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The U.S. Government and Global Tuberculosis

Overview

Tuberculosis (TB), an infectious disease caused by bacteria, is one of the world's major causes of illness and death, despite being preventable and often curable. Approximately one-third of the world's population carries the TB bacteria, about 9 million of whom develop "active" TB each year, which can be spread to others ("latent TB" disease cannot be spread, see box below). TB is found in every country in the world, though the majority of TB cases are concentrated in developing countries.[1]

In the 1990s and early 2000s, concern about rising incidence in some areas, new outbreaks, TB/HIV co-infection, and the emergence of TB drug resistance prompted key global health actors and governments, including the U.S. government (USG), to make preserving and advancing the progress of global efforts against TB a priority.[2] Particularly in the past decade, global efforts to address TB have become more prominent, and global TB incidence, prevalence, and mortality rates have fallen.[3] Still, as deadlines for reaching key global TB control goals draw near, significant challenges remain.

> **Tuberculosis (TB):**[4] A bacterial infection caused by *Mycobacterium tuberculosis*. Not all people who become infected with TB will develop symptoms. Those who do not become ill are referred to as having "latent TB" and cannot spread the infection to others, while those who become ill with "active TB disease" have symptoms like coughing (sometime with sputum or blood), chest pains, weakness, weight loss, fever, and night sweats. The disease usually affects the lungs, but in serious cases, it can affect other parts of the body and, if not treated properly, can be fatal. When a person with active TB coughs, sneezes, or spits, the bacteria spreads into the air where it may be inhaled by and infect others.[5] According to the World Health Organization (WHO), people with active TB can infect up to 10-15 other people through close contact over the course of a year, and without proper treatment, up to two-thirds of people ill with TB will die.[6]

USG involvement in global TB efforts was relatively limited until the late 1990s. Since that time, its efforts to address TB have grown, and the USG is now one of the largest donors to global TB control through its bilateral and multilateral activities.[7] The passage of the legislation that launched the President's Emergency Plan for AIDS Relief (PEPFAR, the expanded USG response to global HIV/AIDS) in 2003 placed a heightened priority on U.S. global TB efforts that continues to this day.

Current Global Snapshot

In 2013, there were approximately 11 million cases of people living with active TB, including 9 million new cases of people who developed active TB disease. Although active TB is treatable and curable in most cases, an estimated 1.5 million people died from TB that year (see Figure 1). Detecting TB cases – and then linking diagnosed cases to treatment — remains a significant challenge.[10]

- **Affected Areas:**[11] Nearly all cases and deaths (more than 95%) occur in low- and middle-income countries, particularly in South-East Asia, Africa, and the Western Pacific. Additionally, twenty-two high-burden countries (HBCs) that have high numbers of TB cases collectively account for approximately 80% of TB cases globally. Growing urbanization – particularly in

Figure 1: TB Cases by Incidence, Prevalence, and Mortality by Region, 2013[8]

WHO Region[9]	# of HBCs	Incidence*			Prevalence*		Mortality* (excluding HIV-related)	
		Number (in thousands, %)		Rate (per 100,000 population)	Number (in thousands)	Rate (per 100,000 population)	Number (in thousands)	Rate (per 100,000 population)
Global Total	**22**	**9,000**	**100%**	**126**	**11,000**	**159**	**1,100**	**16.0**
Africa	9	2,600	29%	280	2,800	300	390	42.0
Americas	1	280	3%	29	370	38	14	1.5
E. Mediterranean	2	750	8%	121	1,000	165	140	23.0
Europe	1	360	4%	39	460	51	38	4.1
South-East Asia	5	3,400	38%	183	4,500	244	440	23.0
Western Pacific	4	1,600	18%	87	2,300	121	110	5.8

NOTES: * Represents WHO's "best estimate" for each indicator. Prevalence and incidence include HIV-related cases of TB. Global mortality does not include 360,000 deaths due to HIV-related TB.

developing countries – is contributing to the spread of the disease.[12]

- **Affected/Vulnerable Populations:** WHO reports that while people of all ages are at risk, TB mostly affects young adults during "their most productive years," posing significant challenges to the livelihoods of individuals as well as to developing economies.[13] Additionally, people who suffer from other conditions that impair the immune system (e.g., HIV) are at a higher risk of developing active TB, as are people who use tobacco.[14] People in resource-poor settings, especially those living in poverty or in crowded living conditions with poor ventilation (e.g., prisons or mines), are disproportionately affected.[15]
- **TB & HIV:** TB and HIV are frequently referred to as co-epidemics (or dual epidemics) due to their high rate of co-infection. TB is a leading cause of death among people with HIV, especially in developing countries.[16] In 2013, an estimated 1.1 million of the 9 million new active TB cases affected people who were also HIV-positive, and of the 1.5 million people who died from TB, an estimated 360,000 were HIV-positive.[17]
- **Drug-Resistant TB:**[18] Drug-resistant TB has emerged as a major challenge to global TB control efforts. Five percent of global TB cases are estimated to be drug-resistant. Cases that fail to respond to standard first-line drugs are known as multidrug-resistant TB (MDR-TB), while those that fail to respond to both first- and second-line drugs are known as extensively drug-resistant TB (XDR-TB).[19] In 2013, there were an estimated 480,000 new cases of MDR-TB, and WHO estimates that 9% of these cases were XDR-TB. MDR-TB has been reported in most countries, with 27 countries identified as having a high burden of MDR-TB specifically. XDR-TB has been reported in 100 countries and territories.

Effective Interventions

DOTS ("directly-observed therapy short-course") is the internationally recommended TB control strategy aimed at decreasing TB-related morbidity, death, and transmission. DOTS is comprised of 5 components: sustained political and financial commitment, quality diagnosis via sputum-smear microscopy, treatment (usually a six-month course of antibiotics) taken under direct supervision, a regular and uninterrupted supply of effective drugs, and standardized data collection and monitoring and evaluation of outcomes. Other interventions include scaling up diagnosis and management of MDR- and XDR-TB, addressing TB/HIV co-infection,[20] strengthening health systems and the health workforce's capacity to respond to TB, and developing new tools (e.g., new TB diagnostics, drugs, and vaccines) and improved approaches through support for research, among other activities.[21]

Global Goals

Since the 1993 declaration of TB as a global health emergency by WHO,[22] major global TB goals have been set through:

- **the adoption of the Millennium Development Goals (MDGs)** in 2000 by all member-states of the United Nations, which included a TB target under MDG 6: to halt and begin to reverse the incidence of TB by 2015 (monitoring progress through improvements in incidence, prevalence, and death rates associated with TB).[23] The world has met this target, with the TB incidence rate falling worldwide, though progress varies within regions.[24]
- **the 2006 international *Stop TB Strategy*,**[25] in which WHO outlined the goals of halving TB prevalence and death rates by 2015 (compared with 1990 levels[26]) and eliminating TB as a public health problem by 2050.[27] *The Global Plan to Stop TB* outlines the steps and resources needed to achieve the *Strategy's* goals and is periodically updated by the Stop TB Partnership (an international network of public and private entities working to eliminate TB).[28] Between 1990 and 2013, TB prevalence has fallen by 41% and TB mortality has fallen by 45%.[29]
- **the post-2015 global tuberculosis strategy (known as the *End TB Strategy*)** endorsed by governments at the 2014 World Health Assembly, which set an overarching goal of ending the global TB epidemic as well as targets for achieving, by 2035, a 95% reduction in TB deaths and a 90% reduction in TB incidence (compared with 2015 levels).[30]

The U.S. Government Response

In 1998, the U.S. Agency for International Development (USAID) began a global TB control program, and over the following decade, the USG assigned a heightened priority to and provided greater funding for bilateral and multilateral TB efforts.[31] The *U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003* (the legislation that created PEPFAR) included TB under its umbrella, authorizing five years of funding for bilateral TB efforts and the Global Fund to Fight AIDS, Tuberculosis and Malaria (an independent, international financing institution created in 2001 that provides grants to countries to address TB, HIV, and malaria). The *Lantos-Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008,* which reauthorized PEPFAR, set targets for USG bilateral TB efforts and authorized another five years of funding.[32]

More recently, in 2015, the USG released its five-year *USG TB Strategy 2015-2019*, which outlines current USG TB goals.[33] These goals include, by 2019, to contribute to: treatment of 13 million new sputum-smear positive TB cases, maintaining treatment success rates of 90% for individuals with drug-susceptible TB, diagnosing and initiating treatment of 360,000 new MDR cases of

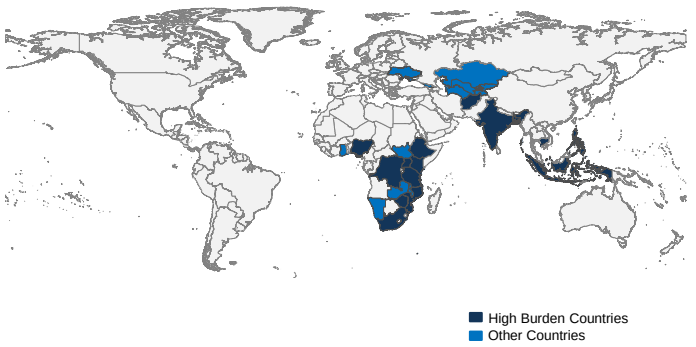
TB, providing antiretroviral therapy to 100% of the people diagnosed with HIV and active TB, and a 25% reduction in TB incidence relative to a 2015 baseline.

Structure and Approach

USAID serves as the lead implementing agency for USG global TB efforts. Other agencies involved in responding to TB include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the State Department's Office of the U.S. Global AIDS Coordinator (OGAC), and the Department of Defense (DoD). All USG global TB efforts are coordinated under the international working group of the Federal Tuberculosis Task Force (a coalition of federal agencies involved in USG global and domestic TB efforts).[34]

USAID TB Program. USAID's bilateral TB program aims to support specific country needs[35] in more than 25 countries where it currently carries out TB efforts, including at least 15 of the 22 HBCs (see Figure 2[36]), and to focus on key interventions: accelerated detection and treatment of TB for all patients, scaled up prevention and treatment of MDR-TB, expanded coverage of interventions for TB-HIV co-infection (in coordination with USG HIV efforts under PEPFAR), improvements in the TB service delivery platforms and overall health system, and support for accelerated research and innovation. The agency reports that in USAID-supported countries, TB-related mortality and TB prevalence have decreased by 43% and 42%, respectively, since 1990.[37]

Figure 2: U.S. Government Global Tuberculosis (TB) Countries, FY 2013



SOURCES: USG, *Impact and Leadership: USG Report on International Foreign Assistance for TB, FY 2013*, 2014.

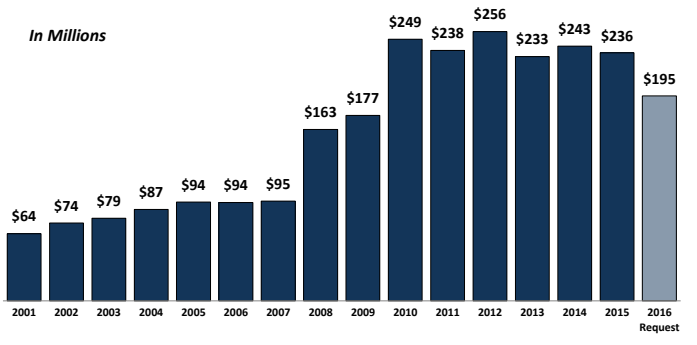
Other USG TB Efforts.[38] The USG also supports TB activities through several other agencies. CDC provides technical support on epidemiology and surveillance, laboratory strengthening, and clinical and program operations, and also supports clinical and operational research. NIH, as the leading funder of TB research and development (R&D),[39] supports basic, applied, and clinical R&D of new drugs, vaccines, and diagnostics. OGAC leads USG efforts to address TB-HIV co-infection. DoD's overseas laboratories help to monitor the quality of TB diagnostic services and conduct operational research.

Multilateral Efforts. The USG partners with international institutions and supports global TB funding mechanisms. Key partners include WHO and the Stop TB Partnership. The USG is the largest donor to the Global Fund, which has committed approximately $4.9 billion in funding for TB programs worldwide, and one of the largest donors to the Global Drug Facility (a mechanism of the Stop TB Partnership that provides grants to countries for TB drugs).[40]

U.S. Government Funding[41]

Most USG funding for TB is provided through the Global Health Programs (GHP) account at USAID with additional funding provided through the Economic Support Fund (ESF) account.[42] Total Congressional appropriations to USAID for TB have increased from $64 million in FY 2001 to a high of $256 million in FY 2012 (see Figure 3). The FY 2016 budget request included $191 million through the GHP account. If approved by Congress, this would be a decrease of $45 million (-19%) below the FY15 level, and would be the lowest level of funding since FY 2009. The FY 2016 budget request also includes $4 million for TB through the ESF account (TB funding through the ESF account in FY 2015 is not yet known; in FY 2014, it was $6.5 million). All TB funding is counted as part of PEPFAR, which also includes funding for USG global HIV/AIDS efforts and contributions to the Global Fund.

Figure 3: Bilateral Tuberculosis (TB), FY 2001-FY 2016 Request



NOTES: Includes base and supplemental funding for bilateral TB programs. Bilateral TB includes funding for the Global TB Drug Facility. FY13 includes the effects of sequestration. FY15 is based on funding provided in the "Consolidated and Further Appropriations Act, 2015" (P.L. 113-235) and is a preliminary estimate. TB funding provided through the Economic Support Fund (ESF) account is not yet known for FY15, and is not included in the FY15 total. As such, final FY15 TB funding is likely to be above $236 million (in FY14, TB funding through the ESF account was $6.5 million).
SOURCE: Kaiser Family Foundation analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and U.S. Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov.

Looking Ahead

The USG is one of the largest donors to global TB control efforts and has highlighted TB as an important component of its global health investment. Key issues and challenges for the USG going forward include: implementing TB control programs in the context of weak health systems, limited laboratory capacity, and treatment barriers and complications; tackling the emergence of drug-resistant TB; supporting a range of research and development efforts to advance new drugs and vaccines but also to lay the

foundation for future elimination efforts; coordinating TB control efforts with other global health efforts, particularly HIV and maternal and child health (given the impact of TB during pregnancy and childhood); addressing the cost of treatment;[43] continuing to expand access to TB services in the current restrained fiscal environment; and coordinating efforts with other donors (including the Global Fund) in order to maximize the impact of available resources, given WHO estimates that about $8 billion[44] is required per year to respond to TB in low- and middle-income countries.

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[1] WHO, *Global TB Report 2014,* 2014.
[2] WHO, "Global Tuberculosis Programme," World Health Assembly Resolution 44.8, 1991; WHO, *WHO Report on the Global TB Epidemic 1998*, 1998; WHO, "Tuberculosis," fact sheet, August 2002; TB Alert, "TB Timeline," webpage, http://www.tbalert.org/about-tb/tb-in-time/tb-timeline/; WHO, *Global TB Report 2014,* 2014.
[3] WHO, *Global TB Report 2014,* 2014.
[4] CDC, "Multidrug-Resistant Tuberculosis (MDR TB)," fact sheet, June 2012; WHO: "Tuberculosis," fact sheet, Oct. 2014; *Global TB Report 2014*, 2014.
[5] These bacteria can float in the air for several hours, depending on the environment. Persons who breathe in the air containing these TB bacteria can become infected. Since initial symptoms may be mild for months, people can sometimes delay seeking care, exposing more people to the bacteria.
[6] WHO, "Tuberculosis," fact sheet, Oct. 2014.
[7] KFF, Mapping the Donor Landscape in Global Health: Tuberculosis, 2013.
[8] WHO, *Global Tuberculosis Report 2014,* 2014; KFF analysis of data therein.
[9] For definition of WHO regions, see WHO, "About WHO: WHO Regional Offices," webpage, http://www.who.int/about/regions/en/.
[10] WHO, *Global TB Report 2014*, 2014.
[11] WHO, *Global TB Report 2014*, 2014.
[12] USG, *USG Report on International Foreign Assistance for TB, FY 2013*, 2014.
[13] WHO, "Tuberculosis," fact sheet, Oct. 2014.
[14] WHO, "Tuberculosis," fact sheet, Oct. 2014.
[15] USG, *USG Report on International Foreign Assistance for TB, FY 2013*, 2014.
[16] WHO, "Frequently asked questions about TB and HIV," webpage, http://www.who.int/tb/challenges/hiv/faq/en/.
[17] WHO. *Global Tuberculosis Report 2014*, 2014.
[18] WHO: *Drug-Resistant TB Surveillance & Response*, 2014; *Global TB Report 2014*, 2014.
[19] These forms of TB "can take two years or more to treat with drugs that are less effective, more toxic and more expensive." WHO: *Multidrug-resistant tuberculosis (MDR-TB)*, fact sheet, Oct. 2013.
[20] According to WHO, "Besides early initiation of ART [antiretroviral treatment], the main intervention to prevent [active] TB in people living with HIV is isoniazid preventive therapy (IPT)." WHO, *Global TB Report 2014*, 2014.
[21] WHO, *The Stop TB Strategy*, March 2006.
[22] WHO, "Tuberculosis," fact sheet, August 2002.
[23] UN, "Official List of MDG Indicators," webpage, http://unstats.un.org/unsd/mdg/Host.aspx?Content=Indicators/OfficialList.htm.
[24] WHO: *Countdown to 2015: Global TB Report 2013 Supplement*, 2013; *Global TB Report 2014*, 2014.
[25] WHO, *The Stop TB Strategy,* March 2006.
[26] "Specifically, this means reducing prevalence to 155 per 100,000 or lower and deaths to 14 per 100,000 per year or lower by 2015 (including TB cases coinfected with HIV). The number of people dying from TB in 2015 should be less than about 1 million, including those coinfected with HIV."
[27] This means that "the global incidence of TB disease will be less than 1 case per million population per year."
[28] Stop TB Partnership: *The Global Plan to Stop TB 2006–2015*, Jan. 2006; *The Global Plan to Stop TB 2011-2015*, 2010.
[29] WHO, *Global TB Report 2014*, 2014.
[30] This means the incidence rate will be an average of less than 10 TB cases per 100,000 population. WHO: "Post-2015 Global TB Strategy and targets," fact sheet, Dec. 2014; "WHO End TB Strategy," webpage, http://www.who.int/tb/post2015_strategy/en/.
[31] USAID: USAID, *Expanded Response to TB*, Sept. 2004 and updated Jan. 2009; USAID, *Fast Facts: Tuberculosis*, Oct. 2010.
[32] U.S. Congress, Public Law 108-25, May 27, 2003; U.S. Congress, Public Law 110-293, July 30, 2008.
[33] USG, *USG Global TB Strategy 2015-2019*, 2015. This succeeds the prior five-year *Lantos-Hyde USG TB Strategy*, March 2010.
[34] CDC, "Federal TB Task Force," webpage, http://www.cdc.gov/tb/about/taskforce.htm.
[35] As outlined in a partner country's national TB strategic plan, per the current and prior USG global TB strategies.
[36] According to USAID, *USG Report on International Foreign Assistance for TB, FY 2013*, 2014, USAID efforts reached 27 countries during FY 2013, while data on the U.S. Foreign Assistance Dashboard (foreignassistance.gov) shows that USAID's planned FY 2013 TB funding allocations spanned 26 countries and several regional TB efforts, which may reach additional countries.
[37] USG, *USG Global TB Strategy 2015-2019*, 2015.
[38] USAID: *USG Report on International Foreign Assistance for TB, FY 2011/2012*, 2013; same report for FY 2013, 2014.
[39] Treatment Action Group, *2014 Report on Tuberculosis Research Funding Trends, 2005–2013*, 2014.
[40] Global Fund: "Grant Portfolio," accessed Feb. 2015, http://portfolio.theglobalfund.org/en/Home/Index; "Pledges and Contributions," as of Feb. 21, 2015. Global Drug Facility, "The Global Drug Facility: Access and Opportunity," brochure, 2009.
[41] KFF analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and U.S. Foreign Assistance Dashboard (www.foreignassistance.gov).
[42] Represents specified funding for international TB programs in the President's budget request, ForeignAssistance.gov, and Congressional appropriations bills. Additional support for international TB programs is provided through bilateral HIV programs at the State Department to address TB/HIV co-infection, for technical support and research activities through the CDC, and for research activities at the NIH.
[43] According to WHO, in 2013, per-person treatment costs with first-line drugs are $100-500 in most countries with a high burden of TB, while per-person treatment costs for MDR-TB are $5,000-10,000. WHO, *Global TB Report 2014*, 2014.
[44] For 2015, WHO reports that about $2 billion is required from international donor sources (whose funding reached about $0.7 billion in 2014) to supplement the $6 billion that could be mobilized from domestic sources (whose funding reached about $5.5 billion in 2014). WHO, *Global TB Report 2014*, 2014.