined in this discussion as those obtaining permanent United States residency (green card holders), increased from 3.6 million during the decade of the 1970s, to 6.2 million in the 1980s, and to 9.8 million in the 1990s, with 9.2 million arriving during the nine-year period 2000 through 2008. Immigrants from countries in Africa, Asia, and Latin America (Mexico, the Caribbean, Central America, and South America), where rates of tuberculosis range from moderately elevated to extremely high, accounted for 95% of all immigrants from 1980 through 2008.[40] The total foreign-born population residing in the United States in 2007 was estimated to be 37.9 million, one third of whom were undocumented. Foreign-born persons account for one in eight US residents now, up from one in 13 in 1990.[41]

2. Tuberculosis Screening Requirements for Foreign-born Persons Coming to the United States

The current overseas tuberculosis screening of foreign-born persons entering the United States is focused on those likely to be long-term residents, primarily refugees and immigrants. The main purpose of the screening is to detect infectious tuberculosis cases and ensure that treatment is adequate to eliminate infectiousness before travel to the Unites States. In 2008, the numbers of refugees and permanent residents who arrived in the United States after pre-departure screening were 60,000 and 467,000, respectively, representing just 527,000 of the 39 million persons who entered the

United States that year. The vast majority of entrants undergoes no screening for tuberculosis at all, including over 3 million students and workers who are likely to remain in the United States for several years. Table 9 (next page) indicates which US entrants are screened for tuberculosis before arrival and the percentage from countries in regions with increased risk for tuberculosis (Asia, Africa, Mexico, the Caribbean, Central America, and South America).

The tuberculosis screening process from 1991 through 2007 required a chest radiograph for adult overseas applicants (defined as 15 years of age or older). Those with chest radiograph findings of active tuberculosis were required to submit three sputum specimens for microscopic examination for acid-fast bacilli (AFB). Applicants with AFB present in one or more sputum specimens were considered to have infectious tuberculosis and could not travel until treated.[42]

The 2007 Technical Instructions for tuberculosis screening and treatment for panel physicians added sputum culture and drug susceptibility testing for *Mycobacterium tuberculosis* isolates, increasing threefold the number of applicants with the diagnosis and treatment of tuberculosis[43] and ensuring that cases due to drug-resistant strains were appropriately treated. The 2007 Technical Instructions also require tuberculin skin testing for diagnosis of latent tuberculosis infection in children 2 through 14 years of age. Treatment of latent tuberculosis infection is not required before departure, but a referral is made to the state health department in the state of intended residence in the United States. The 2007 Technical Instructions were implemented for refugees and/or other immigrants from four counties in 2007 and will be implemented in other countries as laboratory and other capabilities are approved.

The 2007 revised tuberculosis screening methods are predicted to reduce the number of immigrants and refugees who arrive with AFB smear-negative tuberculosis (positive sputum cultures but negative microscopic examination), but this will probably reduce the number of tuberculosis cases among foreign-born persons by only 250 cases per year.[44] In 2008 an additional 641,000 persons residing in the United States on short-term visas (such as students and workers), were approved for permanent residency by change-of-status after screening for tuberculosis (Table 9, next page). Tuberculosis screening for change-of-status applicants, done by designated civil surgeons, involves a two-step process of tuberculin skin testing of all adults and children 2 to 14 years of age. Applicants with a tuberculin skin test reading of 5 mm or more are required to have a chest radiograph, and those with abnormal chest radiographs are referred to the local or state health department to be evaluated for tuberculosis and treated if diagnosed. For those diagnosed with latent tuberculosis infection, there are no requirements for treatment to prevent future tuberculosis.

Most of the 39 million non-immigrants who legally entered the United States in 2008 (Table 9, next page) did so for only short periods of time, but 64.7% of over 3.6 million short-term residents came from tuberculosis-endemic regions. These include 1.4 million students and nearly 2 million workers (including family members) who may reside in the United States for years at a time, but who have no federal requirements for tuberculosis screening or testing for latent tuberculosis infection.

TABLE 9

US Entrants, 2008: Tuberculosis Screening Requirements and Percentage from Higher Tuberculosis Risk Countries

Tuberculosis Screening Requirements	Number of US Entrants	Percent from Higher TB Risk Countries* (%)
TUBERCULOSIS SCREENING REQUIRED		
Applicants for permanent residency	1,107,000	98.0
Applicant examinations overseas: chest radiographs of adults, tuberculin skin test (TST) ages 2-14 years	467,000	--
Status adjustment applicant examinations in the United States: TST, chest radiograph if TST-positive	641,000	--
Refugees examinations overseas: chest radiographs of adults, TST ages 2-14 years	60,000	96.1
NO TUBERCULOSIS SCREENING REQUIRED		
Asylees who apply in the United States	12,000	85.6
Non-immigrants	39,382,000	55.4
Short-term residents	3,688,000	64.7
Students, exchange visitors, and family members	1,424,000	68.1
Workers and family members	1,950,000	63.6
Diplomats, other	315,000	56.1
Non-residents	35,434,000	54.4

*Asia, Africa, Mexico, the Caribbean, Central America, and South America.

Source: Monger R and Barr M. *Nonimmigrant Admissions to the United States: 2008.* Annual Flow Report. Washington, DC: US Department of Homeland Security Office of Immigration Statistics. April 2009. Available at http://www.dhs.gov/xlibrary/assets/statistics/publications/ois_ni_fr_2008.pdf.

3. Diagnosis and Treatment of Latent Tuberculosis Infection

Although arriving with tuberculosis disease is not common due to the overseas screening process, the prevalence rates of latent tuberculosis infection are quite high for the 1,267,000 persons from Asia, Africa, or Latin America in 2008 who arrived as refugees or achieved permanent residency status (Table 9, page 53). This is reflected in the much higher prevalence of latent tuberculosis infection documented among foreign-born persons and their rates of tuberculosis compared to US-born persons (Figure 4, page 27).

The authors of the Institutes of Medicine (IOM) report *Ending Neglect* recommend requiring testing and treatment for latent tuberculosis infection among all immigrants from countries with elevated risk for tuberculosis,[12] but this has remained a voluntary process. The national guidelines were revised in 2000 to recommend targeting the testing and treatment of latent tuberculosis infection among recently arrived foreign-born persons due to the higher rates of tuberculosis within the first five years of arrival compared to later years.[17]

More recent research shows that persons born outside the United States have tuberculosis case rates 4.7 times higher during their first two years after entry in the United States than in the years that follow,[44] but this does not mean that the risk of tuberculosis decreases in all persons after arrival. Compared to US-born persons, refugees and immigrants from high-burden countries have tuberculosis case rates up to ten times higher for two, five, or more than 20 years after arrival in the United States.[45] The number of tuberculosis cases in refugees who have been in the United States for more than 20 years will continue to increase because 1980 to 2000 was a period of unprecedented refugee resettlement in the United States, with a very significant spike in numbers from 1989 through 1991.[46] In addition, the absolute number of refugees accepted by the United States has been increasing again since 2002, and several new large groups of refugees have been approved for resettlement over the ten years from 2006 from countries that show the highest tuberculosis rates among refugees in the United States.[44,47]

Despite the documented higher prevalence of latent tuberculosis infection among foreign-born persons and the increased lifetime risk for life-threatening and disabling tuberculosis conferred by this infection, there are unique challenges for many foreign-born persons that predispose them to disparities of care. These challenges must be recognized and addressed to avoid delays in diagnosis and curative treatment of tuberculosis, in identifying and protecting the health of persons exposed to infectious tuberculosis, and in preventing tuberculosis through targeted testing and treatment for latent tuberculosis.

4. Cultural/Linguistic and Socioeconomic Challenges to Care

Most foreign-born tuberculosis patients in the United States face cultural, linguistic, and socioeconomic challenges to care, which may exacerbate the shortcomings of the current strategy to control tuberculosis among the foreign born. Delays in diagnosis are

in part the result of patient delays in seeking care, different perceptions of disease, definitions of disease, attribution of symptoms to different illnesses, unfamiliarity with or distrust of biomedical care, fear of stigmatization, fear of government and possible deportation, and lack of a means to pay for care (such as medical insurance). Provider factors contributing to delays in diagnosis include delays in recognizing the possibility of tuberculosis and/or in initiating diagnostic evaluation, delays or failures to report suspected cases of tuberculosis to health departments to ensure complete evaluations, and failure to initiate timely treatment.

Data supporting the scientific basis for cultural challenges to care have focused mostly on linguistic access and socioeconomic factors that have been shown to create health disparities, but other cultural challenges may also limit access to care and reduce cooperation with contact investigations and adherence to therapeutic and programmatic interventions for people with active tuberculosis and their contacts.[48]

To some extent, the challenges outlined below may apply to any foreign-born person with tuberculosis or latent tuberculosis infection, but the following sections highlight specific challenges that are especially acute in particular sub-groups of foreign-born tuberculosis patients.

5. Additional Challenges Faced by Migrant Workers

Poverty, limited transportation, mobility or unstable residency, low literacy, limited English proficiency, and cultural differences create significant challenges to care for migrant workers. Most low wage jobs are hourly and do not provide sick leave or other benefits such as health insurance, which makes migrants reluctant to miss work, fearing the inability to pay as well as loss of their jobs if they take time off to get medical care.[49] If migrants fear that seeking health care might lead to trouble with immigration authorities, then they are even more likely to delay seeking care, resulting in disease progression and an increased risk of transmission of tuberculosis to others.[50] A further challenge is that migrant workers can face psychological stresses from uncertain employment, housing, and immigration status. What part stress may play in the development of tuberculosis disease is unknown, though rates of tuberculosis have been seen to increase in stressed populations.[51] In addition to these social, economic, and cultural challenges, many healthcare providers assume that migrants will be unable to complete their treatment. This assumption is often offered as a reason for not conducting screening for active tuberculosis or latent tuberculosis infection and for not initiating treatment of latent tuberculosis infection.

6. Additional Challenges Faced by Refugees

Refugees are usually from countries with a high burden of tuberculosis, so they arrive with high rates of latent tuberculosis infection acquired in their countries of origin or in refugee camps, and case rates of tuberculosis are much higher within the first two years after entry into the United States. Timely diagnosis and treatment for a variety of medical conditions including tuberculosis and latent tuberculosis infection is challenging even with the resources provided by the Office of Refugee Resettlement

and eight months of Medicaid insurance. Refugees struggle to adjust to the US medical culture and healthcare system and often have not found employment that provides medical insurance before their Medicaid coverage lapses.

During and beyond this first two years, refugees face other challenges that complicate medical care. Refugees also often have disrupted families and may have limited community support systems. Other issues that complicate timely diagnosis and refugees' ability to complete treatment can include linguistic barriers to accessing care, different understandings of illness, unfamiliarity with laboratory tests and medication schedules, inexperience with treating latent tuberculosis infection, and having other priorities in adapting to life in a new society that take precedence over health concerns. In addition, trauma or torture in their home countries can make it difficult to trust government officials or to form a trusting relationship with a case manager. All of these issues are exacerbated in many communities by the lack of trained medical interpreters and identified cultural brokers who can facilitate work with healthcare providers, especially for new refugee groups.

7. Additional Challenges Faced by Undocumented Persons

As of March of 2006, the Pew Hispanic Center estimated that between 11.5 and 12 million of the foreign-born persons in the United States were undocumented.[52] Among the foreign-born in the United States, undocumented persons are largely from countries with a moderate or high prevalence of tuberculosis and have not undergone screening.

In addition to the fear of apprehension and deportation, which makes them reluctant to seek medical care, undocumented persons face other obstacles to accessing health care common to foreign-born persons, such as culture and language differences, poverty, housing instability, and limited employment options affecting economic survival.

B. Action Plans for Tuberculosis Elimination among Foreign-born Populations

For a summary of the action plans for eliminating tuberculosis among foreign-born populations, refer to Table 6: Action Plans for Tuberculosis Elimination among the Foreign-born, pages 13-14.

1. Interconnected Health Problems and Social Conditions

To understand the factors contributing to the disparity in tuberculosis rates between foreign-born and most US-born populations, it helps to view tuberculosis as one aspect of the "coinfection and synergistic interaction of diseases and social conditions at the biological and population levels."[53]

For example, the high rates of diabetes in Asian and Hispanic populations and high rates of human immunodeficiency virus (HIV) infection among sub-Saharan African

immigrants contribute to the progression from latent tuberculosis infection to tuberculosis disease. These are not just co-occurring epidemics in these populations, but are a set of "mutually enhancing epidemics involving disease interactions at the biological level that develop and are sustained in a community/population *because of harmful social conditions and injurious social connections.*"[53] The social conditions of many immigrants and refugees in their home countries and in the United States provide a greater risk of exposure to tuberculosis and HIV and also contribute to lifestyle patterns that increase malnutrition (another biological condition synergistic with tuberculosis) and hinder access to medical care, as described above.

This perspective is a syndemic orientation, which is defined as "a way of thinking about public health work that focuses on connections among health-related problems, considers those connections when developing health policies, and aligns with other avenues of social change to assure the conditions in which all people can be healthy."[54] To address the ongoing disparities in case rates among foreign-born groups, disparities reduction requires an approach that takes into account the biological and social contexts in which tuberculosis occurs and addresses factors related to the health system, care process, and the patient. The Centers for Disease Control and Prevention's Syndemic Prevention Network website at http://www.cdc.gov/syndemics/overview.htm offers information and resources for further exploring a syndemic orientation for public health.

There is a need to do more contemporary research from a syndemic orientation to document the specific contexts and causes of new cases of active tuberculosis among foreign-born persons in the United States. This research needs to be stratified by comorbidities, ethnicity, and time in the United States; family structure and living patterns; social location; and age at which disease is identified. In addition, targeted genotyping by mycobacterial interspersed repetitive unit analysis (MIRU) may be necessary to document recent transmission in non-pediatric cases. Specific epidemiologic/risk factor studies are needed in long-settled immigrant communities to assess the risk of tuberculosis among immigrant and refugee children and children of foreign-born parents, especially where aging immigrants have high rates of comorbidities, such as diabetes, that affect progression from latent tuberculosis infection to active tuberculosis.

Finally, while continuing to use federal racial/ethnic surveillance categories for reporting, there is an urgent need to develop and define more specific operational and research categories for immigrant and refugee groups which will be meaningful for local tuberculosis control activities. More specific and detailed demographic information, available from research and advocacy groups such as the Migration Policy Institute or Hmong National Development, for example, will enable local public health programs to identify needs and plan for targeted community outreach, cultural competence training, interpretation, and partnership building among the groups they serve.[55]

2. Strategies for Identifying and Treating Latent Tuberculosis Infection among Foreign-born Residents

Notification of Inactive Tuberculosis among Refugees and Immigrants

One strategy to identify foreign-born persons with latent tuberculosis infection is to enhance screening and follow-up by health departments in the United States of persons diagnosed with inactive pulmonary tuberculosis and latent tuberculosis infection both pre-departure and at change-of-status visa adjustments. Under the technical instructions for tuberculosis screening of refugees and applicants for permanent residency, those persons whose chest radiographs are consistent with tuberculosis but who have negative sputum cultures for *M. tuberculosis* are often diagnosed with inactive tuberculosis. (Overseas panel physicians and health departments also use the term *Class B1 pulmonary tuberculosis*.)

These persons are recommended for follow-up in US health departments due to increased risk for future tuberculosis. Children diagnosed with latent tuberculosis infection during overseas screening and both adults and children with this diagnosis during change-of-status evaluation are at increased risk for developing tuberculosis that can be prevented by treatment with isoniazid. This health department follow-up and treatment can be enhanced by continued improvement both in the electronic notification of local jurisdictions receiving immigrants and refugees and in the inter-jurisdictional notifications for patients who move (federal government items 1 and 2; local and state government item 4, bullets 1 and 2; and community partners item 6).

Targeted Testing and Treatment for Latent Tuberculosis Infection

Another strategy to identify foreign-born persons with latent tuberculosis infection is to enhance targeted testing and treatment for latent tuberculosis infection among foreign-born US residents. Local capacity should be built to develop epidemiologic profiles of local foreign-born groups and to better understand which groups to focus on for targeted testing.[56] Tuberculosis elimination among foreign-born residents will require greatly expanded diagnosis and treatment of latent tuberculosis infection with isoniazid (federal government items 1 and 2; local and state government item 4, bullets 1 and 4; and community partners items 5, 6, 7, and 8).

In addition, the promising new tools for detecting and treating latent tuberculosis infection need to be evaluated and implemented. The Division of Tuberculosis Elimination must continue to pursue development of better diagnostic tests for latent tuberculosis infection. The bacilli Calmette-Guérin (BCG) vaccination is common in most high-burden countries, and positive tuberculin skin test results are often dismissed by immigrants as only reflecting BCG. The tuberculin skin test is less specific for *M. tuberculosis* than the two interferon gamma release assays (blood tests) that have been approved to diagnose latent tuberculosis infection. The use of the blood tests could provide a more specific test for latent tuberculosis infection and could be a more useful tool for persuading persons with latent tuberculosis infection or newly infected contacts to complete medical evaluation for tuberculosis disease and, if needed, to complete treatment for latent tuberculosis infection.

The Division of Tuberculosis Elimination must also continue to evaluate shorter treatment regimens for latent tuberculosis infection. Latent tuberculosis infection treatment regimens of nine months of isoniazid and four months of rifampin present formidable barriers for many immigrants and other travelers to the United States. The increased adherence to treatment that is likely with a shorter regimen is particularly important for the foreign-born who may face many economic, cultural, and linguistic barriers. The journal article "New Approaches to the Treatment of Latent Tuberculosis" reviewed current regimens for treatment of latent tuberculosis infection, both standard and alternative, as well as regimens under investigation and those with potential for future development.[57] For example, development of regimens using longer-acting rifamycins and fluoroquinolones may permit taking medicine only once or twice weekly. Because of the potential difficulty in enrolling sufficient numbers of patients in the United States into clinical studies of such proposed regimens, consideration should be given to multinational clinical trials for new shorter latent tuberculosis infection regimens.

College Students and Workers from Moderate- and High-burden Countries

A third strategy to identify foreign-born persons with latent tuberculosis infection is to require that students and workers from moderate- and high-burden tuberculosis countries, who are not screened prior to arrival in the United States, undergo tuberculosis screening after arrival (local and state government item 4, bullet 4).

Targeted screening of college students and workers from high-tuberculosis-burden countries can identify immigrant students eligible for latent tuberculosis infection treatment and diagnose active tuberculosis earlier, reducing the risk of transmission. If diagnosed with latent tuberculosis infection, these persons should complete treatment for latent tuberculosis infection. Health departments should begin by engaging with college campuses in developing evidence-based practices in diagnosing and treating latent tuberculosis infection.

3. Enhanced Tuberculosis Control Tools for Working with Foreign-born Populations

Cultural Competency

Specific local information on foreign-born demographics, community organizations, cultural background information, and challenges to healthcare access is needed. This information would identify ways to bridge language and cultural challenges, to improve case management and contact investigation outcomes, and to identify and develop resources, such as interpreters and cultural brokers, who can be partners in providing culturally and linguistically appropriate care. In addition, information about local access barriers would inform both national and local tuberculosis control strategies.[53]

Local capacity to quickly initiate treatment and ensure completion of treatment should be enhanced by implementing patient-centered care practices, including eliciting patient illness models, working with traditional healers, accommodating family decision-making processes, and understanding how different cultural child-rearing

practices affect the process of treating children with active tuberculosis and tuberculosis infection.[58] Further, tuberculosis control at all levels needs to coordinate efforts to address disparities in tuberculosis case and latent tuberculosis infection rates in all populations, by adopting a skills-based approach to developing cultural competence. Other groups at high risk of tuberculosis, such as homeless or incarcerated persons—whose members also often include foreign-born persons—have additional specific cultural factors that shape health practices and internal group social organization that affect tuberculosis transmission. Foreign-born groups are also situated within a larger society whose structural influences contribute to the syndemic effects of poverty and exposure to active tuberculosis.

Cultural competency skills and disparities analysis are the tools that tuberculosis control staff need in order to learn about the cultures and structural contexts of each foreign-born group they work with, so that tuberculosis control practices and strategies can be tailored effectively to these groups' specific circumstances. Since no organization can hire staff from all local groups, most tuberculosis control staff will work with people from a variety of backgrounds and cannot be culturally proficient in every group's culture. So, cultural competence needs to be based on developing skills to work effectively with any group, skills that are patient-centered and include knowing how to find specific information about communities and build relationships with community leaders.[59]

It is important to recognize that the challenges in access to care and in treatment completion are not located primarily within the immigrant or refugee patient. A synergy of structural, cultural, and biological contexts leads to high rates of latent tuberculosis infection and tuberculosis disease in foreign-born populations.[60] Some case management challenges arise from poverty, lack of insurance, or other structural conditions of immigrant communities, not from cultural differences. Local programs should institute and expand the use of culturally-relevant incentives and enhance local programs' knowledge of economic and social challenges and the corresponding effective enablers for specific populations and communities. Using incentives and enablers helps to increase completion of treatment rates and to continually build cooperative relationships with local immigrant communities that can enhance acceptance of treatment of latent tuberculosis infection.

These cultural competency strategies can be implemented by both hiring staff from local foreign-born communities, working with community organizations to encourage and facilitate training in healthcare interpreting or medical fields, and providing skills-based cultural competence training to health department staff at all levels, to ensure that all staff have the skills to work with all foreign-born patients.

SUCCESSFUL PARTNERSHIPS:

Partnering with Traditional Healers at Healthy House

There is usually a range of healing practices in immigrant and refugee communities—from people who provide information and materials for self-treatment, such as herbalists, to therapeutic massage practitioners, spiritual healers or diviners, and practitioners of complementary systems of medicine, such as Ayurvedic, Tibetan, or Chinese medicine.

Partnership with healing practitioners from these diverse communities, as cultural brokers, can include efforts to learn their practices in specific communities while providing opportunities for them to learn about biomedical practices, engaging patients and family members in discussions about treatments for specific illnesses, such as tuberculosis and comorbid conditions, building alliances to encourage referrals to medical care facilities for specific symptoms, and receiving assistance from traditional healers in identifying contacts to persons with tuberculosis disease.

One model of such a partnership is the Healthy House in Merced, California, which has established a program to orient medical providers to Hmong shamans' practices and to introduce shamans to biomedical practices and facilities.[61] For more information, refer to this National Center for Cultural Competence publication: *Bridging the Cultural Divide in Health Care Settings: The Essential Role of Cultural Broker Programs* online at http://www11.georgetown.edu/research/gucchd/nccc/documents/Cultural_Broker_Guide_English.pdf .

Case Detection and Treatment

As noted earlier, only a very small percentage of the foreign-born population is screened before US entry. Other strategies must also be used to address case detection in the majority of foreign-born persons who are not screened (federal government items 1 and 3; local and state government item 4, all bullets; and community partners item 5).

To eliminate transmission of tuberculosis from foreign-born persons with tuberculosis in the United States, it is necessary to understand that the risk of tuberculosis transmission to others increases when there are delays in diagnosis and curative treatment of infectious tuberculosis. Persons with delayed diagnosis or treatment may transmit tuberculosis, often to family members. For example, there is a marked racial and ethnic disparity for tuberculosis among US-born children less than five years of age with at least one foreign-born parent. Delays in diagnosis and treatment also increase the risk of disability and death, even in persons who are not infectious.

Community outreach and collaboration with other public health programs, community service organizations, and ethnically-based mutual assistance associations can improve familiarity with and trust of healthcare systems. This can be enhanced further by collaboration with traditional healers to demonstrate respect for culturally-based health practices and to encourage referrals. In addition, addressing systemic factors

which limit access, including lack of insurance and insufficient access to interpreters, can help to eliminate delays in receiving an appropriate diagnosis. Finally, providing targeted education and medical consultation from health department experts and from the Regional Training and Medical Consultation Centers, with a focus on physicians who treat foreign-born populations at high risk of tuberculosis, would help to address physician-provider unfamiliarity with tuberculosis.

For new refugee groups without pre-existing community organizations, such as the Burmese and Bhutanese, more avenues and funding must be found to quickly train medical interpreters and develop their English language skills as a first step in developing the cross-cultural resources that bridge cultural, linguistic, and access challenges.

SUCCESSFUL PARTNERSHIPS:

TBNet: Multinational Patient Tracking and Referral

In 1996, the Migrant Clinicians Network, working with a consortium of public health organizations and funded by a grant from the Texas Department of Health, founded TBNet, a multinational tuberculosis patient tracking and referral project designed to work with mobile, underserved populations. Originally created with migrant farm workers in mind, TBNet has expanded its patient base to include the homeless, immigration detainees, prison parolees, and anyone who might be mobile during treatment.

Each enrollee is given a wallet-sized Health Network card with information about how to obtain the patient's medical records. TBNet maintains a central storehouse of enrollee medical records, which can be accessed by the patient's healthcare providers in the United States, Mexico, or Central America. Mobile patients can also call TBNet's toll-free helpline to locate treatment facilities at their next destination. The wallet card, central medical record warehouse, and toll-free telephone number help to coordinate the continuous treatment of mobile tuberculosis patients. At the conclusion of treatment, TBNet notifies the enrolling clinic as well as the state or regional tuberculosis control contact person that the patient has completed treatment.

TBNet has experienced consistently high treatment completion rates for patients with tuberculosis disease. For more information, see http://www.migrantclinician.org/network/tbnet.

New Outreach and Service Provision Practices

Immigrant, international visitor, refugee, and migrant worker communities are unfamiliar with US public health and often do not understand or lack access to most medical care providers in the public or private sectors. Thus, reaching a larger proportion of these populations for tuberculosis control, especially through the new initiatives proposed for identifying and treating latent tuberculosis infection, requires a significant shift in outreach and service provision practices.

As the 2005 tuberculosis control guidelines outline, the public health sector must remain the lead in planning, coordinating, and evaluating tuberculosis control efforts in order to maintain the necessary specialized knowledge required for effective tuberculosis surveillance, case management, and contact investigation.[13] Partnering with other public health programs, social service organizations, immigrant community organizations, and federally qualified community health centers at local levels would make the most effective use of culture- and population-specific expertise, relationships, outreach, and access for foreign-born groups.

Contact Investigation

To enhance the yield of contact investigations of foreign-born cases of tuberculosis, tuberculosis control staff need to be familiar with family structure, residence patterns, social organization, and culturally-specific life cycle observances, religious practices, and socializing patterns of the immigrant populations they serve and to have their trust. Relationships with organizations that provide services to immigrants, such as English language classes or religious schools, would enhance the effectiveness of contact investigations in congregate settings.

4. Programmatic Strategies for Ensuring Continuity of Care

Transnational Continuity of Care

In most states that share borders with Mexico, binational projects have been developed within Mexican states that support the treatment of complicated tuberculosis cases. These services involve medical consultation from tuberculosis experts, laboratory support, and second-line tuberculosis medication support. These binational projects are managed by the Mexican public health physicians and staff. Cross-jurisdictional continuity of care should be improved by this collaboration and legal issues resolved, especially between the United States and Mexico, including improving tuberculosis information sharing and tracking of patients who move.[56]

SUCCESSFUL PARTNERSHIPS:

CureTB: Bi-National Tuberculosis Referral Program

The CureTB program, a service of the Health and Human Services Agency in San Diego, California, facilitates and supports the continuity of care for patients with active tuberculosis disease and their contacts who travel between the United States and Mexico, facilitates the exchange of information between healthcare providers from both countries, and provides guidance and education to patients and/or their contacts about their tuberculosis risk and need for diagnostic or treatment services. For more information, see http://www.sdcounty.ca.gov/hhsa/programs/phs/cure_tb/.

US Immigration and Customs Enforcement Detainees

Any undocumented foreign-born person apprehended by the US Immigration and Customs Enforcement (ICE) should be considered at high risk of tuberculosis infection and disease and receive appropriate screening. In federal fiscal year 2006, ICE detained 256,842 foreign nationals.[62] When brought into custody and detained, ICE detainees undergo tuberculosis screening at intake. Tuberculosis rates in the ICE detention system are substantially higher than in the general population, with a rate of 121.5 cases of tuberculosis per 100,000 persons in 2005. Tuberculosis cases with positive cultures were detected at a rate of 55.8 per 100,000 persons in 2005, a prevalence rate that was 2.5 times higher than the annual case rate in the US foreign-born population.[63]

Ideally, if a person held in ICE custody is diagnosed with active tuberculosis, every effort should be made for that person to complete a full course of treatment prior to repatriation, within the constraints of US immigration law and in the least restrictive setting.[64] US immigration law authorizes ICE to detain people for administrative reasons incident to their immigration proceedings, not for public health considerations. There are statutory limits on the duration of ICE custody, and there are ethical considerations on retaining ICE detainees in custody after their immigration issues have been resolved that need to be considered on a case-by-case basis in the contexts of personal and public health issues.

Tuberculosis control is a public health responsibility, and public health authorities are challenged to find a solution to help detained individuals with active tuberculosis complete treatment prior to repatriation. However, sometimes for political, personal, or legal reasons it is necessary to repatriate a person before treatment is completed.

Continuity of care should be ensured for ICE detainees with confirmed or suspected active tuberculosis who may be repatriated before completing treatment. In this situation, a plan for bridge case management and continuity of care must be in place and coordinated by one of the two current transnational bridge case management and patient navigation programs: TBNet (Migrant Clinicians Network, Austin, Texas) or CureTB (San Diego County Tuberculosis Control Program, San Diego, California) (local and state government item 4, bullet 3).

5. Investment in Global Tuberculosis Control and Elimination

Despite the fact that the global tuberculosis incidence rate is leveling off, the number of tuberculosis cases continues to increase due to population growth. The estimated number of tuberculosis cases in 2007 was 9.27 million worldwide,[65] and a third of the world's population is believed to have latent of tuberculosis infection.[66]

Additional research is needed, such as that conducted by Schwartzman et al.,[67] to ensure that investment in global tuberculosis control includes strategies that will affect populations and groups that immigrate to the United States. Schwartzman concluded that US support of expanded availability of directly observed therapy in Mexico would reduce importation of active tuberculosis and reduce by 130 the number of tuberculosis cases reported in the United States each year.[67] Accurate case rate

information for foreign-born populations in the United States, stratified by country of origin, would indicate in which countries similar targeted strategies could have an effect on tuberculosis incidence in the United States

If a short-course latent tuberculosis infection treatment were developed, research might indicate where targeted support for the adoption of latent tuberculosis infection treatment by national tuberculosis programs in high-burden countries with high immigration to the United States could also help to reduce the importation of latent tuberculosis infection.

TO CONCLUDE AND MOVE FORWARD: The persistence of over 7,500 tuberculosis cases per year among foreign-born residents of the United poses the greatest single barrier to tuberculosis elimination in the United States. Over 90% of the foreign-born residents arriving over the past 30 years arrived from countries in Asia, Africa, and Latin America where rates of tuberculosis remain high and the disease is endemic. These demographic realities among US arrivals result in an increasing proportion of the United States population with latent tuberculosis infection that remains largely untreated.

Effective diagnosis and treatment of latent tuberculosis infection require improved diagnostic tests and treatments, skills to overcome linguistic and cultural barriers, access to health care, and sufficient public health funding. In addition, issues of global tuberculosis, including drug resistance, require continued international efforts.

While investing in global tuberculosis activities is an important strategy for tuberculosis elimination in the United States, efforts to control global tuberculosis are not a substitute for tuberculosis control in the United States because of prior and ongoing immigration. Both domestic and international efforts need to be undertaken to address tuberculosis in the foreign-born population in the United States.

VI. Tuberculosis in Low-incidence Areas

The 2002 report of the Advisory Council for the Elimination of Tuberculosis (ACET) described the challenges to eliminating tuberculosis in areas with low-incidence rates of tuberculosis and noted that national progress toward tuberculosis elimination will necessarily lead to low tuberculosis incidence in all areas of the United States.[23] This call for action presents an updated analysis of the progress toward tuberculosis elimination in low-incidence areas with data provided by the Centers for Disease Control and Prevention (CDC). By the year 2006, 26 of the 50 states in the United States reached the status of *low incidence,* defined as having 3.5 or fewer cases of tuberculosis per 100,000 persons per year. This represented an increase from the 22 states for the year 2000 as described in the ACET report on progress toward tuberculosis elimination in low-incidence areas.[23]

The changing epidemiology of tuberculosis in low-incidence areas reveals unique and persistent challenges for tuberculosis elimination. Many of the strategies recommended in this chapter address challenges that are particularly acute in low-incidence areas but that also occur in medium- and high-incidence areas. These strategies are included here to comprehensively address low-incidence areas because, as tuberculosis elimination progresses, more areas will become low incidence and face the challenges that these strategies address.

A. Trends and Challenges

1. Changing Epidemiology

Low-incidence states with low case loads (fewer than 50 cases of tuberculosis per year) in 2000 (Idaho, Iowa, Nebraska, New Hampshire, New Mexico, North Dakota, Maine, Montana, South Dakota, Utah, Vermont, West Virginia, and Wyoming) had an 11.8% decrease in tuberculosis case rates from 2000 to 2006 that was less than the 17.9% decrease for nine low-incidence states with intermediate case loads (more than 50 cases per year) in 2000 (Colorado, Connecticut, Indiana, Kansas, Michigan, Ohio, Oregon, Pennsylvania, and Wisconsin) or the 21.2% decrease for the remaining 28 states (Table 10, page 67). Although low-incidence states are defined by case rates across the state as a whole, local case rates in cities and towns can be as high as those in high-incidence states. Low-incidence states with low case loads often face challenges in maintaining high-quality and timely clinical, laboratory, and public health services for patients with suspected or confirmed tuberculosis, yet they must meet the same complex challenges that exist in more robustly funded programs in high-incidence states such as treating patients who are foreign-born, are human immunodeficiency

virus (HIV)-infected, or have histories of homelessness or substance abuse (Table 11, page 68).

A recent example in Montana highlights the fact that low-incidence areas are not isolated from the global burden of tuberculosis.[68] Public health departments in these areas must maintain the capability to respond to multidrug-resistant cases of tuberculosis among visitors, new immigrants, and residents who travel abroad.

The data in Tables 10 and 11 illustrate that, to meet the goals of the national tuberculosis elimination campaign, we need to reinforce tuberculosis prevention and control efforts even in areas with few cases of active tuberculosis. Continuing to provide high-quality and timely services will require bolstering the tuberculosis control infrastructure through novel approaches such as the successful regionalization efforts discussed below and increasing public-private partnerships.

TABLE 10

Tuberculosis Cases and Case Rates for 2000 and 2006 in Low-incidence States by Case Load Compared to Other States

Case Load (Rate, Cases)	2000 Cases	2006 Cases	2000 Rate	2006 Rate	% Rate Change
Low **≤3.5 Case Rate** **≤50 Cases**	304	270	1.7	1.5	-11.8
Intermediate **≤3.5 Case Rate** **>50 Cases**	1,643	1,377	2.8	2.3	-17.9
Other States **≥3.5 Case Rate** **≥50 Cases**	14,363	12,132	7.0	5.5	-21.2

HIV = human immunodeficiency virus.
Source: R. Pratt, T. Navin, M. Chen, J. Becerra, CDC.

TABLE 11

Percent of Tuberculosis Cases with Specific Risk Factors: By Case Rate and Case Load (2000-2006)

Case Load (Rate, Cases)	Foreign-born (%)	AI / AN* (%)	Homeless (%)	HIV+ (%)	Alcohol and/or Drug Abuse (%)
Low ≤3.5 Case Rate ≤50 Cases	48	13	7	7	16
Intermediate ≤3.5 Case Rate >50 Cases	46	<1	5	11	15
Other States ≥3.5 Case Rate ≥50 Cases	53	1	6	16	18

AI/AN = American Indian / Alaska Native; HIV = human immunodeficiency virus.
Source: R. Pratt, T. Navin, M. Chen, J. Becerra, CDC.

2. Challenges

The most threatening challenge to tuberculosis control is the loss of infrastructure and funding similar to the environment that preceded the 1985-1992 tuberculosis resurgence. Other important challenges specific to low-incidence areas include diminishing clinical and laboratory expertise, scarcity of special facilities for prolonged health care and/or respiratory isolation, and providing tuberculosis care in settings where large geographic distances separate patients from providers.[23] Tuberculosis control programs today are losing the capacity for maintaining functions essential for tuberculosis control and are reaching conditions that set the stage for a resurgence in tuberculosis.

Diminished Infrastructure and Funds

Findings from the recent surveys by the National Tuberculosis Controllers Association on resources for tuberculosis control activities and by the National Tuberculosis Nurse Coalition and the National Society of Tuberculosis Clinicians on tuberculosis public health infrastructure have important implications for tuberculosis programs in low-incidence areas.[69] Survey results suggest that the most commonly reported barriers to reaching the national objectives for tuberculosis control were funding issues (81%), restrictions upon out-of-state travel (including for training/educational purposes) (78%), restrictions upon in-state travel (44%), hiring freezes (41%), and a loss of

tuberculosis nursing case management capacity. This loss of key infrastructure comes at a time when tuberculosis nursing case managers report increasing case management difficulties due to greater linguistic and cultural diversity of patients.

The end result for low-incidence states is that in many areas tuberculosis control efforts have been forgone for lack of resources, even within core tuberculosis program functions. For example, contact investigations may be restricted in scope with little effort made to identify contacts outside of the household setting. The result of this type of belt-tightening is a missed opportunity for early identification of persons with infectious tuberculosis and high-risk persons with latent tuberculosis infection who would benefit from treatment—and hence, and the opportunity to prevent ongoing transmission. For other high-risk persons, very few low-incidence states have the capacity to expand and/or collaborate with other medical care providers in expanding targeted testing and treatment of latent tuberculosis infection to prevent future tuberculosis cases among persons with latent tuberculosis infection.

Other factors are affecting resource allocations. Many low-incidence areas are experiencing demographic shifts and are treating increasingly complex tuberculosis cases at the same time that funding needed to maintain tuberculosis expertise and capacity is declining. Greater numbers of persons from areas of the world with a high incidence of tuberculosis are settling in regions that are unprepared to provide culturally competent care for recently arrived immigrants.[23] Public health staff face the challenges of treating and managing patients with multidrug-resistant tuberculosis, other medical conditions, and/or substance abuse and the challenges of identifying and quickly responding to tuberculosis outbreaks. One outbreak or one multidrug-resistant tuberculosis patient can absorb the entire annual budget of the tuberculosis program.[68] Public health tuberculosis control programs often have fewer resources and less knowledge and/or experience with the use of newer tools that would provide epidemiologic assistance to programs, such as using genotyping results of strains of *Mycobacterium tuberculosis* for tracking chains of tuberculosis transmission and implementing electronic information systems.

Further, having one or fewer full-time employees to perform statewide tuberculosis control functions threatens the continuity of programmatic core activities when staff are diverted to other public health activities. Tuberculosis programs in low-incidence areas are vulnerable to diminishing and co-mingled funding with other programs, which can lead to de-emphasis of tuberculosis in favor of equally important, but more visible, infectious disease threats.

Loss of Tuberculosis Control Expertise

When the incidence, prevalence, and case rate of active tuberculosis declines to a low enough level, providers (both in the private and public sectors) have less opportunity to see patients with tuberculosis, resulting in limited knowledge of the diagnosis and treatment of tuberculosis. This loss of knowledge in the basic clinical aspects of tuberculosis, the lack of familiarity with newer tests and tools (for example, the new interferon gamma release assays and molecular genotyping), and lack of awareness of

updated guidelines (for example, contact investigation) may result in negative consequences such as delays in diagnosis.

Each state has access to a public health laboratory that performs tuberculosis testing, including acid-fast smear microscopy, culture, and drug susceptibility testing. However, some providers use private tuberculosis testing laboratories which may cause delays in obtaining the test results needed for effective management of the tuberculosis patient or contact investigation. Other testing delays are due to the large geographical areas in some low-incidence states, requiring long transport times for specimens to reach the state public health laboratory.

Scarcity of Special Facilities

The historical shift of tuberculosis treatment to the outpatient setting left many low-incidence states with an unfilled void for long-term specialized centers to manage difficult tuberculosis cases that require isolation or management of nonadherence issues. Effectively managing these patients in the absence of isolation facilities presents challenges to tuberculosis control programs and increases the risk of tuberculosis transmission within communities.

Geographical Distances

In rural low-incidence states, long distances can separate patients from their healthcare providers and case managers. These distances may translate into delays in tuberculosis diagnosis and treatment as well as delays in evaluation and treatment of contacts of tuberculosis cases. These delays may limit the tuberculosis control program's ability to prevent tuberculosis transmission. Challenges in providing timely and effective case management in remote areas for patients with tuberculosis may lead to treatment failures that, in turn, may lead to acquired drug resistance.

B. Action Plans to Accelerate Tuberculosis Elimination in Low-incidence Areas

To date, there has been a notable implementation gap around ACET's call advocating that the nation "[M]ake progressing toward tuberculosis elimination in low-incidence areas a national priority."[4] That implementation gap must be addressed by action plans that require steps beyond simply controlling tuberculosis. Creative models that expand the capacity of the public health infrastructure to meet the elimination goal must be further evaluated and implemented. Following are examples of approaches to address challenges described above.

For a summary of action plans for eliminating tuberculosis in low-incidence areas, refer to Table 7: Action Plans for Tuberculosis Elimination in Low-incidence Areas, pages 14-17.

1. Stopping the Loss of Infrastructure and Capacity

The goal of tuberculosis elimination requires that tuberculosis control programs have sufficient funds and expertise to effectively perform three core functions: tuberculosis case detection and management necessary for curative treatment; identification, evaluation, and treatment of contacts of tuberculosis cases; and targeted testing and treatment of latent tuberculosis infection (local, state, and federal government item 1, bullet 1). The CDC plays an essential role in maintaining tuberculosis control capacity in low-incidence areas. Key CDC responsibilities include assessment, funding, staffing, operational research, technical assistance for surveillance and program evaluation, surge capacity for outbreaks, and support for interstate access to facilities (local, state, and federal government item 2, all bullets). State and local governments are responsible for maintaining high-quality core tuberculosis control functions by providing health infrastructure and staff and the funding to pay for care for the uninsured, regardless of visa status or citizenship (federal government item 2, all bullets; state and local government item 5, bullets 1, 2, and 3).

2. Regional Collaboration among State Tuberculosis Control Programs

Two regionalization approaches, developed in response to the Institute of Medicine (IOM) and ACET recommendations, rely on networks of experts and consultants along with regionalization of some programmatic activities.[70] Both of these approaches are meant to enhance and provide added value (not replace) existing state and local tuberculosis control programs.

SUCCESSFUL PARTNERSHIPS:

Regional Collaborations

New England Tuberculosis Consortium
http://newenglandtb.pbworks.com/

Proposed Approach to Tuberculosis Control and Elimination in the Low-Incidence Region of Idaho, Montana, Utah and Wyoming

http://www.nationaltbcenter.ucsf.edu/research/patce.cfm

The use of these approaches to date suggests that, in order to facilitate this work, resources are needed to support field-based dedicated regional staff and that individual states (or persons within those states) must be willing to work as a team and collaborate on joint activities.

The principal difference between these two models is the allocation of resources to develop, evaluate, and sustain them (local, state, and federal government item 1, bullet 2; federal government item 2, all bullets; state and local government item 5, bullet 1). For example, in the New England model, the CDC supports a medical consultant based

in Connecticut and a health educator based in Massachusetts. These persons provide the coordination and support necessary to assess regional needs and work with the New England tuberculosis controllers to design interventions. With additional federal resources to bolster individual state support, these models could be further expanded, supported, and evaluated to identify other regions for potential collaboration.

TABLE 12

What the Regionalization Model Provides

1. A formal mechanism for communication and collaboration among state partners
2. Increased capacity for program expertise, policy development, training, and advocacy
3. Local decision-making that provides greater flexibility and faster responses to change
4. Low-incidence specific resources (such as templates of a tuberculosis manual, an outbreak response plan, and tools for performing statewide case management teleconferences)
5. Ongoing clinical consultation
6. Ongoing regional training tailored to low-incidence areas (In New England, a Regional Training and Medical Consultation Center [RTMCC] educator provides on-the-ground training, working side-by-side with the state and local programs; in the Western Region of the United States, the Centers for Disease Control and Prevention (CDC)-funded RTMCC provides a similar training in its nurse-to-nurse training model.)
7. Support for a regional laboratory network to build enhanced capacity for diagnosis, treatment, and monitoring of treatment response
8. Identification of local cultural and linguistic resources
9. A regional genotyping cluster investigation and outbreak surveillance system to rapidly identify potential transmission events (or false positives)
10. Enhanced interstate shared case and contact management when patients cross state borders (e.g., inmate or homeless connections, immigrant and refugee needs)
11. Opportunities for the use of a regional specialized tuberculosis medical unit for tuberculosis patients with complex medical and/or adherence issues (e.g., the Tuberculosis Treatment Unit at the Lemuel Shattuck Hospital in Massachusetts)
12. Cost efficiencies with shared resources
13. Opportunities to work with other regional models (e.g., Federal Training Centers) and to work collaboratively on CDC Program Integration and Service Collaboration (PCSI) initiatives

3. Collaboration among Disease Programs

In addition to regional collaboration, sharing resources and expertise across disease programs has benefits at the state and local level. Because of challenges posed by different program priorities and variations in the epidemiology and interventions for different diseases, written agreements or procedures may be helpful to assure that tuberculosis control functions are maintained.

SUCCESSFUL PARTNERSHIPS:

Program Collaborations to Share Resources and Expertise

Below are three examples of collaborative activities that support the Centers for Disease Control and Prevention's Program Collaboration and Service Integration efforts.

In the Massachusetts Department of Public Health:

A Bureau of Infectious Disease nursing response team provides cross-bureau surge capacity. For example, nurses responded to a cluster of tuberculosis cases and performed contact investigation and screening in a prison setting and responded to hepatitis vaccination initiative in the county jails.

A simplified electronic case management and communicable disease surveillance system provides outbreak response capacity and immediate electronic transmission of laboratory results and susceptibilities at the state and local level.

In Connecticut:

The tuberculosis control program initiated cross training so that tuberculosis case managers could become certified human immunodeficiency virus (HIV) counselors. This cross training allowed for testing of tuberculosis patients and their contacts in non-medical settings thereby facilitating testing and improving case management of patients coinfected with tuberculosis and HIV.

4. Education and Training to Build Public Awareness and Provider Expertise

To address issues of tuberculosis awareness and expertise, tuberculosis control programs in low-incidence areas should have access to the recommended resources to promote general awareness of tuberculosis and maintain private and public sector provider competence (state and local government item 5, bullet 2; community partners item 6, bullets 1 and 2).

5. Interstate Collaboration for Access to Special Facilities

To address the need for special facilities for prolonged care for tuberculosis—both for patients who have complicated case management issues including drug resistance, HIV, or other comorbidities and for those who are nonadherent to treatment or necessary

testing—small tuberculosis control programs and programs in low-incidence areas should consider regional partnerships through contractual agreements or mutual aid agreements. These agreements can support a regional tuberculosis referral center that allows patients throughout that region to have access to specialized multidisciplinary tuberculosis treatment and management.

Specific activities to implement this general recommendation include the following:

- Support current facilities with appropriate expertise (such as existing centers in Massachusetts and Florida) and assess cross-jurisdictional issues related to their capacity to accommodate patients from other jurisdictions and challenges for doing so (legal and non-legal)
- Replicate and support successful models so that all low-incidence areas (and other states with no long-term hospitalization resources) have the ability to hospitalize these patients when needed
- Assess current tuberculosis control laws and regulations and develop model tuberculosis laws which can be adapted as needed

6. Enhancing Laboratory Capacity and Access to Services

Timeliness of laboratory information is critical to rapid identification of persons with tuberculosis, appropriate treatment, and case management. Low-incidence areas should assess whether there is adequate need (as defined by the Association of Public Health Laboratories) to maintain their own expertise and/or whether there is an option for use of other public health or private laboratories (state and local government item 5, bullet 3).

Specific activities for low-incidence areas include: analyzing public health regulatory options (for example, in Wisconsin a portion of each specimen must be provided to the state tuberculosis laboratory, thereby eliminating the difficulties associated with specimens sent out-of-state to private laboratories); building a consortium model of in-state tuberculosis laboratories organized and facilitated by state public health laboratories; assuring that an electronic information system exists for laboratory reporting to the public health agency; assuring access to external laboratories for specialized services such as second-line and rapid drug susceptibility testing and genotyping; supporting laboratory training in mycobacteriology and incentives to new graduates of microbiology to learn about tuberculosis; and assuring that a courier service provides timely delivery of specimens to the central tuberculosis laboratory.

For states with a low tuberculosis case load resulting in few specimens tested at the state mycobacterial laboratory, it is still necessary to ensure high-quality and timely tuberculosis diagnostic laboratory services in order to avoid missed or delayed diagnosis and to help guide in the treatment of tuberculosis. Maintaining the resources and laboratory expertise needed for the full range of laboratory services in low-burden areas may not be feasible, and certain specialty tests such as molecular drug susceptibility testing should be done at contract laboratories or regional public health

laboratories. Careful monitoring of performance of external laboratories that provide these services, with mechanisms to improve unsatisfactory performance, should be a core function of the state public health laboratory.

7. Public and Community Health Teams

Geographic isolation presents a host of challenges for tuberculosis control in low-incidence areas with low population density. The CDC and state tuberculosis control programs should collaborate in piloting two potential public health models based on population density: permanent on-site assigned teams and ad hoc community teams.

Where the population density allows, public health teams could be assigned on-site to a defined location. The on-site approach could have teams responsible for all communicable disease follow-up including tuberculosis (and perhaps other chronic health issues as well). These teams should link a public health nurse and a public health advisor with medical, epidemiologic, and programmatic consultants. In this scenario, community members could be recruited and trained to perform the daily activities (such as directly observed therapy). This type of approach would require a cross-disease shift of thinking by policy makers.

Alternatively, in less dense, remote areas, an ad hoc community health team could be identified and mobilized when required, supported by technical assistance and education as needed at the state and federal level.

TO CONCLUDE AND MOVE FORWARD: Tuberculosis trends from 2000 to 2006 indicate that the declines in tuberculosis rates are lowest in the low-incidence and low-case-load states, suggesting that even greater efforts will be needed to maintain the necessary mobilization to eliminate tuberculosis as rates decline. As the nation progresses toward tuberculosis elimination, more states and local areas will face the challenges of providing their residents with timely and high-quality services for the diagnosis, treatment, and prevention of tuberculosis. The lessons learned in two successful regionalization efforts should be adapted and applied in other regions of the nation.

Addressing the ongoing challenge of tuberculosis in low-incidence areas will require stopping the loss of infrastructure and capacity, education and training to build public awareness and provider expertise, interstate collaboration for access to special facilities, and enhancing laboratory capacity and access to services. As well, there is a need for creative and innovative approaches such as regional collaboration among state tuberculosis control programs, collaboration among disease programs, and public and community health teams.

VII. Mobilizing Partners in the Fight against Tuberculosis

The well-defined epidemiology of tuberculosis, evident health disparity in those that suffer from tuberculosis, and the curable and preventable nature of the disease make tuberculosis a provocative social issue for change. Eliminating this common preventable and curable contagious disease has huge individual and public health benefits as described in the earlier sections, and we must address these health disparities more effectively if we are to reach the revised 2035 goal for tuberculosis elimination.

The 2000 Institute of Medicine (IOM) report identified the lack of political will as a major barrier to tuberculosis elimination and listed social mobilization to build and sustain the political will in the United States as one of the five specific goals (Table 1, page 6). Since the resources for tuberculosis elimination have actually been decreasing rather than increasing over the last decade as recommended by the IOM (Figure 5, page 31), we must seek more effective approaches to social mobilization. This section will briefly describe the history of social mobilization in the United States and suggest answers to the questions about how to achieve the local, state, and national political will to eliminate the threat of tuberculosis from the United States.

A. History

In 1798, President John Adams signed into law an act which furnished medical services for merchant seaman called the Marine Hospital Services. This service existed until 1878 when its functions were expanded greatly. The prevalence of major epidemic diseases caused Congress to enact a national law to prevent the introduction of contagious and infectious diseases into the United States, later extending it to preventing the spread of disease among the states. This was the beginning of the US Public Health Service.[71]

State and local health departments maintained authority for disease control, including the treatment and control of tuberculosis. The overwhelming number of tuberculosis cases at the turn of the century challenged states' abilities to provide care and treatment for tuberculosis; thus came the emergence of partnerships from many different individuals and organizations.

In 1904, the National Association for the Study and Prevention of Tuberculosis was founded as the first nationwide, voluntary health organization aimed at conquering a specific disease and is known today as the American Lung Association (ALA). The ALA and the American Thoracic Society (ATS) played major roles in the successful social

mobilization that occurred in response to the tuberculosis resurgence that began in the 1980s.

Also in the early 1900s, other local voluntary organizations across the country formed partnerships to fight tuberculosis. For example, in 1917, in Columbia, South Carolina, the Daughters of the Holy Cross, an Episcopal Church women's group, started an organization called the Richland Anti-Tuberculosis Association. Its purpose was to "promote the dissemination of useful and authentic facts as to the origin and spread of tuberculosis and to put in operation preventive methods, to establish and maintain clinics, dispensaries and sanitariums for persons suffering from tubercular disease in Richland County." This organization provided funding to the South Carolina State Board of Health to hire the state's first public health nurses to specifically work in tuberculosis control. The Richland Anti-Tuberculosis Association, a philanthropic organization, is still active today providing funding for patient housing, the TB PhotoVoice project,[72] and other small projects directed toward tuberculosis elimination.

While these are examples of previous successful efforts at the national and local levels, we will need to achieve and sustain a far broader level of social mobilization for tuberculosis elimination to be successful in the United States. Cooperation and collaboration will be required by policy makers at federal, state, and local levels, the public health sector, medical practitioners, professional societies, community-based organizations, and voluntary organizations. This chapter describes the various partners that are needed to succeed in this effort.

B. Advocacy and Mobilization

Advocacy is one of the most important tools available for the prevention and control of tuberculosis. Building a framework for tuberculosis advocacy requires a mobilization of partners and public health organizations to address the need for changing attitudes and conditions that exist concerning the prevention and control of this public health menace.

Advocacy is more than confronting public officials and lobbying in support of certain legislative issues. Advocacy is a process of building awareness of tuberculosis, supporting patient-centered activities, and maximizing resources and services for the care of persons with tuberculosis. Advocacy opens doors and creates opportunities to change minds and end the neglect of tuberculosis as a disease that impacts people and communities across the globe.

The Centers for Disease Control and Prevention (CDC) has provided a valuable toolkit for advocacy, mobilization, and building partnerships, *Forging Partnerships to Eliminate Tuberculosis, 2007,* that is available online at http://www.cdc.gov/tb/publications/guidestoolkits/forge/default.htm.

1. Communication Strategies

A picture is worth a thousand words, and the visual presentation of local surveillance data is a powerful visual education tool that can be used to create partnerships and has been used by programs successfully. Painting a local picture with surveillance data is important for health commissioners, community taskforce groups, and politicians. More use needs to be made of geographical mapping of cases and illustrating chains of transmission through the use of molecular genotyping to identify specific strains of *Mycobacterium tuberculosis*. In San Francisco, molecular genotyping data has been used to link cases of recent transmission to a community drop-in center and convinced site managers that mandatory screening for tuberculosis was necessary and would greatly benefit their community.

Patients, who are willing to tell their personal stories to community groups, media, and journalists, put a face on tuberculosis and provide the engagement often lacking in programs advocating for support of health departments and tuberculosis elimination efforts. Encouragement of patients and family members to speak out and join tuberculosis advocacy organizations is currently lacking and sorely needed.

Tuberculosis prevention and control activities in communities where foreign-born persons reside are often hampered by challenges associated with a lack of knowledge of tuberculosis transmission patterns, a lack of providers who understand the culture of the populations at risk, and the inability of this population to trust and navigate the healthcare system. There is a tremendous need for community organizations and healthcare providers to advocate for these communities. There is a need for voices to speak out and communicate the need for culturally specific interventions.

Within every US state, there is an urgent need for advocacy and expanded tuberculosis-related collaboration among state and local lung associations, professional organizations (such as Thoracic Societies, College of Chest Physicians groups, etc.), other key community advocacy groups (such as RESULTS), and other organizations fighting respiratory diseases including the state and/or local health departments and lung association spin-off organizations. These organizations should all become effectively involved in a state (or community) specific Stop TB Coalition to design and support tuberculosis elimination campaigns, related resources, partnerships, and efforts. These collaborations should include development of mutually agreed upon annual state and/or local tuberculosis elimination advocacy strategies that spell out (1) related annual objectives and (2) related roles and responsibilities for involved organizations.

Internationally, there is a need for organizations like the Pan American Health Organization (PAHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD) to create opportunities for advocacy around tuberculosis.

2. Partnerships

State or community tuberculosis elimination advocacy campaigns and related partnerships should include participants from at-risk populations and groups. The

advocates should fully understand the goals and the mission of the community advocacy campaign, and the campaign also should include community gatekeepers.

Strategies for partnering with correctional facilities, shelters, and providers of substance abuse treatment provide opportunities to increase awareness of tuberculosis in their communities, as well as to ensure better care and focus on eliminating tuberculosis. Legislative actions, requests for additional resources, and funding opportunities carry more weight when partnerships are involved. Partnership can take many forms such as creating local task force groups or designating individual tuberculosis control personnel as liaisons for homeless shelters, correctional facilities, or other facilities. Regional corrections and tuberculosis control councils can bring together correctional health and custody staff with local and state health department officials to identify and solve common problems.

In communities where foreign-born persons reside, the risk of tuberculosis and the opportunities for control and elimination must be considered. Tuberculosis prevention and control programs must be put in place that involve outreach, education, targeted screening, and intensive case management. Case management and other support services must be provided in the patients' native languages and in alignment with their cultural beliefs and personal health priorities. Voices of advocacy must be heard from providers and community leaders stressing the need for community resources to prevent and control tuberculosis.

C. Diversity of Partners

Eliminating tuberculosis in the United States is not an easy task, given the way tuberculosis is transmitted and the current inadequacies of public health systems to properly address tuberculosis. No one agency, organization, or group holds full responsibility

The **President and Congress** must make a bold political commitment and investment if we as a nation are to be successful in eliminating tuberculosis. Over the last ten years, federal funding for our domestic tuberculosis program has been near stagnant despite widely publicized examples of the domestic threat posed by the global spread of multidrug-resistant tuberculosis, which is harder and more expensive to diagnose and treat. We cannot expect to eliminate tuberculosis without additional resources to boost efforts in states and local cities.

Federal agencies, including the US Departments of Health and Human Services (HHS), Homeland Security, Interior and Justice, are important partners. HHS houses the CDC which provides a critical source of funding to support state and local programs. The CDC also produces guidelines for the management of tuberculosis, offers technical and investigative expertise to address tuberculosis outbreaks, and coordinates the multicenter clinical and operational research needed to translate research on new tools into practice. HHS also houses the National Institutes of Health (NIH), the agency

responsible for conducting critical basic science and clinical research to find new tools to fight tuberculosis. Homeland Security focuses on immigration issues and ensures that immigrants to the United States are properly screened and treated for tuberculosis before entering. HHS also houses the Indian Health Service, which addresses tuberculosis within native Indian populations, and houses the HHS-supported Community Health Centers that serve populations at increased risk of tuberculosis, including migrant workers, persons with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), and racial and ethnic minorities. The Federal Tuberculosis Task Force coordinates the activities of these federal agencies in their respective roles in the national tuberculosis elimination effort.

State, territorial, and local health departments drive the work to eliminate tuberculosis as they face the realities and challenges of tuberculosis on the ground. Health departments, at all levels, are charged by law with control of all communicable diseases, including tuberculosis. They are responsible for establishing the rules and regulations which govern reporting, investigation, diagnosis, treatment, and other public and personal health control measures. These laws, rules, and regulations define the screening of high-risk groups and the evaluation, treatment, and isolation of persons suspected of having contagious tuberculosis. Some local health departments provide public health clinics where all patients can receive treatment at no cost. If public health clinics do not exist, local departments partner with community healthcare providers to provide patients adequate and recommended treatment until cure. Coordination of state and local tuberculosis programs with HIV/AIDS programs is also essential in addressing tuberculosis/HIV co-infection. Health departments have a crucial and unwaiverable public responsibility to provide the citizenry and tuberculosis advocacy groups with timely and complete tuberculosis-related surveillance and evaluation data. These data should include information about the occurrence of community and institutional outbreaks of tuberculosis and related control efforts in their jurisdictions. Tuberculosis outbreaks need to be acknowledged and reported upon until ended.

Professional public health organizations are often affiliated or partnered with state, territorial and local health departments and play varied roles in the effort toward tuberculosis elimination. The Association of State and Territorial Health Officials (ASTHO) is primarily made up of state commissioners of public health and other high level health department policy makers. The National Association of County and City Health Officials (NACCHO) addresses policy issues facing public health agencies across the United States. The American Public Health Association (APHA) represents a broad array of health officials, educators, environmentalists, policy makers, and other health providers, of all levels, working both within and outside governmental organizations and educational institutions. APHA collaborates with the ATS in conducting tuberculosis advocacy for increased funding and works closely with the National Tuberculosis Controllers Association (NTCA) and Stop TB USA to educate legislators and policy makers about tuberculosis.

Tuberculosis elimination advocacy campaigns should use health department surveillance and evaluation data. These campaigns should widely publicize successes in meeting state and community tuberculosis control program goals such as completion of tuberculosis treatment and evaluation and treatment of contacts with latent tuberculosis infection. In addition, the success in meeting local and state goals in tuberculosis elimination should be publicized. The NTCA and its associate sections, the National Tuberculosis Nurse Coalition and the National Society of Tuberculosis Clinicians, bring together leaders in tuberculosis control programs across all states and territories as well as in many county and city health departments. Another public health partner is the Association of Public Health Laboratories (APHL), representing state and local public health laboratories, which serve as laboratory first responders protecting the public from disease and environmental health hazards. State and local public health laboratories provide tuberculosis services that are critical to the diagnosis, treatment, and control of tuberculosis. APHL also serves as an advocate to support tuberculosis control programs. The membership of these organizations need to be trained on how to communicate with the media to report on tuberculosis exposures and/or outbreaks. The goal of this interaction is to garner continued public support for tuberculosis elimination while facilitating public responses that are appropriate from public health and humanitarian perspectives.

Medical associations are essential partners providing a variety of services to eliminate tuberculosis. For example, the ATS, once the medical arm of the ALA, is a leading medical association that focuses on medical aspects of tuberculosis and on advocacy for greater federal tuberculosis funding for states. The Infectious Diseases Society of America (IDSA), along with the CDC and the ATS, has participated in the writing and publication of documents critical to the treatment and control of tuberculosis. The American Academy of Pediatrics (AAP) also participates in the writing and publishing of recommendations for tuberculosis treatment and control in children in the *Red Book: 2009 Report of the Committee on Infectious Diseases*. These organizations should all be involved in the tuberculosis advocacy campaigns and related planning.

Academic institutions are expected to provide the training and education to a new generation of healthcare workers and conduct valuable research on basic science, clinical, social, and public health issues pertinent to the treatment and control of tuberculosis and other infectious diseases. Schools of public health, particularly, are training grounds for public health department workers in the areas of management, epidemiology and biostatistics, health education and environmental issues, and advocacy. Students participate in hands-on experiences with public health professionals, and many are recruited to fill key positions in public health departments and partner organizations. However, many medical and nursing schools do not focus on tuberculosis in their curricula, contributing to the occurrence of missed and delayed diagnosis and/or inadequate treatment of tuberculosis cases. Academic institutions need to address these issues in their curricula in order to reduce the preventable disability, death, and acquired drug-resistance due to these clinical errors.

The **private sector**, primarily pharmaceutical and biotechnology companies, is a key partner in the fight against tuberculosis and should play a significant role in developing new and effective tools. Similarly, product development partnerships (PDPs) and public-private partnerships (PPPs) have emerged as important players in the development of new tools. These not-for-profit entities leverage the best practices of industry, academia, public research institutes, and contract research organizations with funding from companies, governments, and philanthropic donors to accelerate product development. As some PDPs and PPPs rely on outside partnerships, resources, and funding, they often engage in advocacy to raise awareness about the need for better tools for tuberculosis.

Faith communities are significant resources for education, outreach, and training for their constituencies, often in partnership with state and local programs. Where tuberculosis services are very weak, **community-based organizations** provide critical services to the underserved and minority populations, and their involvement in tuberculosis elimination campaigns is crucial in bringing voice to the cause of tuberculosis elimination and advocating for increased resources and policies that will have positive impact in moving the country forward toward tuberculosis elimination.

As the National Center for Cultural Competence states, "a major principle of cultural competence involves working in conjunction with natural, informal supports and helping networks within diverse communities. The concept of **cultural brokering** exemplifies this principle and can bridge the gap between healthcare providers and the communities they serve." Cultural brokers exist or can be cultivated in immigrant, refugee, and US-born minority communities, including those with higher risk factors for tuberculosis such as homelessness, substance abuse, mental illness, and correctional facility residence. Among the persons who can become cultural brokers and partners in healing with medical providers are practitioners of healing practices or traditional healers in immigrant, refugee, and minority communities. These persons should be identified and encouraged to join in the state and community tuberculosis elimination advocacy campaigns.

D. Assessment of Progress in Social Mobilization for Tuberculosis Elimination

We should not forget or overlook the successful social mobilization efforts to address the tuberculosis resurgence that occurred two decades ago in the United States. The National Coalition for the Elimination of Tuberculosis (NCET), now known as Stop TB USA, was established in 1991 with funding from the Robert Wood Johnson Foundation as well as the ALA and ATS. NCET's efforts in collaboration with its many partners were apparently successful in achieving the dramatic increase in federal funding for tuberculosis control, but not in bringing about the additional increases in funding that were recommended by the IOM in 2000.

Regarding social mobilization, the IOM specifically recommended that:

- The CDC be provided with significantly increased resources for tuberculosis elimination efforts and sustain public understanding and support for the effort at national, state, local, and risk-group levels
- NCET work with the CDC to secure the support and participation of nontraditional public health partners, ensure the development of local and state coalitions, and gain the assistance of public opinion research experts in evaluating public opinion in order to garner public support for the elimination effort
- The Office of the Secretary of Health and Human Services periodically conduct an evaluation of the actions take in response to the IOM recommendations

The Stop TB USA Tuberculosis Elimination Plan Committee believes the year 2000 IOM recommendations for social mobilization remain valid and should be implemented, but what has been the response to these IOM recommendations on social mobilization? Ten years later, flat-funding, budget cuts, and rescissions have prevented the CDC from providing "significantly increase resources" for eliminating tuberculosis. At a retreat in 2007 on the status and future of NCET, it was noted that NCET had not replaced the initial funding provided in 1991 by the Robert Wood Johnson Foundation, limiting its resources to volunteer efforts. To our knowledge, the recommendation for periodic reports by the Secretary of Health and Human Services on the progress towards addressing the IOM recommendations has not been addressed.

E. Recommendation for Achieving Social Mobilization for Tuberculosis Elimination

The United States has a history replete with examples of social mobilization efforts that have been successful in addressing important health issues including tuberculosis, poliomyelitis, and AIDS. Social mobilization efforts in the fight against tuberculosis were successfully launched again in the 1990s after the resurgence of tuberculosis associated with fatal cases occurring in outbreaks of multidrug-resistant tuberculosis. The successful social mobilization that occurred in response to this tuberculosis resurgence was due in large part to the resources provided to NCET by the Robert Wood Johnson Foundation, the ALA, and the ATS, and it needs to be replicated. We now face a major challenge of launching and maintaining a successful mobilization effort for a life-threatening disease that will become increasingly rare as we progress toward eliminating tuberculosis. We must maintain long-term engagement of a variety of partners in the effort while overcoming the barriers of stigma that inhibit the participation of our communities of immigrants, minorities, and HIV-infected persons who are at highest risk of death and disability due to tuberculosis.

Based upon the recommendations from the 2007 retreat with the CDC, NCET and a number of partners made the following recommendations:

- NCET should transition to Stop TB USA. This name change reflects the need to be more readily identified as the point of contact for the Stop TB Partnership at the World Health Organization and as the point of contact for the United States with the global tuberculosis elimination effort
- Stop TB USA will need to identify a source of infrastructure funding in order to function as an effective coalition. We recommend that national, state, and local voluntary and professional organizations supporting the control and elimination of respiratory and infectious diseases assist Stop TB USA in obtaining the infrastructure funding needed to mobilize all it members and partners in generating the political will to make the elimination of tuberculosis a national priority

TO CONCLUDE AND MOVE FORWARD: The IOM stated, "social mobilization is necessary to build and sustain political will (for tuberculosis elimination) in the United States and can lead to similar efforts internationally." However, today tuberculosis is not generally viewed as a problem in the United States, and there has been only limited success over the last ten years in the social mobilization needed to eliminate tuberculosis.[12]

Stop TB USA and its partners must work together to develop the political will needed to advocate for the development and implementation of new tools needed both domestically and globally to eliminate TB among high-risk US-born and foreign-born populations in the United States and to maintain the TB control infrastructure in low-incidence areas.

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