EXECUTIVE SUMMARY

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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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]

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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.

References

[1] CDC. *Reported Tuberculosis in the United States, 2008.* Atlanta, GA: US Department of Health and Human Services; 2009.

[2] Pasipanodya JG, Miller TL, Vecino M, Munguia G, Garmon R, Bae S, Drewyer G, Weis SE. Pulmonary impairment after tuberculosis. *Chest.* 2007;131:1817–24.

[3] Marks SM. Potential TB treatment cost savings using moxifloxacin-based regimens. *TB Notes.* Atlanta, GA: CDC, US Department of Health and Human Services; 2006;1:13–15. (Costs are in 2004 dollars.)

[4] Manangan LP, Moore M, Macaraig M, et al. Health department costs of managing persons with suspected and noncounted tuberculosis in New York City, three Texas counties, and Massachusetts. *Journal of Public Health Management Practice.* 2006;12:248-53.

[5] Banerjee R, Allen J, Westenhouse J, et al. Extensively drug-resistant tuberculosis in California, 1993-2006. *Clin Infect Dis.* 2008;47:450-7.

[6] Chou L, Harrington M, Huff B, Jefferys R, Swan T, Syed J, Wingfield C. *2008 Pipeline Report.* New York, NY: Treatment Action Group; July 2008.

[7] Cost estimates according to S. M. Marks, unpublished data, 2009.

[8] Fauci, A. Opinion: Fighting TB should be priority: tuberculosis kills almost 2 million every year. Where is the outrage? MSNBC.com Web site. November 17, 2009. Available at: http://www.msnbc.msn.com/id/33890464/ns/health-infectious_diseases/#storyContinued. Accessed February 3, 2010.