NOVEMBER 2016

U.S. Government Roles in Control of Global Tuberculosis

Opportunities for Strengthening Program Effectiveness

AUTHORS

Phillip Nieburg

Audrey Jackson

A Report of the

CSIS GLOBAL HEALTH POLICY CENTER

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

NOVEMBER 2016

U.S. Government Roles in Control of Global Tuberculosis

Opportunities for Strengthening Program Effectiveness

AUTHORS
Phillip Nieburg
Audrey Jackson

A Report of the
CSIS GLOBAL HEALTH POLICY CENTER

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

About CSIS

For over 50 years, the Center for Strategic and International Studies (CSIS) has worked to develop solutions to the world's greatest policy challenges. Today, CSIS scholars are providing strategic insights and bipartisan policy solutions to help decisionmakers chart a course toward a better world.

CSIS is a nonprofit organization headquartered in Washington, D.C. The Center's 220 full-time staff and large network of affiliated scholars conduct research and analysis and develop policy initiatives that look into the future and anticipate change.

Founded at the height of the Cold War by David M. Abshire and Admiral Arleigh Burke, CSIS was dedicated to finding ways to sustain American prominence and prosperity as a force for good in the world. Since 1962, CSIS has become one of the world's preeminent international institutions focused on defense and security; regional stability; and transnational challenges ranging from energy and climate to global health and economic integration.

Thomas J. Pritzker was named chairman of the CSIS Board of Trustees in November 2015. Former U.S. deputy secretary of defense John J. Hamre has served as the Center's president and chief executive officer since 2000.

CSIS does not take specific policy positions; accordingly, all views expressed herein should be understood to be solely those of the author(s).

Acknowledgments

This work was made possible by the generous support of the Bill & Melinda Gates Foundation.

Center for Strategic & International Studies
1616 Rhode Island Avenue, NW
Washington, DC 20036
202-887-0200 | www.csis.org

U.S. Government Roles in Control of Global Tuberculosis

Opportunities for Strengthening Program Effectiveness

Phillip Nieburg and Audrey Jackson[1]

> "[D]espite the fact that nearly all [TB] cases can be cured, TB remains one of the world's biggest threats."—WHO Global TB Report 2015[2]

> "We face an uphill battle to reach the global targets for tuberculosis. There must be a massive scale-up of efforts, or countries will continue to run behind this deadly epidemic and these ambitious goals will be missed."—Margaret Chan, WHO Director General[3]

Executive Summary

Tuberculosis (TB), a persistent global disease challenge, is now the world's number-one cause of infectious disease mortality, replacing HIV/AIDS in that position.[4] In 2015, 1.4 million people died from TB, an additional 400,000 died with both TB and HIV/AIDS, and about 700,000 people died due to HIV/AIDS without TB.[5]

While the great majority of TB cases can be treated successfully with a six-to-nine-month regimen of four drugs, in 2015 an estimated 480,000 new active TB patients globally were

---

[1] Phillip Nieburg is a senior associate with the Global Health Policy Center at the Center for Strategic and International Studies (CSIS) in Washington, D.C. Audrey Jackson is a senior fellow with the CSIS Global Health Policy Center.

[2] World Health Organization (WHO), *Global Tuberculosis Report 2015* (Geneva: WHO, October 2015), 1, http://www.who.int/tb/publications/global_report/en/.

[3] WHO, "WHO report warns global actions and investments to end tuberculosis epidemic are falling far short," news release, October 13, 2016, http://www.who.int/mediacentre/news/releases/2016/tuberculosis-investments-short/en/.

[4] Haidong Wang et al., "Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015," *Lancet* 388 (October 8, 2016): 1459–1544. See also WHO, "Tuberculosis mortality nearly halved since 1990, but TB ranks alongside HIV as a leading cause of death worldwide," news release, October 28, 2015, http://www.who.int/mediacentre/news/releases/2015/tuberculosis-mortality/en/.

[5] WHO records deaths of people infected by both HIV and tuberculosis as HIV deaths but not as TB deaths. However, because tuberculosis is the single most common cause of death among people living with HIV infection, there is a growing acknowledgment of the role that TB plays in the deaths of people with both diseases.

sick with *multidrug-resistant TB* (MDR-TB), defined as a TB infection that is resistant to two or more of the most common TB drugs.[6] Just as with drug-sensitive TB, MDR-TB bacteria can be spread through the air from person to person. MDR-TB requires longer treatment regimens with more expensive drugs, often leads to death, and accounts for a growing number of global TB cases.[7] About 10 percent of MDR-TB patients have an even more drug-resistant and more severe form of TB called *extensively drug-resistant TB* (XDR-TB). Because of the airborne route of infection, the difficulty of treatment, and high mortality rates, MDR-TB and XDR-TB represent true risks to global health security.

MDR-TB and XDR-TB are manifestations of *antimicrobial resistance* (AMR), which has been recently recognized as a global public health threat requiring collaborative global solutions.[8] The Review on Antimicrobial Resistance, an independent group commissioned by the UK prime minister and led by renowned economist Lord Jim O'Neill, predicted that AMR will cause 10 million deaths annually by the year 2050. Drug-resistant TB, the leading cause of AMR deaths, will result in approximately a quarter of those deaths.[9] It is critical that the United States work with global partners to accelerate progress in global TB control before drug-resistant forms of TB become an even more difficult challenge.[10] While the Obama administration has recognized the importance of AMR and global health security to U.S. national security and public health interests, TB should occupy a more central focus within the AMR presidential priority initiative and the Global Health Security Agenda. Ultimately, elimination of TB in the United States will require better control of TB in other countries.

Although the current and future impact of TB is becoming more evident, and although well-managed TB control programs have been found in a number of settings to be a highly cost-effective health intervention,[11] global TB programs have faced a persistent lack of prioritization in national and global health agendas, manifested by inadequate access to financial and other resources; a slow trajectory in the research, development, and uptake of new tools and interventions; and a lack of political will to change these circumstances. The result has been relatively poorer program outcomes, compared to some other globally

---

[6] Beginning in 2015, WHO also began tracking new TB patients with infections resistant only to the major TB drug *rifampicin*; their recommended treatment regimen is the same as for MDR-TB.
[7] U.S. Agency for International Development (USAID), "Tuberculosis: The Global Challenge of TB," October 17, 2016, https://www.usaid.gov/what-we-do/global-health/tuberculosis.
[8] Antimicrobial resistance, or AMR, refers to the development of resistance to antimicrobial drugs by bacteria, viruses, and parasites. See WHO, "Global Action Plan on Antimicrobial Resistance," May 2015, http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1; United Nations, "Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance," September 2016, http://www.un.org/pga/71/wp-content/uploads/sites/40/2016/09/ DGACM_GAEAD_ESCAB-AMR-Draft-Political-Declaration-1616108E.pdf.
[9] Review on Antimicrobial Resistance, *Tackling Drug-Resistant Infections Globally: Final Report and Recommendations* (London: HM Government, May 2016), https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf.
[10] The Obama administration has developed and published a national plan: White House, *National Action Plan for Combating Multidrug-Resistant Tuberculosis* (Washington, DC: White House, December 2015), https://www.whitehouse.gov/sites/default/files/microsites/ostp/national_action_plan_for_tuberculosis_20151204_final.pdf.
[11] Olusoji Adeyi et al., "Economic Benefit of Tuberculosis Control," Policy Research Working Paper 4295, World Bank, August 2007, http://elibrary.worldbank.org/doi/abs/10.1596/1813-9450-4295.

important infectious diseases. TB, malaria, and HIV/AIDS are often considered the "big three" infectious diseases globally and U.S. government agencies and interests have played important roles in control of each of these diseases. While annual numbers of new infections due to HIV/AIDS and malaria fell dramatically between 2000 and 2015, by 32 percent and 18 percent, respectively, annual numbers of new active TB cases[12] have changed more slowly, with only an estimated 1 percent decrease, from 10.5 million to 10.4 million cases, over that 15-year period.[13]

U.S. global TB programs suffer from an absence of high-level executive branch prioritization, inadequate budgetary resources, and a fragmentation of programs across several departments and agencies. While the U.S. government's multiagency program activities against global HIV/AIDS and global malaria are each implemented under the control of a single program authority, the President's Emergency Plan for AIDS Relief (PEPFAR)[14] and the President's Malaria Initiative (PMI)[15] respectively, there is no similar presidential-level initiative for the U.S. government's global TB control activities. The 2010 Lantos-Hyde U.S. Government TB Strategy designated the U.S. Agency for International Development (USAID) as the lead agency for U.S. global TB control activities.[16] USAID receives the bulk of U.S. global TB appropriations. But a number of different agencies, including the Centers for Disease Control and Prevention (CDC), participate in global TB control activities by supporting programs, conducting operational research, and providing technical and financial support to national governments and to multilateral organizations such as WHO, the Stop TB Partnership, and the Global Fund to Fight AIDS, Tuberculosis and Malaria. It is essential to utilize an inclusive whole-of-government approach—bringing to bear all resources that can potentially play useful roles in global TB control—and to make clear, transparent choices about the level of resources made available for various TB program activities. This approach is particularly important given the insufficient resources.

This report examines current programmatic and policy issues in global TB control, highlights opportunities for optimizing the U.S. contribution to programmatic control of global TB, and closes with recommendations for strengthening the leadership, coherence, accountability, and effectiveness of the U.S. government's approach to control of global TB.

Briefly, these recommendations include:

1) More visible, high-level global TB leadership in the executive branch through the appointment of a focal person to lead "whole-of-government" U.S. government global TB efforts.

[12] The term "TB cases" is used in this report to refer to episodes of active TB disease in individuals. This "TB case" term is used instead of "TB infections" because, in fact, about one-third of the world's population is infected by latent TB bacteria; the great majority of these TB-infected people will never develop active TB disease.
[13] WHO, "Tuberculosis (TB): Download Data as CSV files," http://www.who.int/tb/country/data/download/en/.
[14] PEPFAR funding is not intended for drug discovery or product development research or any other research beyond that focusing on program implementation issues. See President's Emergency Plan for AIDS Relief, http://www.pepfar.gov.
[15] See President's Malaria Initiative, http://www.pmi.gov.
[16] USAID, "Lantos-Hyde United States Government Tuberculosis Strategy," March 24, 2010, http://pdf.usaid.gov/pdf_docs/PDACP707.pdf.

2) Increased funding for global TB control activities through the budget and appropriations process, including additional funding for implementation of the MDR-TB National Action Plan. Increased funding for global TB control programs should be primarily directed to USAID and CDC.

3) The empaneling of an external, independent evaluation of the entirety of the U.S. government global TB enterprise, as has been done for U.S. programs to address global HIV/AIDS and malaria.

Background

The Global Burden of Tuberculosis

Among the "big three" global infectious diseases (HIV/AIDS, TB, and malaria), control programs against global HIV/AIDS and malaria have seemingly enjoyed greater disease control success in recent years than global TB control programs (Table 1). For example, between 2000 and 2015, annual numbers of new HIV infections fell by 32 percent, from 3.1 million to 2.1 million. Global HIV/AIDS deaths decreased by 31 percent over that same period, from 1.6 million to 1.1 million. Meanwhile, numbers of global malaria infections fell by 18 percent from 262 million in 2000 to 214 million in 2015.[17] More significantly, global malaria deaths fell by 48 percent over that same 15-year period.

On the other hand, annual numbers of new active TB cases have fallen much more slowly, with only an estimated 1 percent decrease in cases over that 15-year period.[18] The annual population rate of new global TB cases decreased by 18 percent over the 2000–2015 period.[19] Finally, global TB deaths (excluding TB deaths among HIV-infected persons) decreased by 22 percent, from an estimated 1.8 million in 2000 to about 1.4 million in 2015.[20]

These data indicate some differences in the degree of success in controlling the transmission of these three infections. Many factors unrelated to the magnitude and nature of U.S. support may be causally involved in these differences in outcomes. However, because of the magnitude of these outcome differences, the large U.S. investment in control of these three major global infectious diseases, and the need to make further rapid and significant progress in control of global TB, it may be instructive to examine closely how U.S. programs that support global efforts to control these diseases are structured, funded, and led.

[17] UNICEF and WHO, "World Malaria Report 2015," (Geneva: WHO, December 2015), http://www.who.int/malaria/publications/world-malaria-report-2015/report/en/.
[18] WHO, "Tuberculosis (TB): Download Data as CSV files."
[19] While we highlight new TB case *numbers* in this report to allow for a more direct comparison with global HIV and malaria numbers, standard global TB indicators often include the population-based TB case *rate* (i.e., numbers of TB cases per 100,000 population) instead of—or in addition to—new TB case numbers.
[20] WHO, "Global Tuberculosis Report 2016" (Geneva: WHO, October 2016), 30, http://www.who.int/tb/publications/global_report/en/. The World Health Organization records deaths of people infected by both HIV and tuberculosis as HIV deaths but not as tuberculosis deaths.

Table 1: Estimated Occurrence and Outcomes of Some Important Global Infectious Diseases in 2000 and 2015

Infection and Outcome	2000	2015	Decrease	U.S. Bilateral Budget (FY 2016)***
New HIV infections	3.1 million	2.1 million	32%	$4,650 million
Annual rate of new HIV infections (per 1,000 people 15–49 years)	0.08	0.05	38%	
HIV/AIDS deaths	1.6 million	1.1 million*	31%	
New malaria infections	262 million	214 million	18%	$674 million
New malaria infection rate (cases per 1,000 people at risk)	146	92	37%	
Malaria deaths	839,000	438,000	48%	
New active TB cases**	10.5 million**	10.4 million	1%	$236 million
TB case rate (per 100,000 pop.) **	172**	142	18%	
Global TB deaths (*excluding* HIV-infected people)	1.8 million	1.4 million*	22%	

* An estimated 400,000 of the 1.8 million global TB deaths in 2015 were in PLHIV but, as specified by current convention, these deaths were recorded and counted *only* as HIV deaths by WHO and UNAIDS.
** The previous estimates of active TB case number (9.6 million) and case rate (162/100,000 population) for 2000 (as shown in the Global Health Observatory, accessed November 2016) are now considered to have been underestimates.
*** Budget information was drawn from Adam Wexler, Allison Valentine, and Jennifer Kates, "The U.S. Global Health Budget: Analysis of Appropriations for Fiscal Year 2016," http://kff.org/global-health-policy/issue-brief/the-u-s-global-health-budget-analysis-of-appropriations-for-fiscal-year-2016/.

TB Infection and Disease

Tuberculosis is an airborne bacterial disease that in its initial latent form infects about a third of the world's population. Latent TB Infection (LTBI) most often progresses to active TB disease in people whose immune system becomes weakened due to age or disease. Of the more than 2 billion people globally with latent TB infection, only about 10 percent will go on to develop active TB disease over their lifetime. In contrast, the risk that latent TB will progress to active TB disease is far greater in people with lung scarring from previous active but untreated TB, people with suppressed immune systems such as is seen in very young infants and young children, people with diabetes[21] and those with HIV infection.[22]

[21] A.D. Harries, S. Satyanarayana, and A.M.V. Kumar, "Epidemiology and interaction of diabetes mellitus and tuberculosis and challenges for care: a review," *Public Health Action* 3 (Nov. 4, 2013) Supplement 1: S3–S9.
[22] CDC, "Latent Tuberculosis Infection: A Guide for Primary Health Care Providers," April 3, 2013, http://www.cdc.gov/tb/publications/ltbi/targetedtesting.htm#identifyingTBDisease#.

Prevention of new active TB cases can be accomplished by one or more of the following actions: (1) *contact tracing*, that is, identifying newly TB-infected people by TB screening and testing of persons known or suspected to have been exposed to active TB cases; (2) finding additional active TB cases by rapidly identifying and treating other persons with active TB disease to keep them from spreading TB to others[23]; (3) reducing the airborne spread of TB bacteria to currently uninfected patients and hospital staff by improving infection control practices within hospitals and other health facilities; (4) markedly reducing the risk of progression of latent TB infection to active TB disease by providing persons with latent TB with several months of preventive TB drug therapy; (5) further integrating the activities of TB and HIV control programs, including both HIV testing and counseling of TB patients and TB screening and preventive TB drug therapy for people living with HIV infection (PLHIV).[24]

Diagnosis of TB infection and disease has long been complicated by the relative insensitivity and time requirements of most available methods to diagnose TB. The *GeneXpert*™ test and several other molecular diagnostic tests that have become available recently are faster and more accurate than earlier rapid diagnostic testing methods but, at a cost of more than $9 for each person tested, are far more expensive to use. They also require a consistent source of power, which is a challenge in many countries.

Challenges of Global TB

The most recently available data from WHO clearly indicate the magnitude and severity of the current global TB burden challenge.[25] In 2015, about 10.4 million people, including about a million children, were estimated to have developed active TB disease. About 4.3 million of these 10.4 million new TB cases had not been reported in national government TB surveillance systems, either because they were not diagnosed or because they were treated for TB outside of government TB programs. Finding all of these active TB cases is a top priority for national TB control programs.[26] Although most newly diagnosed TB patients are being treated successfully, there were still about 1.8 million TB deaths in 2015, about 400,000 of them in PLHIV.[27]

---

[23] The high frequency of active (and infectious) TB in persons without symptoms is a serious challenge to this high-priority activity. Additional background information can be found in two recently published and relatively nontechnical but detailed descriptions of TB infection, TB disease, the diagnostic and treatment challenges caused by TB bacteria, and the global programs that are working to prevent and treat active TB disease. See Phillip Nieburg, Sahil Angelo, and Talia Dubovi, *Tuberculosis—A Complex Health Threat; A Policy Primer of Global TB Challenges* (Washington, DC: CSIS, April 2015), http://csis.org/files/publication/150409_Nieburg_TBComplexHealthThreat_Web.pdf; and Nellie Bristol, *Toward a Well-Oiled Machine: U.S. Government Engagement with Multilateral Organizations in Pursuit of Global TB Control* (Washington, DC: CSIS, July 2014), https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/140604_Bristol_TowardWellOiledMachine_Web.pdf.

[24] Phillip Nieburg, Sharon Stash, and Alisha Kramer, *The Global Challenge of Tuberculosis among People Living with HIV* (Washington, DC: CSIS, June 2014), https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/140606_Nieburg_GlobalChallengeTB-HIV_Web.pdf.

[25] WHO, "Global Tuberculosis Report 2016."

[26] Most of these new TB cases occurred in Asia (61 percent) or sub-Saharan Africa (26 percent). See WHO, "Global Tuberculosis Report 2016," 24.

[27] Ibid., 28.

A second global TB challenge is the growing number of people infected with multidrug-resistant TB (MDR-TB), bacteria that are resistant to at least two of the four most commonly used TB drugs. Because TB bacteria can mutate relatively quickly, resistance to individual TB drugs can develop in people who receive inadequate TB treatment, for example, who do not receive the correct drug combinations or who do not take their drugs consistently.[28] MDR-TB can also be transmitted from person to person and this airborne route of transmission now represents a significant proportion of the MDR-TB burden in some countries.

Globally, about 4 percent of people with a first-time diagnosis of active TB and about 21 percent of previously treated TB patients have MDR-TB although the frequency within regions or even within countries can vary widely. Of the 580,000 MDR-TB and rifampin-resistant TB cases estimated to have occurred in 2015, only about 22 percent of them, that is, about 125,000 active TB patients, were started on the *second-line TB drugs* recommended to successfully treat MDR-TB. And only about 52 percent of these treated MDR-TB cases are successfully treated.[29] The estimated 60,000 of these MDR-TB patients who were treatment failures plus the other 455,000 patients who were not treated at all either died or continued to spread drug-resistant TB within their families and communities.

Successful treatment of drug-sensitive active TB disease requires that patients take six to nine months of a drug regimen that includes at least four different anti-TB drugs. Those people identified as having MDR-TB disease have until recently required at least 18 months of treatment with a larger number of different drugs, many of which are expensive, difficult to obtain, and can induce severe side effects. However, WHO has recently begun recommending a newer 9-to-12-month seven-drug regimen for treating selected MDR-TB (but not XDR-TB) patients[30] and other new MDR-TB and XDR-TB drug regimens are under development. In addition, the costs of diagnosing and successfully treating drug-resistant TB are far greater than the costs of treating drug-sensitive TB infections.[31] Not surprisingly, success rates for MDR-TB treatment are lower and mortality rates are higher than for drug-sensitive TB. Finally, MDR-TB bacteria can be spread from person to person just as with drug-sensitive TB.

About 10 percent of MDR-TB patients have an even more drug-resistant and more severe form of TB called *extensively drug-resistant TB* (XDR-TB), a form of TB disease that is sensitive to even fewer of the available TB drugs and that has still lower treatment success rates and higher mortality rates.

A third major challenge to global TB control efforts is the 2 billion or more people with latent TB infections. Although their lifetime risk of developing active TB disease may be no greater than 10 percent each, that proportion still represents a future group of at least 200 million new TB patients. In part because some inexpensive TB drugs have been shown to greatly reduce the risk of latent TB infection progressing to active TB disease, WHO, the U.S.

---

[28] Resistance to one or more TB drugs sometimes develops in people who receive and take the correct doses of TB drugs but drug resistance is much less likely to occur in that setting.
[29] WHO, "Global Tuberculosis Report 2016," 75–78.
[30] Although availability of this new regimen is increasing, it is not yet available in all countries. See WHO, "The Shorter MDR-TB Regimen," May 2016, http://www.who.int/tb/Short_MDR_regimen_factsheet.pdf.
[31] White House, "National Action Plan for Combat Multidrug Resistant Tuberculosis," 6.

government, and other groups have begun considering new public health approaches to reducing future TB disease risk among this group.

A fourth challenge is the need to effectively provide antiretroviral drugs (ARVs) to all people who are coinfected with HIV and TB. ARVs both suppress the underlying HIV infection and, by supporting the immune system of PLHIV, help prevent the development of active TB disease. Data from 2015 indicate that while 78 percent of *known* HIV-infected TB patients were taking ARVs, only about a third of all global patients estimated to have both diseases were taking ARVs.[32]

Links between Domestic and Global TB burdens

Recent data from the CDC indicate that numbers of new active TB cases in the United States stopped falling in 2015 for the first time since 1992.[33] In a 2014 CSIS report, several TB experts from the CDC had highlighted the multiple links between TB in other countries and TB cases occurring in both visitors to the United States and residents,[34] most of whom had lived in the United States for five or more years.[35] Both MDR-TB and XDR-TB have been reported in domestic TB cases linked to TB in other countries. Because reducing the overall global burden of TB indirectly reduces the TB risk to U.S. residents, those experts recommended "greater U.S. government engagement in global TB control."

Global TB Control Strategy and Financing

The WHO has developed an overarching *End TB Strategy*, with a goal of reducing the annual TB incidence rate by 90 percent between 2015 and 2035,[36] and the Stop TB Partnership has produced *The Global Plan to End TB 2016–2020*, a roadmap for making progress toward the 2035 End TB goal over the next five years.[37] Consistent with the WHO End TB Strategy, the U.S. government's current target is a 25 percent reduction in TB incidence rate by 2019 in the 23 countries where USAID provides country-level funding.[38] Many of these countries are low-income countries that rely on external financing for TB control. Unfortunately, 23

[32] WHO, "Global Tuberculosis Report 2016," 73, 75.
[33] Jorge L. Salinas et al., "Leveling of tuberculosis Incidence—United States, 2013–2015," *Morbidity and Mortality Weekly Report*, 65 (No. 11) March 25, 2016; 273–78.
[34] Brittany K. Moore et al., *Tackling Tuberculosis Abroad: The Key to TB Elimination in the United States* (Washington, DC: CSIS, June 2014), https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/140604_Moore_TacklingTBAbroad_Web.pdf.
[35] CDC, "Tuberculosis in the United States, 2014," 35, Table 16.
[36] The Sustainable Development Goals 2030 TB target is a new TB case rate of <20 cases per 100,000 population per year whereas the 2035 goal of WHO's End TB Strategy is a new TB case rate of <10 cases per 100,000 population per year. See WHO, "The End TB Strategy," http://www.who.int/tb/post2015_TBstrategy.pdf?ua=1.
[37] Stop TB Partnership, *The Paradigm Shift: Global Plan to End TB 2016–2020* (Geneva: Stop TB Partnership, 2015), http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf.
[38] USAID, "U.S Government Global Tuberculosis Strategy 2015–2019," https://www.usaid.gov/sites/default/files/documents/1864/Reach-Cure-Prevent-2015-2019-TBStrategy.pdf.

percent of the total estimated resources required for successful global TB control is currently unfinanced.[39]

Resources used for global TB control activities come from both in-country (national government) sources and external donors. Funding from the national governments of individual affected countries provided about 84 percent of the world's TB expenditures in 2016 although that figure includes data from the middle-income BRICS countries (Brazil, Russia, India, China, South Africa) in which a large proportion of the world's new global TB cases occur.[40] However, low-income countries receive 87 percent of their TB funding from external sources, and this external financing is essential for continued TB control efforts. The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) uses contributions from the United States, other donor governments, and nongovernmental organizations to provide TB and TB/HIV control resources to many countries around the world.[41] Although the Global Fund is the world's leading donor to global TB control, its overall global funding allocation for TB control programs is currently set at 18 percent of its total annual resource distribution. Individual countries may receive and use greater or lesser proportions of their Global Fund grants for TB control.

U.S. Strategies and Programs in Support of Global TB Control

The U.S. plays a number of significant roles in global TB control programs. According to the 2010 Lantos-Hyde U.S. Global TB Strategy,[42] while USAID is the lead for U.S. global TB activities, the Office of the U.S. Global AIDS Coordinator (OGAC) is the lead for the U.S. government response to TB/HIV coinfection as part of PEPFAR. The CDC provides technical support and assistance to ministries of health and to U.S. government programs for global TB control including those of both USAID and OGAC. The National Institute of Allergy and Infectious Diseases (NIAID) leads the United States in its international TB-related research effort.

The March 2015 U.S. government *Global Tuberculosis Strategy 2015–2019*, spearheaded by USAID, lays out a vision, goals, and objectives for U.S. global TB activities during fiscal years 2015–2019.[43] In the same month, the White House Office of Science and Technology Policy convened an interagency task force and initiated the creation of a *National Action Plan to Combat Multidrug-Resistant Tuberculosis (MDR-TB)*,[44] an outgrowth of a 2014 presidential priority initiative on AMR. In September 2014, in recognition of the growing concern of AMR

[39] Stop TB Partnership, "The Paradigm Shift: Global Plan to End TB 2016–2020."
[40] WHO, "Global TB Report 2016," 108.
[41] Annual U.S. government contributions to the Global Fund are limited by law to no more than one-third of the Global Fund's total budget. The U.S. contribution to the Global Fund in fiscal year 2016 amounted to $1.35 billion. Global Fund awards to recipient countries since 2003 have totaled about $30 billion for all three diseases.
[42] USAID, "Lantos-Hyde United States Government Tuberculosis Strategy."
[43] USAID, "U.S Government Global Tuberculosis Strategy 2015–2019," https://www.usaid.gov/sites/default/files/documents/1864/Reach-Cure-Prevent-2015-2019-TBStrategy.pdf.
[44] White House, *National Action Plan to Combat Multidrug-Resistant Tuberculosis,* December 2015, https://www.whitehouse.gov/sites/default/files/microsites/ostp/national_action_plan_for_tuberculosis_20151204_final.pdf.

as a public health and national security threat, President Obama issued an executive order[45] directing government agencies to create a *National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)*, which was completed in March 2015. Although MDR-TB falls within the scope of the executive order on antibiotic-resistant bacteria,[46] a decision was made during the development of the CARB National Action Plan to create a separate *National Action Plan to Combat MDR-TB*, which was released in December 2015. The reasoning behind that decision is not entirely clear, but the end result is that the MDR-TB effort has been separated from the CARB presidential initiative in its process, timing, and ultimately prioritization. Subsequently, the MDR-TB National Action Plan has not received the same level of support from the White House in terms of governmental oversight, input from external advisers, and additional funding in the president's proposed FY 2017 budget.[47]

Without question, there has been some progress in U.S. efforts against global TB, even in the absence of adequate funding. There was increasing mobilization of U.S. resources for global TB through 2010 and, within the constraints of available resources, implementation of some programmatic components of the 2010 U.S. global TB strategy has advanced. However, these promising U.S. developments have been accompanied by only limited global progress against TB.

As a major recipient and distributor of U.S. global TB resources, and as the designated lead agency for global TB within the U.S. government, USAID now supports TB control efforts in at least 54 countries and includes support for many programmatically important global TB control activities.[48] A partial listing includes:

- Support for the Global Drug Facility, which has succeeded in significantly reducing global prices of drugs used to treat MDR-TB
- The TREAT-TB (Technology, Research, Education, and Technical Assistance for TB) program of the International Union against Tuberculosis and Lung Disease.
- Establishment of many country-level TB drug-management systems
- Support for country-level advocacy for increased political commitment to TB control
- Development of national and global strategy documents though participation on various expert committees
- National TB surveys in an increasing number of countries

[45] White House, "Executive Order 13676: Combating Antibiotic-Resistant Bacteria," September 18, 2014, https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria.
[46] There is one outcome related to domestic TB in the CARB National Action Plan.
[47] In fact, the executive branch proposed a *reduction* in FY 2017 global TB program funding.
[48] A more complete listing of USAID's global TB activities can be found in its most recent reports to Congress. See for example, USAID, "Ending the Tuberculosis Epidemic: Fiscal Year 2015," https://www.usaid.gov/sites/default/files/documents/1864/USAID-AnnualReport-2016-FINAL-WEB-spreads-508.pdf.

- Programs to improve case detection and treatment completion rates for both drug-sensitive and drug-resistant TB
- Efforts to expand outpatient TB care in countries that previously focused on inpatient TB care
- Operational field research to improve case finding and treatment adherence
- Efforts to improve TB infection control practices in health facilities
- Support in preparation of national applications to obtain TB control resources from the Global Fund

Resources for U.S. Global TB Control Activities

In 2008, Congress passed the Lantos-Hyde Act[49] that included a notional authorization of $4 billion for U.S. participation in global TB control efforts over the five fiscal years of 2009–2013. However, the amounts actually appropriated for global TB control over that period totaled only about 40 percent of the authorized amount.[50] In recent years, USAID's TB budget has been around $230–240 million annually, although in each of the most recent fiscal years including budget proposals for FY 2015, FY 2016, and FY 2017, the president's budget has inexplicably proposed reducing the USAID TB budget by 19 percent, to $191 million.[51] Congress reinstated the omitted amounts for 2015 and 2016; a resolution of the 2017 budget numbers is pending. It is noteworthy that no specific additional funds have been requested or allocated for implementation of the MDR-TB National Action Plan.

Over the last 8 to10 years, PEPFAR has allocated almost $1 billion to TB/HIV and TB programs in the multiple countries it serves. PEPFAR's recent annual allocations of $150–160 million[52] for TB-related programs (and particularly for control of TB/HIV coinfection) are probably underestimates of that program's actual financial and programmatic contributions to global TB control. The reason is that the budget amounts allocated to more general PEPFAR programs such as "health system strengthening," laboratory strengthening, or antiretroviral drug support—each of which benefits national TB programs and individual TB patients in various ways—are not included in PEPFAR's TB-specific accounting.

CDC does not receive directly any congressional funding for its global TB work. CDC receives annual funding from PEPFAR to support that program's country-specific work on TB/HIV coinfection and codisease. For some time, CDC had been receiving an annual average of about $2 million from USAID to provide technical expertise and support to

[49] H.R. 5501 (110th): Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.
[50] Kaiser Family Foundation, "The U.S. Government and Global Tuberculosis Efforts," fact sheet, March 2016, http://files.kff.org/attachment/fact-sheet-the-u-s-government-and-global-tuberculosis-efforts.
[51] Executive branch testimony before Congress in March 2016 included an assertion that the proposed reduction in USAID's TB funding would be made up by resources from PEPFAR and from the Global Fund, even though the most recent (2016) U.S. support to those two programs had already fallen below 2014 levels.
[52] PEPFAR's focus on TB and TB/HIV is not represented by a line item in the PEPFAR budget.

USAID's bilateral TB programs. In recent years, that amount has been reduced although actual budget numbers for fiscal years 2016 and 2017 were not available.

U.S. Government Global TB Coordination

The Federal TB Task Force, an interagency task force composed of federal agencies involved in "U.S. TB research and control programs,"[53] was established in 1991 under the leadership of CDC's Division of TB Elimination to manage domestic U.S. outbreaks of MDR-TB. It also includes agencies involved in global TB control because of the impact these activities have on TB elimination in the United States. In 1992, the TB Task Force developed the first national action plan to combat MDR-TB, and, in 2009, a plan to address XDR-TB. Working groups of the task force are focused on specific areas such as diagnostic tests and drug shortages.

There is also a U.S. government "international focus monthly call"[54] that has sometimes been described as a working group of the Federal TB Task Force.[55] The international working group is led by USAID and includes CDC, OGAC, NIAID, and the Department of Defense. The monthly calls serve as an opportunity to share information about agency activities. As a largely informal group associated with a task force that has a domestic mandate, this working group may not be the most effective way of coordinating U.S. global TB programs and strategy. There is also no central structure for soliciting or receiving input on global TB from experts outside the federal government.[56]

Discussion

With the growing challenge of MDR-TB and with TB's new position as the world's most common single infectious disease killer, global TB has begun receiving greater attention over the last few years. It seems clear that with new global TB targets put forward by the WHO, the Stop TB Partnership, and the U.S. government—with new TB drugs coming on line, and with new and more sensitive diagnostic methods—the time is ripe for the United States to effectively support a well-funded set of global structures to take on this challenge.

The central questions under analysis in this report focus on how well various U.S. government global TB-related programs are working, in their entirety, to support current global TB programs. For example,

- Are there ways that the impact of U.S. global TB programs could be enhanced (e.g., through larger budgets, greater coherence, more internal collaboration) to accelerate the pace of the world's progress against global TB?

- Given the global political will currently being invested to combat drug-resistant infections and the current executive branch focus on AMR through the CARB and

[53] CDC, "Federal TB Task Force," http://www.cdc.gov/tb/about/taskforce.htm.
[54] Minutes from the Federal TB Task Force June 8, 2016, meeting, CDC, http://www.cdc.gov/tb/about/pdf/2016_tb_taskforce_annualmeeting_afternoondiscussion.pdf.
[55] USAID, "Impact and Leadership: U.S. Government Report on International Foreign Assistance for Tuberculosis, Fiscal Year 2013," https://www.usaid.gov/sites/default/files/documents/1864/USAID_TBFY13.pdf.
[56] CDC's Advisory Council for the Elimination of Tuberculosis focuses on domestic TB issues.

MDR-TB National Action Plans and the Global Health Security Agenda, are there opportunities to further highlight and more effectively address the risk of MDR-TB and XDR-TB as a global health security threat?

- Finally, is there an opportunity to stimulate the creation of new high-level leadership and support for global TB control in the incoming administration?

Opportunities for Strengthening Program Effectiveness

We have identified critical requirements for an effective government-wide program: a coherent and inclusive strategy, sufficient funding, visible high-level leadership, coordination of policy and program implementation, and periodic external program evaluations. One almost unique aspect of U.S. efforts to address global HIV/AIDS (through PEPFAR) and global malaria (through PMI) is that each of those initiatives have an unambiguous White House imprimatur, are enshrined in congressionally passed public law, and are coordinated and directed by a single leader whose authority includes managing the overall budget as well as the ability to mandate collaboration between individual U.S. government agencies. Such an arrangement does not exist for U.S. activities in support of global TB control (Table 2).

Table 2: Comparison of the U.S. Government's Programmatic Responses to "Big Three" Global Infectious Disease Challenges

Program Situation or Factor	HIV/AIDS*	Malaria*	Tuberculosis*
U.S. government programmatic lead	Office of the Global AIDS Coordinator	President's Malaria Initiative	USAID (PEPFAR for TB/HIV)
Recent (FY16) annual bilateral funding**	$4,650 million	$674 million	$236 million
Explicit presidential (White House) initiative	Yes	Yes	No
Single leader represents all nonresearch U.S. programs to Congress, executive branch, media, international organizations, public	Yes	Yes	No
Single leader controls U.S. government funding stream	Yes	Yes	No
Most common disease control approach	Resources provided to implementers of care	Resources provided to implementers of care	Technical advice and support provided to "health systems"
Formal external program evaluation	Twice, in 2008 & 2013	In 2012	None

* This comparison does not include the fundamental biomedical and product development research of the National Institutes of Health.
** Budget information was drawn from Adam Wexler, Allison Valentine, and Jennifer Kates, "The U.S. Global Health Budget: Analysis of Appropriations for Fiscal Year 2016," http://kff.org/global-health-policy/issue-brief/the-u-s-global-health-budget-analysis-of-appropriations-for-fiscal-year-2016/.

The Need for a Coherent and Inclusive Strategy

U.S. government agencies have made efforts recently to utilize a whole-of-government approach in creating a coherent and inclusive strategy for global TB control. However, improvements can be made in both the process and the resulting outcomes.

Clear accountability for prioritized activities is a critical feature. For example, the U.S. government's *Global Tuberculosis Strategy 2015–2019* does not make clear which U.S. agencies are accountable for each of the stated goals and objectives. The MDR-TB National Action Plan does clearly identify the roles and responsibilities of the agencies mentioned in the plan and it also assigns outcome measures to each agency. However, a significant drawback of the MDR-TB National Action Plan is that it does not include any PEPFAR outcome measures, suggesting lack of a significant PEPFAR role in the development and implementation of that plan. This gap is important because HIV and MDR-TB are epidemiologically linked in several ways, to the degree that effective control of MDR-TB is likely to require an HIV control component.[57] As noted earlier, PEPFAR also contributes to TB control through many general and TB/HIV-specific activities, and should play a stronger role in the action plan.

There are other opportunities to incorporate more U.S. government programs and activities in a whole-of-government approach to global TB control. For example, the Peace Corps has had for some time formal memoranda of agreement (MOA) with PEPFAR and with PMI that provide for Peace Corps volunteers to work on HIV/AIDS and malaria control programs in various settings. These arrangements are considered to have been beneficial to both sides.[58] In contrast, there are no analogous programmatic links between the U.S. Peace Corps and U.S. global TB programs.[59]

Another example of a missed opportunity in global TB control comes from an observation during a recent review of Ethiopia's national TB program that the country's national Field Epidemiology and Laboratory Training Program (FELTP), which has been supported in part by CDC, did not include TB among the diseases that its trainees were being mentored to investigate and control.[60] Reviewers were told that this gap occurred at least in part because the program's focus was intended to be on emerging infections and that TB (and presumably MDR-TB) was not included in that program's emerging disease category. To the degree possible, CDC-affiliated global training programs should be encouraged to include MDR-TB in their emerging disease training curricula.

---

[57] The close epidemiologic links between MDR-TB and HIV infection have been well documented. See, for example, Yonatan Moges Mesfin et al., "Association between HIV/AIDS and Multi-drug Resistance Tuberculosis: A Systematic Review and Meta-Analysis," *PLoS ONE* 9 (January 2014): e82235, http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0082235. Also, Curry International Tuberculosis Center, *Drug-Resistant Tuberculosis: A Survival Guide for Clinicians*, 3rd ed. (San Francisco, CA: Curry International Tuberculosis Center, 2016), 177–78, http://www.currytbcenter.ucsf.edu/sites/default/files/tb_sg3_book.pdf.

[58] Personal communication with Peace Corps senior staff, August 2016.

[59] Ibid.

[60] Randall Reves and Sahil Angelo, *As Ethiopia Moves toward Tuberculosis Elimination, Success Requires Higher Investment* (Washington, DC: CSIS, March 2016), 16, https://csis-prod.s3.amazonaws.com/s3fs-public/publication/160323_Reves_EthiopiaMovesTB_Web.pdf.

Finally, the role of CDC in global TB control could be better leveraged, particularly with new direct funding for global TB activities. There are currently gaps in U.S. government coverage of TB burden countries because some of these countries are not priorities for USAID bilateral programs, PEPFAR or GHSA. CDC's TB capacities and skill sets in surveillance and laboratory systems, infection control, and workforce development could be utilized in these additional countries.

Adequate Resources

Although the recent executive branch decision to develop an MDR-TB National Action Plan signaled an apparent level of White House prioritization, the concomitant request in the president's FY17 budget proposal for a *decrease* in TB funding raises questions about where control of global TB—including MDR-TB—really ranks among competing executive branch priorities. Congressional champions have successfully restored the proposed funding cuts to the USAID TB budget in fiscal years 2014–2016, but maintaining the resource status quo is not sufficient for achieving global TB control. Although some program efficiency can be gained by examining programs' cost-effectiveness,[61] making significant progress against global TB and MDR-TB will be particularly challenging in the absence of a greater U.S. government commitment.

High-Level Leadership

One critical aspect of effective and efficient functioning of multiagency U.S. government disease control programs is a visible high-level leadership that has the legal and political authority to (1) allocate and direct all available resources; (2) direct and enforce collaboration between individual program components; (3) speak for the entirety of the program to domestic and external (international) agencies[62]; and (4) make the case for needed resources. By virtue of their White House imprimatur, legislative authority, and focused leadership, PEPFAR and PMI, two programs that have been recently been recognized as "among the most effective aid programs in the world,"[63] meet these criteria (Table 2).

It is noteworthy that two presidents and several congresses have agreed on the importance of global HIV/AIDS and malaria leadership, legislation, and funding; that agreement has resulted in the creation and successful functioning of PEPFAR and PMI. In fact, the 2016 State

[61] Recent work related to control of HIV/AIDS has highlighted the benefit of analyzing an existing program by examining program performance in terms of what is being achieved at current resource levels and what could be achieved if programs were "optimally" efficient. See Wu Zeng et al., "Resource needs and gap analysis in achieving universal access to HIV/AIDS services: a data envelopment analysis of 45 countries," *Health Policy and Planning* 31, 2016, 624–33.

[62] The U.S. government has TB-related representation and other links to a number of international agencies, for example, WHO, Global Fund, Green Light, STOP TB Partnership, and Parliamentarians' Caucus. See Bristol, *Toward a Well-Oiled Machine*.

[63] Amanda Glassman and Rachel Silverman, "Restructuring US Global Health Programs to Respond to New Challenges and Missed Opportunities," in *The White House and the World 2016* (Washington, DC: Center for Global Development, 2016), K1, http://www.cgdev.org/publication/ft/restructuring-us-global-health-programs-respond-new-challenges-and-missed-opportunities.

of the Union address listed control of global HIV/AIDS and malaria as explicit goals.[64] Similarly, the White House message about the most recent (FY 2017) U.S. executive branch budget proposal explicitly mentions the need to address HIV/AIDS and malaria.[65] Such White House attention and publicity makes programs and their leadership far more visible and popular with the general public. Unfortunately, the need for the United States to help support global TB control programs was not mentioned in either the State of the Union address or the White House budget message.

Coordination of Global TB Policy and Program Implementation

The U.S. government TB international working group currently serves as a coordinating group for TB program implementation, but it is unclear how much that group discusses policy and strategy options. The working group does not have a formal structure or corresponding advisory council to solicit or receive input from external TB experts. It was not designated by the White House as the coordinating body to develop or implement the MDR-TB National Action Plan because it did not have clear authorizing language or executive branch directive.[66]

When the White House establishes a priority initiative, it often establishes a single leader or creates an interagency structure to implement it, conferring a high-level legitimacy to the group. While there was an existing Interagency Task Force on Antibiotic Resistance, a new CARB Task Force with senior agency representatives and an external Presidential Advisory Council on CARB were created by executive order to lead the development and implementation of the CARB National Action Plan. Since the MDR-TB effort was separated from the CARB initiative, the MDR-TB Action Plan is not being implemented or closely monitored by the CARB Task Force and Presidential Advisory Council on CARB. This gap leaves global TB without a strong coordinating body, high-level oversight, or external input.

External Program Evaluation

Another critical aspect of ensuring the effectiveness of multiagency or whole-of-government disease control programs is the need for optimizing their processes and outcomes through periodic formal external (independent) evaluation(s).[67] In particular, evaluation of the entirety of multiagency or multicountry TB programs is important because of the complexity in those

---

[64] White House, "Remarks of Barack Obama—State of the Union as Delivered," January 13, 2016, https://www.whitehouse.gov/the-press-office/2016/01/12/remarks-president-barack-obama-%E2%80%93-prepared-delivery-state-union-address.

[65] White House, "The Budget Message of the President," February 9, 2016, https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/message.pdf.

[66] Personal communication, senior administration representative.

[67] In fact, USAID's recently updated evaluation policy is clear in its emphasis on the need for evaluators to be external to the groups being evaluated as well as the need for a whole-of-government approach when multiple agencies are involved. See USAID, *Evaluation: Learning from Experience: USAID Evaluation Policy* (Washington, DC: USAID, January 2011), Preface and 5–7, https://www.usaid.gov/sites/default/files/documents/1868/USAIDEvaluationPolicy.pdf; Amanda Glassman and Rachel Silverman, "First Hundred Days for Global Health," Center for Global Development, October 28, 2016, part 3. http://www.cgdev.org/sites/default/files/health-transition-memo-2016_0.pdf.

settings of attributing programmatic successes or failures and, more important, identifying actionable lessons.

Although allocation of responsibility to specific program activities for the degrees of success of complex global disease control programs is never easily done, external evaluations of complex U.S. global health programs that have been conducted recently have been considered valuable in several ways[68] and have led to programmatic changes.[69] In contrast, although bilateral U.S. TB programs in individual countries have been evaluated,[70] the entirety of U.S. global TB programs has not ever been formally evaluated.

Some options for arranging an external evaluation of U.S. government programs include the National Academy of Medicine,[71] which has studied tuberculosis issues in the past[72] and has formally evaluated PEPFAR on two occasions[73]; the Global Health Technical Assistance Project, which carried out a detailed evaluation of the President's Malaria Initiative in 2011[74]; and the U.S. Government Accountability Office (GAO), which recently published results of a detailed evaluation of the whole-of-government approach to this nation's multiagency biodefense programs.[75] Terms of reference for an external evaluation should include an assessment of—and recommendations for—appropriate leadership and structure of U.S. global TB activities.

Conclusion and Recommendations

TB is now the leading infectious disease killer in the world, and the spread of MDR-TB is a growing health security risk to the United States and to the world. In order to make greater

[68] Sangheeta Mookherji and Kate Meck, "How Can We better Evaluate Complex Global Health Initiatives: Reflections from the January 2014 Institute of Medicine Workshop," *Global Health Science and Practice* 3, no. 2 (March 2015): 174–79, http://dx.doi.org/10.9745/GHSP-D-14-00184.
[69] USAID, "External Evaluation of the President's Malaria Initiative: PMI Management Response," February 15, 2012, https://www.pmi.gov/docs/default-source/default-document-library/pmi-reports/audit_manageresp.pdf?sfvrsn=11; also, personal communication with Eric Goosby, recent U.S. Global AIDS Coordinator.
[70] See, for example, USAID, "USAID/Philippines: External Evaluation of the Tuberculosis Portfolio (2006–2011)," June 2012, http://pdf.usaid.gov/pdf_docs/pdact786.pdf.
[71] The National Academy of Medicine, a component of the National Academy of Sciences, was formerly named the Institute of Medicine.
[72] Institute of Medicine, *Ending Neglect: The Elimination of Tuberculosis in the United States* (Washington, DC: National Academies Press, 2000), https://www.nap.edu/catalog/9837/ending-neglect-the-elimination-of-tuberculosis-in-the-united-states; and Institute of Medicine, *Addressing the Threat of Drug-Resistant Tuberculosis: A Realistic Assessment of the Challenge* (Washington, DC: National Academies Press, 2009), https://www.nap.edu/catalog/12570/addressing-the-threat-of-drug-resistant-tuberculosis-a-realistic-assessment.
[73] Institute of Medicine, *PEPFAR Implementation: Progress and Promise* (Washington DC: National Academies Press, 2007), https://www.nap.edu/catalog/11905/pepfar-implementation-progress-and-promise; and Institute of Medicine, *Evaluation of PEPFAR* (Washington, DC: National Academies Press, 2013), https://www.nap.edu/catalog/18256/evaluation-of-pepfar.
[74] Jonathan Simon et al., "External Evaluation of the President's Malaria Initiative: Final Report," Global Health Technical Assistance Project, Washington, DC, December 2011, https://www.pmi.gov/docs/default-source/default-document-library/pmi-reports/audit_execsum.pdf?sfvrsn=12.
[75] U.S. Government Accountability Office, "Biodefense: The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance," Publication GAO-16-547T, April 14, 2016, http://www.gao.gov/assets/680/676548.pdf.

strides in the fight against global TB, and slow the rise of drug-resistant TB, the United States needs an adequately resourced global TB program that employs a whole-of-government approach to support U.S. and international goals for control of global TB. To that end, we recommend the following:

1. To the Executive Branch:

The executive branch should appoint a single focal person with full responsibility for leading U.S. global TB efforts. We believe strongly that long-term success of U.S. global TB activities will ultimately require an office and a leader supported by a presidential-level initiative and with legislative authorities similar to those provided by Congress for the leadership of PEPFAR[76] and the President's Malaria Initiative.[77]

Until that goal is achieved through collaboration with the legislative branch, the executive branch could demonstrate high-level leadership and prioritization of global TB through the appointment of a senior expert within the Executive Office of the President. It is critical that this individual have a high-level position outside the agency structure in order to: 1) raise the prioritization of global TB within the White House, and 2) mobilize an inclusive, whole-of-government approach to strategy development and mediate across sometimes competing priorities of departments and agencies. Given the potential global health security risk posed by drug-resistant TB, this individual could be situated at the National Security Council and have the responsibility of highlighting the obvious health security risks arising from drug-resistant TB.[78]

2. To the U.S. Congress:

The U.S. Congress should strengthen its oversight of U.S. global TB programs and work with the executive branch to establish an office and a leader with legislative authorities similar to PEPFAR and PMI.

Congress should, through the budget and appropriations process, increase funding for global TB control activities, including specific funding for implementation of the MDR-TB National Action Plan. These increased resources should include appropriations to USAID and CDC. Among other things, increased resources to USAID should enable it to establish a specific office dedicated to the management of its global TB program activities. Increased resources for CDC's global TB activities, which would facilitate that agency's ability to more effectively use its skill sets in the U.S. government's global TB control activities, should probably come in the form of a direct budget appropriation, which currently does not exist.

---

[76] United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25), 721–23, https://www.gpo.gov/fdsys/pkg/PLAW-108publ25/pdf/PLAW-108publ25.pdf.
[77] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Public Law 110-293), 2961–62, https://www.congress.gov/bill/110th-congress/house-bill/5501.
[78] The TB lead could also have other infectious diseases or global health security risks within his or her portfolio. See Glassman and Silverman, 2016, for recommendation of a position within the NSC to oversee global health, which is consistent with our recommendation.

3. To the Executive Branch and/or Congress:

Congress or the executive branch should request (and arrange funding for) an independent program evaluation of all U.S. government activities that relate to global TB and the linkage of global TB to domestic (U.S.) TB. The scope of this evaluation should include specific recommendations for an administrative and leadership structure. The gravity of current global TB challenges (including MDR-TB) indicates that such an evaluation should be repeated at regular intervals.

COVER PHOTO DAVID EVANS/NATIONAL GEOGRAPHIC CREATIVE

CSIS | CENTER FOR STRATEGIC & INTERNATIONAL STUDIES

1616 Rhode Island Avenue NW
Washington, DC 20036
202 887 0200 | www.**csis**.org