

Tuberculosis

**AN OPPORTUNITY TO ELIMINATE A DISEASE
IN THE UNITED STATES**



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ABOUT NTCA

The National Tuberculosis Controllers Association (NTCA) is a nonprofit, professional, member service organization located outside Atlanta, Georgia. NTCA was created in 1995 to bring together the leaders of tuberculosis (TB) control programs in all states and territories, as well as many county and city health departments that organize their own TB control activities. NTCA represents TB public health programs throughout the US, the US territories, including the US-Affiliated Pacific Islands, speaking with “one voice” for geographically and structurally diverse TB public health programs. The mission of NTCA is “to protect the public’s health by advancing the elimination of TB through the concerted action of state, local, and territorial TB programs.”

ABOUT STOP TB USA

The Stop TB USA Partnership is a coalition of individuals and organizations working toward the elimination of TB in the US. The Partnership’s vision is to assist in the elimination of TB as a public health problem in the US through public health, scientific, and educational activities, and the mission is to strengthen TB prevention, care, and control in the US. Originally formed as a voluntary organization, the National Coalition for the Elimination of TB (NCET), Stop TB USA’s history dates back to the early 1990s, in preparation of the resurgence of TB in the US. In 2007, recognizing the need to collaborate within the broader global TB elimination movement, NCET members agreed to transition to Stop TB USA, the US partner within the global Stop TB Partnership at the World Health Organization (WHO).

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EXECUTIVE SUMMARY

Tuberculosis (TB) is an airborne disease, spread from person to person resulting in 1.8 million deaths per year worldwide. According to the World Health Organization (WHO), TB is now the leading infectious killer of people in the world (ahead of human immunodeficiency virus infection and acquired immune deficiency syndrome [HIV/AIDS]), and strains of TB resistant to antibiotics are increasing. 480,000 cases of multidrug-resistant TB (MDR-TB) were reported in 2015, despite TB being a preventable and curable disease.

US-SPECIFIC IMPACTS

TB remains a major public health threat in the US, and 9,287 cases of the disease were reported in 2016.

This represents an excess of almost 9,000 people with TB disease relative to published TB elimination goals. Moreover, up to 13 million Americans are believed to be infected with TB but are not yet ill and likely unaware they are infected. TB outbreaks occur across the US every year at schools, workplaces, and in correctional facilities. In 2016, the state of Alabama experienced two major outbreaks, where three people died and over 1,200 required costly medical testing and evaluation for TB.

Approximately 500 people in the US die of TB each year.

SOCIETAL COSTS

Treatment costs for MDR-TB range from \$100,000 to \$300,000 per person, while extensively drug resistant TB (XDR-TB), which does not respond well to any known antibiotics, can exceed \$1 million per person. Between 2008 and 2015, there were 822 people with MDR-TB (totaling \$82.2–\$246.6 million), and 18 people with XDR-TB (exceeding \$18 million) in the US. The societal cost to the US of not eliminating TB over the past 20 years is estimated from \$19.9 to \$27.7 billion and is likely to continue at over \$400 million per year if our ongoing failure to eliminate TB is not addressed.

SOLUTIONS

A national plan for eliminating TB in the US was proposed in 1989 and reaffirmed by an Institute of Medicine review in 2000, but key components of the plan were never adequately funded and fully implemented. As a result, there has been no progress towards eliminating TB over the past several years. In 2015, an interagency committee developed a *National Action Plan for Combating Multi-drug-Resistant Tuberculosis* but, again, no funding was provided to implement the well-articulated and systematic plan.

This administration and Congress could start the US on a successful path toward TB elimination and

dramatically reduce the health and economic costs of TB in the US. Central to eliminating TB will be a prevention initiative, identifying those at highest risk and treating the infection before an individual breaks down with disease and is able to infect others.

KEY RECOMMENDATIONS INCLUDE:

- ▶ **Establish a focus on domestic TB elimination within the Executive branch** by forming a presidential tuberculosis elimination initiative.
- ▶ **Support funding for domestic TB elimination activities** of up to \$195.7 million, to address funding gaps for US TB control programs due to chronic underfunding, to develop a national prevention initiative, and to support increased research for new diagnostic tools, vaccines, and antibiotics.
- ▶ **Increase funding for global TB control** and prevention programs through CDC and United States Agency for International Development (USAID) to \$450 million.

Specific actions for each recommendation are detailed in this statement, *Tuberculosis: An Opportunity to Eliminate a Disease in the United States*, along with references. **We are confident that by working with the current administration and Congress, we can achieve the historic goal of eliminating TB in the US.**

INTRODUCTION

Tuberculosis (TB) is an airborne disease, spread from person to person resulting in 1.8 million deaths per year worldwide. According to the WHO, TB is now the leading infectious killer of people in the world (ahead of HIV/AIDS), and strains of TB resistant to antibiotics are increasing. 480,000 cases of MDR-TB were reported in 2015,¹ despite TB being a preventable **and** curable disease.

A national plan for eliminating TB in the US was proposed in 1989 and reaffirmed by an Institute of Medicine review in 2000.² The key components of this plan, and the implementation status of each, are as follows:

- **Maintain control of TB** while adjusting control measures to declining incidence of disease and changing system of health care management.

TB cases in the US have decreased by 64% over the past 20 years, with estimated total societal benefits of \$6.7 to \$14.5 billion.³ However, during the same period, state and local public health programs suffered continuous erosion to the infrastructure that is needed to achieve TB elimination.

Why is public health important?

Capacity to contain and eliminate TB in the US rests with state and local departments of public health, where essential, specialized expertise and interventions, such as contact investigations and nursing case management, reside. These services are provided outside of the domain of private healthcare.

In a 2012 survey of US state, city and county/regional TB programs, 58% reported decreased funding and 60% reported loss of critical staff necessary to ensure excellent care, investigate cases, and ensure TB patients complete their course of treatment.⁴ Even more concerning is that 33% of states and 56% of large cities reported decreased capacity to identify and provide testing and preventive treatment for people with TB infection.⁴ This loss of services significantly impacts state and local TB program capacity to (1) diagnose and treat TB disease and (2) identify persons who have been exposed and infected and reduce their risk of TB disease. (3) It precludes any option of conducting targeting testing among high-risk populations that aims toward TB elimination in the US.

Without increased federal leadership and funding to rebuild the US public health infrastructure, the US will lack state and local capacity to respond to new TB outbreaks. Individuals, families, and communities will suffer from this preventable disease.

An additional challenge to our ability to maintain control of TB relates to an extremely vulnerable TB drug supply. In the current US market, TB drugs are at constant risk of stock shortages or radical price hikes that render the drugs unavailable or unaffordable by patients and public health programs. For example, isoniazid (one of two main drugs used to treat TB disease and infection) was unavailable in the US from mid-December, 2012 through April, 2013, and remained on back-order until June, 2013. During these six months, US TB programs had to prioritize which patients to treat and even stop treating some patients. Inconsistent supplies and unaffordable prices of TB drugs jeopardize the health of Americans and bring increased collateral costs when public health programs must find and procure alternate (often more expensive) drugs. In contrast, the global market has a stable supply of inexpensive, quality-assured TB drugs organized by the Global Drug Facility (GDF).

Americans and our public health programs do not currently have access to these drugs through GDF due to drug registration limitations. Leadership from this administration and engagement with US public health programs and the US Food and Drug Administration (FDA), could revolutionize the availability and affordability of TB drugs in the US. Such leadership could prevent stock shortages for the American public and support local TB elimination efforts, while allowing US patients and healthcare providers to access top-quality drugs affordably, with guaranteed availability.

► **Accelerate the decline of TB by increasing efforts at targeted testing and treatment of latent TB infection (LTBI).**

The Centers for Disease Control and Prevention (CDC) estimates that up to 13 million people in the US have LTBI.⁵ People with LTBI are not sick with TB disease but are at risk of developing TB disease if not diagnosed and treated. People with TB disease may spread it to others. Improved diagnostic tests and safer treatments are now available that can reduce this risk by at least two-thirds.⁶ Each person with LTBI represents an opportunity to prevent TB disease in the future, yet LTBI testing and treatment have declined in recent years because of decreased public health resources for TB.

In September, 2016, the US Preventive Services Task Force (USPSTF) recommended expanded testing for LTBI among people at high risk of being exposed to TB. To eliminate TB in US, we must immediately scale up public health programs to expand treatment of high-risk populations and to enable health departments to engage primary medical care providers in treating the millions of people with LTBI.⁷

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

Success in achieving this goal has been limited, and antibiotic resistance has increased steadily in the US for the past decade. Almost 10% of laboratory-confirmed TB cases in 2015 were resistant to isoniazid, one of our two most powerful anti-TB drugs. MDR-TB is resistant to the two major antibiotics used to treat drug-sensitive TB and can be rapidly diagnosed but requires treatment regimens that are lengthy, often toxic, and expensive. New, safe, and effective regimens are critically needed to treat the 90 to 100 US patients diagnosed with MDR-TB each year.⁸ MDR-TB treatment costs an average of \$150,000 per person, increasing to \$280,000 when disability and death are included.³ However, even the most effective treatments are responses to problems that have already happened. Given the burden of TB infection in the US and globally, an effective vaccine is the only way to assure that our communities are no longer at risk for TB exposure or infection.

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

Support for and involvement of the US in global TB control remains limited compared to HIV/AIDS and malaria, despite the larger number of deaths caused by and expenses associated with TB. The WHO has estimated the global funding gap for TB prevention and treatment services for low- and middle-income countries to be \$2 billion per year, and the Treatment Action Group (TAG) estimates the annual gap for TB research and development to be \$1.3 billion.¹

These funding gaps result in ongoing transmission of TB, especially due to drug-resistant strains, directly and indirectly impacting health in the US.

- ▶ **Mobilize and sustain public support for elimination of TB and regularly measure progress toward the goal.**

The limited implementation of the above outlined goals attest to the failure to achieve this goal.

Despite a national action plan to eliminate TB, the US remains unsuccessful in achieving this important public health goal.

As articulated by recent reports from the Center for Strategic & International Studies (CSIS),^{11,12} TB in the US is a threat to domestic health security and is driven in large part by the global TB pandemic. International travel and trade are vital parts of the US economy, and maintaining these international relations are foremost in our national interests. As CSIS notes, each year over 2 million Americans travel to India and China, which have burdens of TB almost 68 times and 21 times that of the US, respectively. It is neither practical, nor in our best national interests, to consider reduced travel to or from the US in response to the global TB pandemic.

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Eliminating TB in the US requires increased investments to combat the global spread of TB, in addition to increased efforts within our own borders. The same new tools that are needed in the US are critically needed in higher burden countries and would pay off both domestically and globally. For example, more effective drugs would benefit US residents directly but would also reduce the global burden of TB and thereby reduce the risk for Americans to be exposed to TB abroad. Stronger public health programs and improved capacity to detect rapidly and treat both TB disease and TB infection will improve the quality of life and productivity in our key partner countries, leading to increased trade and development.

The CDC has estimated the US societal cost of not eliminating TB over the past 20 years to total \$19.9 to \$27.7 billion,³ and these costs are likely to continue at over \$400 million per year if our ongoing failure to eliminate TB is not addressed.^{9,10} In a worst-case scenario, we are at risk of a resurgence of TB similar to that experienced in the late 1980s and early 1990s.² This resurgence

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of TB required billions of dollars invested by federal, state, and local governments to put us back on the path to TB elimination. The successes of those investments are threatened by years of flat funding for public health TB programs and TB research and development.

The implementation of the 1989 and 2000 recommendations has been far too slow and incomplete, due mainly to lack of political will and monetary investment. We urge the current administration and Congress to galvanize sustained political and monetary investment toward eliminating TB in the US. Such leadership would pay off, not only in protecting the health and well-being of the people, but would ensure an adequate public health infrastructure for addressing TB and other health security threats to the US, while producing substantial cost savings.

OUR KEY RECOMMENDATIONS FOR THIS ADMINISTRATION AND CONGRESS, BASED IN PART ON THOSE BY THE CSIS,^{11,12} INCLUDE:

1 Establish a focus on domestic TB elimination within the executive branch by forming a Presidential Tuberculosis Elimination Initiative.

- a.** Support options for importing quality-assured TB drugs to the US from the US-supported GDF. Americans and our public health programs do not currently have access to drugs through the GDF due to drug registration limitations, leaving us vulnerable to stock shortages or price hikes that make crucial TB drugs unavailable to US residents. Leadership from this administration and the Congress, and engagement with US public health programs and the FDA, could revolutionize the availability and affordability of TB drugs in the US.
- b.** Support the CDC and the Department of State to expand the current successful TB screening and treatment criteria for individuals seeking entry to the US, to include applicants for temporary or nonimmigrant visas that allow stay in the US of six months or more (for example: B-1, H-1B, H-2A, H-2B, J).
- c.** Through the Office of the US Surgeon General, deliver a comprehensive national prevention initiative and a campaign to educate the public and healthcare providers, which establishes TB elimination as the goal.

2 The administration and Congress should support funding for domestic TB elimination activities of at least \$195.7 million.

Such support is needed to address funding gaps for US TB control programs and prevention efforts and support increased research for new diagnostic tools, vaccines, and antibiotics.

- a.** Ensure adequate funding to the CDC, Department of Defense, and National Institutes of Health for implementation of the *National Action Plan for Combating Multidrug-Resistant Tuberculosis* to address both domestic and global MDR-TB.
- b.** Increase federal funding for the public health infrastructure that is needed to achieve TB elimination.
- c.** Engage the Surgeon General, CDC, and Health Resources and Services Administration (HRSA) to implement fully the US Preventive Services Task Force recommendations promoting testing for TB infection among people at increased risk for contracting TB. Domestic TB programs must be funded to expand LTBI screening and treatment for people at increased risk.

3 The administration and Congress should increase funding for global TB control programs through CDC and USAID to \$450 million.

- a.** Ensure that drug-resistant TB is front and center in responses to antimicrobial resistance. Drug-resistant TB accounts for about 30% of all deaths due to antimicrobial resistant infections each year and constitutes a direct health security threat to the US.¹³
- b.** Engage high-burden nations to establish bilateral agreements focused on stopping the spread of TB globally. Accelerate TB control in 10–15 countries of strategic importance to the US.
- c.** Promote access and delivery of new diagnostics and treatments to underserved populations, especially in high-burden countries.

The administration and the Congress could start the US on a successful path toward TB elimination and dramatically reduce the health and economic losses caused by TB in the US.

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