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CSIS GLOBAL HEALTH POLICY CENTER

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Acknowledgments

This report draws upon facility visits and interviews conducted by a CSIS team in October and November 2015 in both urban and rural sites in Ethiopia. Team members met with U.S. Embassy officials; senior Ethiopian government representatives, including the president of Ethiopia and external organizations implementing health programs in Ethiopia. In addition, the team visited hospitals, health centers, health posts, labs, and other facilities in Addis Ababa, the Oromia region, and the Southern Nations, Nationalities, and Peoples' Region (SNNPR). The visit was supplemented by extensive discussions with health policy experts and representatives from other U.S. and international organizations. The CSIS team is grateful to everyone who shared his or her time and insights, although the views expressed here are solely those of the authors. This work was made possible by the generous support of the Bill & Melinda Gates Foundation.

Executive Summary

The World Health Organization (WHO) recently announced that tuberculosis (TB) was the most common global cause of infectious disease deaths in 2014, when more than 9 million TB cases[1] and 1.5 million TB deaths occurred.[2] Based on recognition of the urgent need to prevent these annual global health and economic burdens, the WHO and the Stop TB Partnership recently released a new End TB Strategy and 2016–2020 Global Plan that includes among its 2025 targets a rate of TB case detection and treatment of 90 percent, including in high-risk populations, and a cure rate of 90 percent of detected TB cases.[3, 4]

Despite an aggressive global strategy, large TB control challenges remain. For example, two critical steps in stopping TB transmission are the diagnosis (detection) and the cure of TB cases, yet in 2014 more than a third of individuals with contagious TB disease globally went undiagnosed and untreated.[5] This global TB control picture provides an important context to the CSIS team's visit to Ethiopia.[6]

Current Strengths and Challenges of TB Control in Ethiopia (See Box 1)

In the context of global TB, Ethiopia matters significantly. In 2014, WHO estimated that there were 200,000 new TB cases in Ethiopia, ranking the country 10th among the world's 22 high-burden countries for TB, and 4th in sub-Saharan Africa.[7] While TB kills an estimated 32,000 Ethiopians every year (more than 80 people per day), it also has a long-term corrosive impact on the health of Ethiopia's population. The economic consequences of TB include those due to lost income and productivity during diagnosis and treatment, direct household expenditures for TB care, and the unmeasured disabilities due to permanent lung damage in up to 50 percent of survivors. Since the majority of TB cases occur among young adults and children, TB cumulatively exacts a heavy economic cost, impeding the country's drive toward becoming a middle-income country.

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[1] As used globally and in this report, the term "TB case" refers to a person with active TB disease and the "case-detection rate" refers to the proportion (percent) of all people with active TB disease who are diagnosed and then reported to the national health system.
[2] World Health Organization, *Global Tuberculosis Report 2015* (Geneva: WHO, 2015), 13, http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf?ua=1.
[3] World Health Organization, *The End TB Strategy* (Geneva: WHO, 2015), http://www.who.int/tb/End_TB_brochure.pdf?ua=1.
[4] Stop TB Partnership, *The Paradigm Shift, 2016–2020: Global Plan to End TB* (Geneva: Stop TB Partnership, 2015), http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf.
[5] WHO estimates that only 63 percent of global TB cases were identified in 2014. See WHO, *Global Tuberculosis Report 2015*, 36.
[6] This TB-specific report describes only one aspect of current CSIS work on Ethiopia. A more general assessment of the health aspects of the bilateral U.S.-Ethiopia relationship can be found in Richard Downie, *Sustaining Improvements to Public Health in Ethiopia* (Washington, DC: Center for Strategic and International Studies, 2016), http://csis.org/files/publication/160226_Downie_SustainImprovementsEthiopia_Web.pdf.
[7] Ethiopia follows Nigeria, South Africa, and the Democratic Republic of the Congo in the rankings of Africa's high-TB-burden countries. See WHO, *Global Tuberculosis Report 2015,* 22.

With the funding and technical support of donors including the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC), the Global Fund for AIDS, Tuberculosis and Malaria (Global Fund) and other external donors, Ethiopia was one of nine of the 22 high-burden countries to meet all three of the 2015 WHO targets for TB incidence, prevalence, and mortality. A major barrier to progressing toward TB elimination in Ethiopia and other high-burden countries is the TB "case-detection rate" of only 60 percent,[8] meaning that an estimated 80,000 Ethiopians who developed TB in 2014 were never diagnosed or treated, leading to ongoing spread of TB to family members and communities. The gap in case-detection rate is even worse for the more severe multidrug-resistant TB (MDR-TB), where less than a quarter of an estimated 2,200 Ethiopian MDR-TB patients are identified each year.

These problems notwithstanding, the Ethiopian government's strong commitment to TB control efforts makes it a possible "model country" for TB control.[9] For example, a major strength of the national TB control program is the government's commitment to provide health care for the entire population, with carefully crafted five-year plans for improving access to health services. One illustration of this commitment is the government training and employing a cadre of health extension workers (HEWs) designed to provide basic health services down to the neighborhood level. Ethiopia has also committed to the End TB Strategy, with a revised National TB Strategic Plan that aims for a 50 percent reduction in TB incidence (annual new TB cases) and a 75 percent reduction in TB deaths by 2025.[10] Ethiopia is also widely recognized for using donor funds wisely and effectively, including funds provided by USAID, CDC, the Global Fund, as well as other external donors.

Insufficient budgetary resources limit Ethiopia's ability to provide adequate clinical, laboratory, and pharmaceutical services for those patients currently identified with TB. For example, of the $82 million budgetary requirements of the National Tuberculosis and Leprosy Control Program (NTLP) in 2015, only $35 million in donor funds and $9.1 million in domestic funding were available, leaving a $38 million funding gap.[11, 12]

Such funding gaps for TB control, it would seem, are eminently manageable. Yet if not bridged, these gaps will likely undermine the country's ability to successfully achieve TB elimination. Beyond Ethiopian government and donor resources, 36 percent of national health expenditures (NHE) for tuberculosis was paid by individual affected households; it is yet another telling indicator of the impact that tuberculosis has on individual family income in the face of inadequate government services. Based upon the corrosive impact

[8] The case-detection rate (CDR) is the proportion of a county's (or region's) estimated TB cases that are actually identified and notified (reported) to the national TB program. Since 1991, WHO's global goal for CDR has been at least 70 percent, but that has still not been achieved in many countries.
[9] Talha Burki, "Ethiopia could be a model country for tuberculosis control," *Lancet* 386, no. 10010 (December 2015): 2241–42.
[10] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015* (Addis Ababa: Federal Ministry of Health), 76–77.
[11] WHO, *Global Tuberculosis Report 2015*, Finances Table 7.3.
[12] TB funding accounted for only 3.1 percent of national health expenditures in 2010/2011 compared to 18.7 percent and 14.7 percent for HIV and malaria, the two other national programs that have demonstrated remarkable achievements in Ethiopia. See Federal Government of Ethiopia, *Ethiopia's Fifth National Health Accounts Highlight of Major Findings: Briefing Notes* (Addis Ababa: Federal Ministry of Health, 2014), https://www.hfgproject.org/wp-content/uploads/2014/04/Ethiopia-NHA-Findings-Briefing-Notes.pdf.

that TB presently has on Ethiopia's mortality, health, and productivity, there is a clear case for the Ethiopian government and donors alike to step up investments in TB control.

As part of its humanitarian and health interests in ending TB globally, the United States has invested significant resources in Ethiopia to tackle TB, primarily through USAID bilateral TB programs, other health initiatives that provide comprehensive TB services, and the President's Emergency Plan for AIDS Relief (PEPFAR), which supports provision of TB services for persons infected with—or at risk of infection by—HIV.

Recommendations to address these challenges include:

To the U.S. government:

1. Make it a priority to increase U.S. and multilateral resources available to the Ethiopian government for TB control. These options should include: a) strong encouragement to the Ethiopian government to increase the amount of public and private domestic resources devoted to TB control; b) U.S. political and technical support to the Ethiopian government; and c) U.S. government exploration of potential additional U.S. resources in support of related goals, for example, bilateral USAID resources, additional PEPFAR resources, and the new U.S. Action Plan for Combating Multidrug-Resistant TB (or other U.S. programs or resources addressing antimicrobial drug resistance).

2. Ensure through careful monitoring that PEPFAR's ongoing transition (PEPFAR 3.0) does not inadvertently create adverse consequences on Ethiopia's TB control programs.

3. Enhance U.S. investments in research and development for TB in order to provide new, safe, and effective treatment regimens that can be scaled up in developing countries like Ethiopia.

To the government of Ethiopia:

1. Explore all possible domestic and international funding sources to help address current shortages.

2. Engage Ethiopia's Field Epidemiology Training Program (FETP) in MDR-TB control. Including MDR-TB as one of the emerging diseases addressed by the FETP and its trainees is a step that would both educate Ethiopia's future public health leaders about MDR-TB and provide additional human resources to address epidemiologic and public health aspects of MDR-TB.

3. Accelerate efforts to address the multiple TB program gaps.

4. Monitor—and encourage further progress in reducing—the financial burden of TB on Ethiopian families.

Box 1. Highlights of Recent Ethiopian Tuberculosis (TB) and TB/HIV Data*

Annual new TB cases, including TB/HIV	200,000	
TB cases among HIV infected	19,000	
TB deaths excluding HIV infected	32,000	
TB deaths among TB/HIV coinfected	5,500	
Total TB-related deaths	37,500	
TB case detection rate	60 percent	
TB treatment success rate among new drug-sensitive TB cases (2013)	89 percent	
New TB cases among children <15 years old	15,917	
MDR-TB among 119,592 notified TB cases		
Number and percent tested for MDR-TB	10,151	8.5 percent
MDR-TB cases among 81,662 pulmonary cases: number of MDR estimated and percent with MDR	1,300	1.6 percent
Laboratory-confirmed MDR-TB cases: number detected and percent of estimated number	503	39 percent
Known MDR-TB cases started on 2nd line treatment in 2012**	271	83 percent
Estimated proportion of XDR-TB cases^2	1–4.4 percent	
HIV among TB patients		
Proportion of TB patients with known HIV status	75 percent	
Proportion (and number) of TB patients infected by HIV	10 percent	(8,670)
Proportion of coinfected patients taking antiretroviral drugs	39 percent	
TB among people living with HIV (PLHIV)		
PLHIV screened for TB	341,534	
PLHIV provided with TB preventive therapy	10,385	.
National TB budget needs, U.S.$ millions (2015)* **	$82 million	
Government funding provided	$9 million	
External funding provided	$35 million	
TB program funding gap	$38 million	

* Source: World Health Organization Global TB Report, 2015, "Ethiopia tuberculosis profile 2014," https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=ET&outtype=pdf.
** Number in the cohort for analysis.
*** WHO uses country data to produce estimates in consultation with countries.
^XDR-TB is a more severe form of MDR-TB that is more difficult and more expensive to treat.

As Ethiopia Moves toward Tuberculosis Elimination, Success Requires Higher Investment

Randall Reves and Sahil Angelo[1]

Introduction

Ethiopia's population of 101 million lives in its nine regions and its two city administrations of Addis Ababa and Dire Dawa.[2] These are further divided into 78 zones, 956 *woredas* (districts), and finally into 16,541 *kebeles* (neighborhoods). The population is 76 percent rural, 16 percent urban, and 8 percent pastoralist. The operation of the health system has been decentralized to regional governments and district health offices below them. Each district has a primary hospital with multiple health centers, and every health center is administratively linked to five health posts—the lowest tier of Ethiopia's health care system. Each neighborhood has its own health post with two health extension workers (HEWs) who provide a package of up to 16 basic services to rural populations, including TB prevention and treatment follow-up. Ethiopia's Federal Ministry of Health (FMOH) oversees a National Tuberculosis and Leprosy Control Program (NTLP) that functions at national and regional levels with the goal of using the HEW program to ensure the equitable provision of TB control services, but this goal has not yet been achieved in all neighborhoods.[3]

Ethiopia is one of the 22 high-TB-burden countries, which together account for 80 percent of all global TB cases. Based on WHO estimates for 2014, Ethiopia had 200,000 incident (new) TB cases in 2014. This number ranks Ethiopia 10th globally and 4th in Africa in terms of absolute TB burden, after Nigeria, South Africa, and the Democratic Republic of Congo.[4, 5]

Ethiopia also ranks 15th among the 27 countries with high burdens of MDR-TB, defined as TB bacteria resistant to the two most important first-line TB drugs, isoniazid and

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[1] Randall Reves, MD, is a professor in the Division of Infectious Diseases at the University of Colorado School of Medicine. Sahil Angelo is a research associate with the CSIS Global Health Policy Center.
[2] The population is currently estimated at 101 million. However, the most recent tuberculosis figures are based on the 2014 population figure of 97 million people.
[3] In some urban and pastoralist regions, health extension worker (HEW) services are less comprehensive and may not yet include TB activities. See Richard Downie, *Sustaining Improvements to Public Health in Ethiopia* (Washington, DC: CSIS, March 2016), http://csis.org/files/publication/160226_Downie_SustainImprovementsEthiopia_Web.pdf.
[4] WHO, *Global Tuberculosis Report 2015*, 27.
[5] As in many other developing countries, TB detection and reporting are incomplete in Ethiopia; the statistics on TB prevalence, incidence, and mortality are based primarily on WHO estimates supported in part by results of in-country studies.

rifampin.[6] MDR-TB is deadlier, harder to diagnose, and much more difficult to treat. According to a recent unpublished study in Ethiopia, the proportions of MDR-TB among the nation's new and recurrent TB cases are 2.3 percent and 17.6 percent, respectively.[7, 8] Ethiopia has also seen patients with cases of extensively drug-resistant TB (XDR-TB), cases due to MDR-TB bacteria that are also resistant to the backup, or second-line, TB drugs usually used for treating MDR-TB.[9] Compared to MDR-TB, diagnosing XDR-TB is even more difficult and treatment outcomes are even worse, leading to higher mortality rates.[10]

As in many other countries, Ethiopia saw a surge of TB cases in the 1990s due to the spread of HIV,[11] reaching a peak TB incidence rate of 419 per 100,000 people in 1995.[12] The incidence rate for 2014 dropped to 207 cases per 100,000 people and mortality to 33 deaths per 100,000 people.[13] Based on these data, Ethiopia successfully achieved WHO's 2015 TB targets.[14] Table 1 provides a timeline of Ethiopia's efforts to control TB.

Despite a reduction in Ethiopia's annual TB mortality rate from 94 to 33 deaths per 100,000 persons from 2004 to 2014, TB still causes more than 30,000 fatalities annually—more than 80 TB deaths every day. The national TB problem is exacerbated by the slowly but steadily rising rates of drug-resistant TB.[15] In addition, there are unmeasured economic costs among survivors due to household expenditure and lost productivity during diagnosis and treatment. Since the majority of these TB cases are occurring

[6] Multidrug-resistant TB (MDR-TB) is a growing global pandemic with 480,000 incident cases and 190,000 deaths estimated by WHO for 2014. Originally, MDR-TB was associated with physician treatment errors or poor patient adherence to treatment. Over half of MDR-TB cases globally are diagnosed in individuals never previously treated for tuberculosis, meaning their MDR-TB resulted from ongoing transmission in the community rather than from human error. Ongoing transmission of MDR-TB is to be expected since only 11 percent of the estimated 480,000 people with new MDR-TB globally actually completed treatment.
[7] Interview with senior U.S. official, Addis Ababa, October 26, 2015; noted to be from a preliminary report of the 2014 Second Round National Anti-tuberculosis Drug Resistance Surveillance—Ethiopia.
[8] Retreatment cases refer to people who are diagnosed with TB and started on treatment after having been previously treated for TB. This may result from failure of the previous treatment, failing to complete treatment, relapse of TB after responding to treatment, or being infected with a new TB bacterium.
[9] Oral quinolone drugs and several injectable TB drugs are usually reserved for MDR-TB cases. XDR-TB accounts for about 10 percent of MDR-TB cases globally. See J. P. Cegielski et al., "Global Preserving Effective TB Treatment Study (PETTS) Investigators. Extensive drug resistance acquired during treatment of multidrug-resistant tuberculosis" *Clinical Infectious Disease* 59 no. 8 (October 15, 2014): 1049–63.
[10] The global spread of MDR-TB and XDR-TB may eventually threaten much of the recent progress made in TB control. See World Health Organization, "Drug Resistant Tuberculosis," http://www.who.int/tb/areas-of-work/drug-resistant-tb/en/.
[11] People living with HIV are more susceptible to developing TB disease, due to weakened immune systems. This complicates the diagnosis and treatment for HIV positive individuals infected with TB. For more information, see Phillip Nieburg, Talia Dubovi, and Sahil Angelo, *Tuberculosis—A Complex Health Threat* (Washington, DC: CSIS, April 2015), http://csis.org/files/publication/150409_Nieburg_TBComplexHealthThreat_Web.pdf.
[12] Federal Democratic Republic of Ethiopia, Ministry of Health, *Health Sector Transformation Plan*, *2015/16–2019/20*, August 2015, 25.
[13] WHO, *Global Tuberculosis Report 2015*, 15.
[14] The three targets were: falling incidence (new infection) rate, and 50 percent reductions in both TB mortality and TB disease prevalence (current infection) by 2015 compared with 1990. See WHO, *Global Tuberculosis Report 2015*, 17.
[15] For comparison, deaths due to HIV/AIDS in Ethiopia totaled about 23,000 in 2014, a major drop from the peak of 85,000 deaths in 2004. See UNAIDS, "AIDS Info—Ethiopia," 2014, http://aidsinfo.unaids.org/#.

Table 1: Timeline of TB Control Activities in Ethiopia

1960s	First TB sanatorium established
1976	National TB Control Program (NTCP) begun
1992	First TB DOTS program piloted in Ethiopia[16]
1994	Central office of NTCP combined TB and Leprosy Control Programs → TBL prevention and control team established
1995	1996–2000 Project Development Plan announced
1996	Agreement between FMOH, WHO, KNCV Tuberculosis Foundation to implement DOTS across Ethiopia
1997–2001	TB and Leprosy control program is integrated into general health services
2001	Center for Global Health and Prevention office established
2002–2010	U.S. government TB support began through the TBCTA/TB CAP agreements
2003	Health Extension Worker Program introduced
2004	Initial rollout of collaborative TB/HIV activities
2007	WHO Green Light Committee application submitted for approval and support for implementing MDR-TB treatment
2008	Tuberculosis, Leprosy and TB/HIV Prevention and Control Program Manual, 4th Edition
2008	Green Light Committee application approved for a pilot MDR-TB treatment program for 45 patients at St. Peters Hospital
2009	Private Health Sector Program (PHSP) launched by USAID in partnership with Abt Associates Inc.
2010–2014	USAID's TB CARE I program leads to 140% increase in national MDR-TB treatment program enrollment
2010–2015	Funding awarded by the Stop TB Partnership for four projects to improve TB case-detection and treatment completion in rural residents, prisons, and among refugees
2011–2015	USAID-designed and -funded HEAL TB (Help Ethiopia Address Low TB Performance) program launched in partnership with several NGOs
2011	Most recent national TB survey conducted
2011	Release of National TB and Leprosy Strategic Plan 2011–2015
2012	Guidelines for Clinical Management and Programmatic Management of TB, Leprosy and TB/HIV, 5th Edition
2014–2019	Launch of Challenge TB program, a USAID cooperative agreement with KNCV, Management Sciences for Health, WHO, and other partners
2016	Challenge TB and HEAL TB programs are scheduled to merge to carry out TB control activities for over 80% of Ethiopia's population

[16] DOTS refers to "Directly Observed [TB] Treatment, Short-Course," the key component of which includes a six- to eight-month course TB drug treatment with at least two months of direct observation of patients taking their drugs by health workers or trained family or community members. See C. Lienhardt et al., "Global tuberculosis control: lessons learnt and future prospects," *National Review of Microbiology* 10 (2012): 407–16; and E. B. Shargie and B. Lindtjørn, "DOTS improves treatment outcomes and service coverage for tuberculosis in South Ethiopia: a retrospective trend analysis," *BMC Public Health* 5 (June 6, 2005), 62, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1173119/.

among young adults and children, TB imposes a considerable economic burden, impeding Ethiopia's drive toward middle-income status.[17]

Ethiopia's future progress in TB control matters not just to Ethiopia itself but also to the global community, in advancing implementation of the global End TB Strategy, and to the long-term interests of the United States, for which Ethiopia is a major health partner (see Appendix for the impact of TB in Ethiopia on the United States). This report describes Ethiopia's strengths and challenges for achieving TB elimination as well as U.S. and other partners' contributions that have been—and will continue to be—critical to future success.

Current Strengths and Challenges for Tuberculosis Control in Ethiopia

The government's commitment to providing health care for the entire population is a major strength of Ethiopia's NTLP.[18] The most recent FMOH health development plans have focused on rapidly expanding access to services. Considerable progress has been achieved in numbers of health facilities providing TB services: 156 government hospitals, 3,335 public health centers, 48 private hospitals, 222 private health facilities, 7 primary clinics, and 10,013 health posts. The FMOH has also expanded the number of medical schools from 3 to 33 in order to address the shortage of physicians.

Much of the government's TB strategy rests on the success of its flagship Health Extension Program, which uses HEWs operating out of more than 30,000 health posts to deliver a basic package of health services to the country's predominantly rural population. The expansion of TB prevention and control services is being rolled out as part of the HEW package with the support of the Health Development Army (HDA), a group of community-based women trained to provide basic TB information and symptom screening for potential patients. Unlike the HEWs, HDA members are unpaid, do not provide treatment, and are limited in their responsibilities to only five households. If they suspect someone is sick with a disease like TB, they are supposed to notify HEWs for follow-up. Although the HDA could theoretically help in educating communities about TB, it is unclear how well they are trained and how effectively these volunteers are supporting TB control activities. In 2013, 30 percent of Ethiopia's 921 woredas reported HEW contribution to TB case notification (accounting for 11 percent of notifications) and 5 percent reported TB treatment adherence support (for 16 percent of patients). Donors are providing financial and technical support to the HEW program in order to enhance their effectiveness. For example, a USAID-funded REACH TB project in Southern Ethiopia markedly improved TB case detection, TB treatment completion, and evaluation of childhood contacts in rural Ethiopia.[19] Despite current levels of donor

[17] According to the Ethiopian government, it seeks to become a lower-middle-income country by 2025 and a middle-income country by 2035.
[18] Talha Burki, "Ethiopia shows it is single minded in tackling disease," *Lancet Infectious Disease* 16, no. 2 (February 2016): 153–4.
[19] Ibid.; and M. A. Yassin et al., "Innovative community-based approaches doubled tuberculosis case notification and improve treatment outcome in Southern Ethiopia," *PLoS One* 8, no. 5 (May 2013).

support, key challenges remain, including high turnover of HEW, inadequate monitoring by leadership, and limited civil society engagement.[20]

In terms of laboratory capacity, Ethiopia has 2,986 health facilities with laboratories providing quality-assured microscopy for TB diagnosis, meeting the WHO recommendation for number of laboratories. However, using smear microscopy alone, which was previously recommended by WHO and is still common practice in Ethiopia and most high-TB-burden countries, identifies only half of TB cases that could be diagnosed by laboratory culture, resulting in a greater reliance on clinical diagnosis.[21] There are presently eight laboratories capable of performing TB cultures and drug-susceptibility testing. While this represents a recent improvement from a single laboratory, the expansion still fails to meet the WHO-recommended ratio of one laboratory per every 5 million people. It also indicates the steep challenge Ethiopia faces in reaching the End TB Strategy target of using WHO-approved rapid diagnostic tests and obtaining drug-susceptibility results for 100 percent of patients with culture-proven TB.[22]

Overall, major policy and programmatic initiatives by the Ethiopian government have contributed to significant gains in TB control in Ethiopia, but there is still a long road ahead.

First, the government's overall strategy has helped make significant strides in health, including in TB. In fact, the country far exceeded the rather modest 2015 WHO TB targets.[23] Despite Ethiopia's significant commitment to eliminating TB and its progress in reducing TB disease and death rates over the last 20 years, the government recognizes the gravity of the current TB burden, and has been frank about the challenges that need to be addressed in order to eliminate this disease.[24] However, current rates of community-based TB prevention and care under the Health Extension Program still fall well short of the 80 percent target.[25] The FMOH also acknowledges the need for new approaches to control the spread of drug-resistant TB and to address the disproportionately high prevalence of both drug-sensitive and MDR-TB among pastoralist populations.

In addition to the enduring access issues, improvement in service quality is now perhaps the biggest priority for the government. The FMOH has also identified incomplete implementation of community-based TB care strategies, inadequate laboratory capacity, poor infection control practices, TB data-quality gaps, and some drug stock-out challenges as major barriers to quality TB control and prevention. On a more basic level, there are still public misconceptions about how TB is transmitted and how it is cured (see

[20] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*, 42–43.
[21] A. H. Kebede et al., "The first population-based national tuberculosis prevalence survey," *International Journal of Tuberculosis and Lung Disease* 18, no. 6 (2014): 635–9.
[22] The current number of laboratories is only 40 percent of the recommended coverage ratio. See WHO, *Global Tuberculosis Report 2015*; and WHO, *The End TB Strategy*, Annex 1.
[23] The three WHO targets were falling incidence (new infection) rate, and 50 percent reductions in both TB mortality and TB disease prevalence (current infection) by 2015 compared with 1990. See WHO, *Global Tuberculosis Report 2015*, 17.
[24] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*, v.
[25] Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan* (Addis Ababa: Ministry of Health, 2015), 26.

Box 2). While the entire health system struggles to improve service quality, TB patients are particularly affected, in part because completing TB diagnosis and treatment can require up to several years.[26, 27]

In light of these challenges, the Ethiopian government has recently launched a new five-year Health Sector Transformation Plan (HSTP), in which improving both quality and access to TB care is a major priority: "detecting and curing tuberculosis are among the key health interventions for addressing poverty and equity."[28] This sentiment was echoed by Ethiopian government officials we spoke with at all levels of seniority—even down to the health post.[29]

Box 2: Public Perceptions of TB[1]

Getting the public to understand TB is a major challenge facing policymakers and practitioners. A senior government TB expert recounted meeting an educated man on a bus in Addis Ababa who believed that opening windows would increase the risk of contracting TB. The TB expert tried to explain that better ventilation was crucial to preventing the transmission of TB bacteria, but the man remained unconvinced. Clearly frustrated, the expert told us, "[We] need to measure the effectiveness of our messaging, because it is not working. The Health Extension Program and Health Development Army must play an important role in reaching every household."

The work of HEWs and the HDA do present a real opportunity to get the correct message out, but this story is an example of how a lack of quality—and lack of data on quality—can undermine the success of innovative programs.

1. Interview with senior Ethiopian government TB expert, Addis Ababa, October 31, 2015.

The Ethiopian government overtly acknowledges the magnitude and complexity of the country's TB problem. In addition to the HSTP, the government has a revised National Tuberculosis and Leprosy Strategic Plan 2013–2020, which is more specific—and sets more concrete targets—for TB than the HSTP. The strategic plan outlines nine strategic objectives (Box 3].[30] The Standard of Care tool introduced by the USAID-funded HEAL TB project is being used to institute a quality improvement cycle on many of these issues. The FMOH has also committed to global TB targets such as the three pillars of the current global WHO/Stop TB Partnership's End TB Strategy: 1) integrated, patient-centered care and prevention; 2) bold policies and supportive systems; and 3) intensified research and innovation.[31] The FMOH has recently accepted WHO's End TB Strategy goal for achieving 90 percent treatment success by 2020,[32] and has made major changes to the NTLP that

[26] Treatment drugs for active TB is taken for six to nine months, and for up to two years if the TB bacteria are drug-resistant. Furthermore, diagnosing TB can take up to four to six weeks, with treatment regimens being contingent on suitable drug-sensitivity testing.
[27] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*, v.
[28] Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan*, 26.
[29] For more analysis on the HSTP, see Downie, *Sustaining Improvements to Public Health in Ethiopia*.
[30] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*.
[31] For the full text, see WHO, *The End TB Strategy*.
[32] In fact, Ethiopia hosted an international meeting in Addis Ababa to launch the new strategy in November 2015. See World Health Organization, "WHO Consultation Meeting to Enhance the Engagement of Communities, Nongovernmental and other Civil Society Organizations in the Implementation of the End TB Strategy," 2015, http://www.who.int/tb/areas-of-work/community-engagement/who_ngos_consultation_nov2015/en/; and Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan*, 101.

guides the country's national and regional TB control efforts.[33] The outline of its strategic vision for addressing TB has been useful in demonstrating domestically and internationally that Ethiopia is a country that can plan and achieve results. In fact, the Ethiopian government's energy and commitment to TB have prompted experts to suggest that "it could serve as a model country" in implementing the End TB Strategy.[34]

Box 3: Strategic Objectives of Current TB National Strategic Plan 2013–2020[1]

1. Improve access to TB, TB/HIV, MDR TB and Leprosy services
2. Improve community ownerships on prevention and control of TB, TB/HIV, MDR TB and Leprosy
3. Maximize resource mobilization and utilization of resources for the prevention and control of TB, TB/HIV, MDR TB and Leprosy
4. Improve the quality of TB, TB/HIV, MDR TB and Leprosy service delivery
5. Enhance harmonization and alignment to strengthen TB partnerships at all levels
6. Improve TB, TB/HIV, MDR TB and Leprosy pharmaceutical supply system
7. Improve evidence-based decisionmaking in the prevention and control of TB, TB/HIV, MDR TB and Leprosy
8. Improve human capital and leadership for the prevention and control of TB, TB/HIV, MDR TB and Leprosy
9. Improve health infrastructure for the prevention and control of TB, TB/HIV, MDR TB and Leprosy

1. Federal Democratic Republic of Ethiopia, *Revised National Tuberculosis and Leprosy Strategic Plan 2013–2020* (Addis Ababa: Ministry of Health, 2013), 75.

Current Challenges in Addressing Ethiopia's TB Burden

Detecting TB Cases

How can a potential model country that met the 2015 WHO targets for TB continue to experience such deleterious impacts from a treatable and preventable disease? The answer can be seen readily in Ethiopia's WHO-estimated case-detection rate of 60 percent, a statistic well known to the Ministry of Health, its NTLP, and their international partners.[35] This 40 percent case-detection gap means that the estimated 80,000 Ethiopians who develop TB each year but are not diagnosed or treated will experience the natural history of untreated TB: continual TB exposure and transmission in their families and communities for an average of three years before death or spontaneous (but often temporary) remission.

TB case detection in Ethiopia and in most high-burden countries has been based upon the previous WHO DOTS approach of identifying individuals with prolonged coughing and/or other TB symptoms and encouraging testing of their sputum.[36] Ethiopia's

[33] NTLP policies were updated in 2012 to meet most of the guidelines recommended by the WHO.
[34] Burki, "Ethiopia could be a model country for tuberculosis control."
[35] Ethiopia is more of an example than an exception in failing to meet the 1991 World Health Assembly goal of 70 percent case detection and 85 percent treatment cure rate. The 2014 global case-detection rate was only 63 percent and was only 48 percent in the entire WHO African Region. See WHO, *Global Tuberculosis Report 2015*.
[36] Sputum is a non-saliva bodily fluid collected during coughing. Testing requires laboratory technicians to put special dyes into the sputum and then look for TB bacteria under a microscope. Testing by microscope detects TB in only about half of specimens that are positive by culture.

expanding HEW system provides a framework for maximal impact of this strategy. HEWs are taught to look for TB symptoms and to encourage potential patients to attend health centers for further TB testing, particularly if they have been exposed to other people diagnosed with TB, but as noted above, the engagement of HEW in TB case detection in 30 percent of woredas falls far short of the national goal of 80 percent. In effect, the vast majority of HEWs are likely not screening for TB.

Second, as in many countries, most health facilities, public and private, have limited capacity to diagnose TB. At least some TB diagnostic services are provided by 69 percent of facilities, but in 59 percent of these, the only available TB diagnostic is sputum microscopic examination for TB bacteria.[37] FMOH data for health facilities above the health post level indicate only 6 percent have chest X-ray equipment; and only 2 percent have GeneXpert rapid TB diagnostic kits.[38] The latter two diagnostic tools are important for finding pulmonary TB in high-risk individuals (e.g., household contacts of active TB cases) who do not have the classic TB symptoms of chronic cough, fever, and/or weight loss. Finally, there is a shortage of trained technicians. This lack of diagnostic capacity is exacerbated by the lack of quality control.[39] Although the HEAL TB program has begun addressing quality control in selected areas, a 2014 national survey found that only 24 percent of non-health post facilities had internal and external quality-assurance systems.[40] The gaps in the current case-finding strategy are further illustrated by recently published data from Ethiopia's 2010–2011 national TB prevalence survey[41] in which nearly half (48 percent) of all active TB cases would have been missed by screening based on having TB symptoms. The additional 48 percent were detected by chest X-rays as part of the screening method. Novel approaches will need to be identified for detecting these active TB cases before symptoms develop, perhaps including chest X-rays in high-risk groups.

A program (public-private mix) to involve the private medical sector in providing TB services was initiated in 2013 in Ethiopia. These facilities have identified over 18,000 TB cases, accounting for 14 percent of national notifications. Treatment outcomes in the private sector are similar to those of patients managed entirely in the public sector, but a low proportion of private facilities are participating.[42] Further increases in the contribution of the private sector will require NTLP's provision of resources to private facilities for training, provision of drugs, and diagnostics and outcome monitoring. It is uncertain these actions will be taken, since the government is deeply skeptical of the private sector for political reasons.[43]

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[37] Theodros Getachew et al., "Tuberculosis Service Provision in Ethiopia: Health Facility Assessment," *American Scientific Research Journal for Engineering, Technology, and Sciences* 13, no. 1 (2015): 155–6, http://asrjetsjournal.org/index.php/American_Scientific_Journal/article/view/816/555.
[38] Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan*, 26–27.
[39] "Quality control" refers to a process of routinely having laboratories test known positive and negative TB specimens (e.g., sputum smear, culture) to determine the accuracy of those facilities' TB laboratory results.
[40] Getachew, "Tuberculosis Service Provision in Ethiopia: Health Facility Assessment."
[41] Kebede, "The first population-based national tuberculosis prevalence survey."
[42] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*, 48.
[43] For more information about Ethiopia's views on the private sector, see Downie, *Sustaining Improvements to Public Health in Ethiopia.*

Resistance to the Usual TB Drugs

Ethiopia is one of 27 countries named by WHO as having high burdens of MDR-TB. About 2 percent of new TB cases and 18 percent of retreatment cases are MDR-TB.[44, 45] Based on the latest WHO estimates, only about 39 percent of Ethiopia's MDR-TB patients are being identified.[46]

In 2008, Ethiopia achieved WHO approval for its MDR-TB treatment support application. An excellent 83 percent treatment success rate was achieved for the cohort of 271 MDR-TB patients starting on the recommended two-year treatment regimen in 2012.[47] However, this impressive accomplishment is overshadowed by the fact that the number of patients treated is only a small proportion of the estimated number of new MDR-TB cases each year. The remaining undetected cases continue to transmit MDR-TB.

With direct U.S. government support, the Ethiopian government has begun rolling out GeneXpert TB testing machines designed to rapidly and accurately identify most people with MDR-TB. As of early October 2015, 105 health facilities had access to these machines, but their use and effectiveness is contingent on adequate supplies of electricity and testing materials, and the government of Ethiopia recognizes gaps in implementing the national drug-resistant TB strategies.[48] We were told about an existing backlog of patients waiting for GeneXpert testing, providing one example of current challenges.

Although the reported prevalence of XDR-TB is apparently still low, additional cases can be anticipated as MDR-TB diagnosis and treatment is expanded throughout the country. In addition, an international study documented a 9 percent frequency of progression from MDR-TB to XDR-TB during treatment.[49] However, Ethiopia is also struggling with its limited capacity to conduct the additional drug-susceptibility testing required to confirm the diagnosis of XDR-TB. During our visit, a U.S. official mentioned that the inability to perform this additional testing was undermining a recent investigation into two reported XDR-TB cases. [50]

Detecting MDR-TB and/or XDR-TB is only an initial part of the drug-resistance challenge. Successful treatment is a separate issue. For example, several physicians that care for

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[44] Interview with senior U.S. official, Addis Ababa, October 26, 2015.
[45] Retreatment TB cases refer to people who have been treated for TB in the past, but remained infected, eventually requiring another round of TB treatment.
[46] WHO estimates 1,300 MDR-TB occurred among the 120,000 individuals with diagnosed and notified TB cases but, due to inadequate testing, only 503 (39 percent) were actually identified as having MDR-TB. If one adds in the expected number of MDR-TB cases among the 80,000 undiagnosed TB cases, the total estimate of MDR-TB cases in Ethiopia is about 2,200.
[47] The treatment success rate is the proportion of patients who successfully complete the entire treatment regimen (see Table 1). It may not be the same as the cure rate.
[48] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin*, vi.
[49] Ethiopia's first reported case of XDR-TB was in 2010. See M. Agonafir et al., "Phenotypic and genotypic analysis of multidrug-resistant tuberculosis in Ethiopia," *International Journal of Tuberculosis and Lung Disease* 14, no. 10 (October 2010): 1259–65. Cegielski, "Global Preserving Effective TB Treatment Study (PETTS) Investigators. Extensive drug resistance acquired during treatment of multidrug-resistant tuberculosis."
[50] Interview with senior U.S. official, Addis Ababa, October 26, 2015.

patients with MDR-TB noted to us that some health care staff felt unprepared because they had received limited training on how to manage such patients.[51] Some staff even reported avoiding such patients whenever possible. Not surprisingly, we were told that staff turnover is high in TB care facilities.[52, 53] One nongovernmental organization that focuses on establishing MDR-TB treatment centers complained that "managers and medical directors are not willing to welcome the MDR-TB problem" due to the complications surrounding its diagnosis and care.[54]

Patients with MDR-TB and XDR-TB require additional laboratory tests to monitor for potentially life-threatening side effects of the unusually toxic drugs required for successful treatment.[55] In that regard, the shortage of trained health care workers is compounded by limitations in the required laboratory capacity; physicians expressed concerns about not being able to follow policies for detecting, managing, and limiting the severity of drug toxicity. Because MDR-TB treatment takes up to two years, these side effects often result in poor patient adherence to treatment. Our team heard several concerns that in some cases laboratory support for identifying toxic side effects of treatment was problematic because the chemicals needed to run the necessary laboratory tests were unavailable or expired. Fixing the supply and procurement of laboratory reagents is an essential step for improving the quality of TB care.

TB-HIV Coinfection

People living with HIV infections (PLHIV) are particularly vulnerable to contracting active TB because they have weakened immune systems. Unlike Ethiopia's TB burden, which is predominantly rural, the country's HIV epidemic is largely concentrated in urban areas. This limited overlap, and the country's relatively low HIV prevalence compared to many other sub-Saharan countries, helps explain why Ethiopia's current TB coinfection rate of only 11 percent among PLHIV is far less than the global and African averages.[56] However, this current level is also a significant reduction from the country's earlier coinfection rate of 20 percent, probably reflecting the successes of the Ethiopian government's energetic and donor-supported HIV testing, treatment, and prevention programs.

Much of this success comes from integrated TB/HIV services, where people with either one of these diseases are routinely screened and, if infected, treated for the other. For example, 75 percent of people living with HIV are screened for TB, and about 45 percent

[51] For example, treatment of MDR-TB is more complicated than current treatment of HIV/AIDS, but the mandatory two-day seminar on MDR-TB is much less comprehensive and intensive than the several-weeks-long HIV-treatment seminars.
[52] V. J Ehlers and G. S. Aragaw, "An audit of diagnosis and treatment of tuberculosis in Ethiopia," *African Journal of Primary Health Care and Family Medicine* 6, no. 1 (August 13, 2014): E1–6.
[53] Interview with senior representative from Management Sciences for Health. Addis Ababa, October 27, 2015.
[54] Ibid.
[55] The common and severe side effects of these "second-line" TB drugs used to treat MDR- and XDR-TB include hearing loss, nausea and vomiting, kidney damage, liver damage, depression, psychosis, and life-threatening imbalances of blood sodium and potassium.
[56] The global average TB/HIV coinfection rate is 13 percent and the average for the African continent is about 30 percent. Interview with senior USAID official, Addis Ababa, October 26, 2015.

of this population receives TB preventative therapy. About 80 percent of TB treatment facilities now both screen patients for HIV.

Stockouts of TB Drugs

Interruption of patients' TB treatment because of unavailability of TB drugs can lead to treatment failure and potentially to development of MDR-TB. Ensuring a stable supply of drugs is therefore crucial, and the Ethiopian Pharmaceuticals Fund and Supply Agency was created a decade ago to address these problems. Ethiopia's NTLP has recently reported considerable progress, but notes there is still room for improvement in preventing TB drug stockouts.[57] While national data reveals that 88 percent of health centers have first-line TB medicines readily available for patients,[58] we were unable to obtain information on stockout rates for second- and third-line drugs. Confirming the assessment in the *Annual Tuberculosis and Leprosy Bulletin*, one senior Ethiopian government official admitted that "getting certain drugs to users is a problem."[59]

Health Data Collection and Management

Lack of quality data collection and management is a key obstacle that hampers Ethiopia's TB prevention and control efforts, and was a theme that nearly every in-country expert raised during our visit. The government uses two data-collection tools: the Ethiopian Heath Management Information System (HMIS), which collects patient data from individual health facilities, and the population-based Demographic and Health Surveys (DHS). There are crucial differences between these two data sources in terms of definitions and timeframes for collection of key indicators. These differences as well as poorly defined sampling errors can lead to statistical discrepancies that can obscure what is happening on the ground and can subsequently interfere with various aspects of program management.

Both the national government and the regional health bureaus rely on the HMIS system, primarily for reporting, planning, and budgeting. Interviews with hospital staff and nongovernmental organizations revealed that many facilities collected only the minimal amount of data required for HMIS reporting purposes. As a result, the more detailed information that would be more helpful for appropriate local decision-making is often of poor quality or nonexistent.

The FMOH has recognized that its weak information systems are a rate-limiting obstacle to improving the health care system. Under the HSTP, improving the quality of data collection and management is one of four umbrella priorities of the national government, which plans to create new information communication technologies, increase the number of health information technology workers, implement and strengthen data quality assurance, and create a centralized data repository for researchers and policy planners. It is also hoping to move toward electronic databases.[60]

[57] Federal Democratic Republic of Ethiopia, *Annual Tuberculosis and Leprosy Bulletin 2015*, 51–54.
[58] Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan*, 27.
[59] Interview with a senior official with the National Leprosy and Tuberculosis Program, Addis Ababa, October 31, 2015.
[60] Federal Democratic Republic of Ethiopia, *Health Sector Transformation Plan*, 136.

Achieving these laudable goals will require a significant investment in infrastructure and human resources, but the lack of funding and other basic resources like electricity pose major barriers to implementation.

On a more positive note, USAID has supported ongoing efforts under both HEAL TB and Challenge TB to promote operational research in Ethiopia on TB implementation issues. A key innovation is that researchers and field-level staff form an integrated research team; as a result, not only are research methods sound, but also the research questions are policy-relevant. A consistent national process for prioritizing research questions and funding the research has resulted in a steady stream of peer-reviewed publications.

Box 4: Innovating New Data Tools for TB

Inside Adama hospital in Oromia region, the staff showed the CSIS team their method for tracking TB. In the well-ventilated room, we saw an enormous catalog containing detailed paper records that track the status of each of the hospital's patients, including: how many days they have been on treatment; initial and follow-up sputum tests to assess treatment outcome; and whether the patients were considered to be loss-to-follow-up. The staff then took us to a nearby room with six computers; charts were plastered on the wall, containing information that track the hospital's progress on tackling key diseases like TB. Here we spoke to the information technology workers who manually transfer the paper records into the electronic HMIS system. The hospital also had implemented strong external and internal quality assurance mechanisms. Their data system was impressive—one of the best in the country. Yet, it was still cumbersome and required significant human capital.

Afterwards, we visited a health center and a health post. The difference in capacity was drastic. At the health center we saw the same paper records and only one computer. Both nurses and doctors had to take time away from patients to input the information.

At the health post nearby in Mojo, there were stacks of papers everywhere including the TB register. There were no computers. In fact, there was no electricity. Inside the cramped space, there were two health extension workers who were expected to deliver 16 different services, including tracking TB patients and screening for new ones. Theoretically, all the data from both the health post and health center was referred to the regional health bureau, but given the poor infrastructure and immediate competing priorities, one might anticipate challenges in maintaining the accuracy and quality of the TB information.

Back in Addis Ababa, we met with representatives from Management Sciences for Health, an NGO implementing partner for the USAID initiative HEAL TB, who have spent the past few years building and piloting an innovative Standard of Care TB implementation and quality-monitoring tool for the Oromia region. It was described as an Excel-based data-collection and quality-management system for health facilities in every district. Each hospital had color-coded standard-of-care indicators that could objectively measure gaps like low cure rates, poor TB infection control, drug stockouts, and supply management. Each quarter, local program managers revisited these targets and measured progress against their baseline. The tool allowed health facilities to identify gaps, prioritize and implement quality-control measures, as well as budget for them. The data was collected on laptop computers by independent evaluator, brought back to a central collection site, and analyzed by a zonal coordinator. This platform had been so effective that the government and donors are working together to scale up its use in four regions, under the Challenge TB initiative. (See section: The Roles of the United States and Other Donors in TB Control in Ethiopia.)

Health and Economic Impacts of TB in Ethiopia

In addition to its health burden, TB is having a major economic impact on Ethiopia. As previously noted, the HSTP explicitly argues that treating TB is "among the key health interventions for addressing poverty and inequality." Furthermore, survivors of TB treatment have residual health effects: 50 percent of survivors have persistent lung

damage[61] and survivors face a nearly eightfold increase in death rates due to non-TB causes after treatment.[62]

TB also disproportionately affects young people. Fifty-eight percent of prevalent TB cases in Ethiopia are under 35 years of age.[63] Thirty-nine percent of the estimated 32,000 deaths per year are concentrated among adults from 15 to 64 years of age,[64] leading to losses of family wage earners and parents of small children. This additional direct and indirect burden on Ethiopia's youth, who are the backbone of the current and future economy, is a drag on economic growth and ultimately a barrier to achieving the national goal of achieving middle-income status by 2035.

In particular, our team was struck by the large (36 percent) proportion of total national TB expenditures that individual families and households bore.[65] Beyond these direct costs, there are additional unmeasured indirect economic losses to families in terms of wages and productivity before diagnosis and during treatment. The household costs of TB diagnosis and treatment have been noted to be 35 percent and up to 71 percent of annual household income in Ethiopia, respectively, and these large expenses are the basis of the emphasis found in the current WHO End TB Strategy on preventing catastrophic costs of TB care to individual affected families.[66]

In comparative terms, TB funding accounted for 3.1 percent of national health expenditures (NHE) (Table 2) compared to 18.7 percent and 14.7 percent, respectively, for HIV and malaria, two other national programs that have demonstrated great success in Ethiopia. Although donors contributed 83 percent of the NHE for HIV, there was still a contribution of $43.3 million in government funding, whereas government expenditures for TB accounted for only $6.1 million in 2010–2011.[67]

Table 2. Expenditures of the Ethiopian government and of Ethiopian Households for Control of HIV, Malaria, and Tuberculosis

	Total Expenditures (US$ millions)	Ethiopian Government Proportion (percent)	Household Proportion (percent)	Actual Household Expenditures (US$ millions)
HIV	307	14	2	6.1
Malaria	242	7	14	34
Tuberculosis	51	12	36	18

Source: Federal Democratic Republic of Ethiopia, *Ethiopia's Fifth National Health Accounts—Highlights of Major Findings.*

[61] Mauricio Vecino et al, "Evidence for chronic lung impairment in patients treated for pulmonary tuberculosis," *Journal of Infection and Public Health* 4, no. 5-6 (November 2011): 244–52.
[62] T. L. Miller et al., "Mortality hazard and survival after tuberculosis treatment," *American Journal of Public Health* 105, no. 5 (May 2015): 930–7.
[63] Kebede, "The first population-based national tuberculosis prevalence survey," 635–9.
[64] Y. E. Melaku et al, "Causes of Death among Adults in Northern Ethiopia: Evidence from Verbal Autopsy Data in Health and Demographic Surveillance System," *PLoS ONE* 9, no. 9 (2014).
[65] Federal Democratic Republic of Ethiopia, *Ethiopia's Fifth National Health Accounts—Highlights of Major Findings: Briefing Notes*.
[66] WHO, *The End TB Strategy*; and A. Vassall, A. Seme, P. Compernolle, and F. Meheus, "Patient costs of accessing collaborative tuberculosis and human immunodeficiency virus interventions in Ethiopia," *Inter J Tuberculosis and Lung Disease* 14 (2010): 604–10.
[67] Ibid.

The Roles of the United States and Other Donors in TB Control in Ethiopia

Ethiopia is recognized as a country that uses donor funds wisely and effectively (Table 2). The largest proportion (51 percent) of national TB funding comes from international donors (Table 3), including nearly equal contributions from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and from the United States, through USAID. If one considers only non-household TB-related expenditures, the external donor proportion of the national TB budget is even higher, at 79 percent.[68]

The United States has already invested a significant amount of resources to tackle TB in Ethiopia, in terms of both financial support and technical assistance. In 2014 alone, total U.S. development assistance to Ethiopia for TB was about $13.7 million. The bulk of that funding (approximately $10 million) came through USAID's TB programming, which focuses on providing universal access to TB diagnostics, prevention, and care; strengthening health systems such as supply chain and logistics; improving program management in order to increase staff retention and provide quality mentorship; and developing laboratory capacity. To this end, USAID has launched four major TB projects in Ethiopia: TB CARE, HEAL TB, PHSP, and Challenge TB.

The largest USAID project, HEAL TB, focuses on improving and expanding TB diagnostic and treatment services in the Oromia and Amhara regions, including technical support for these two regions. Overall, the program serves over 51 million Ethiopians, over half of the national population, and has been largely considered successful. Under HEAL TB, these regions have increased the treatment success rate to approximately 90 percent as well as strengthening the overall health system. Notably, HEAL TB has also created an impressive data-management system to help improve quality of care (see Box 4).

In 2016, HEAL TB will transition into Ethiopia's Challenge TB program.[69] Within Ethiopia, Challenge TB is intended to improve the national TB program's case detection and treatment capacity at both the national and regional levels. It will focus on key populations in urban areas, prisons, and mines, as well as bring national attention to the challenges of pediatric TB. In addition, Challenge TB plans to tackle the NTLP's gaps in drug supply, human resources for health, data quality, and capacity building for laboratories. It will build on the progress achieved under HEAL TB, and operate in six regions and the three urban districts—covering approximately 80 percent of the Ethiopian population.[70] The program heavily relies on donor funding, but will operate using a mix of donor, government, and out-of-pocket sources.[71]

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[68] WHO. *Global Tuberculosis Report 2015*, 95.
[69] Globally, the Challenge TB program, which began in 2014, is a five-year $100 million USAID initiative being implemented by a consortium led by the KNCV Tuberculosis Foundation.
[70] Programs funded under Challenge TB are currently operating in the SNNPR and Tigray, as well as the three urban districts of Addis Ababa, Dire Dawa, and Harari. These will expand to Oromia and Amhara regions once Challenge TB incorporates current HEAL TB programming.
[71] Fifty-one percent of the TB programming will be from donors; 12 percent from the government; 35 percent from out-of-pocket household expenditures; and 1 percent from "other" sources. Interview with representative from Challenge TB, Addis Ababa, November 2, 2015.

The United States has also supported Ethiopia's TB control efforts through the President's Emergency Plan for AIDS Relief (PEFPAR). PEPFAR resources—channeled through the U.S. Centers for Disease Control and Prevention (CDC)—have been highly successful in Ethiopia, providing valuable resources and technical assistance for improving clinical TB services and laboratory capacity. Much of Ethiopia's success in reducing TB/HIV coinfection rates has been due to the substantial support provided through PEPFAR. However, there are now concerns that the new PEPFAR strategy of operating primarily in high-HIV-prevalence areas may cause some PEPFAR-funded TB services to be discontinued, especially in areas where a large TB burden does not overlap with a large HIV burden. CDC officials admit they are unsure how this PEPFAR transition will impact TB, but affirm that only 2 percent of patients taking antiretroviral drugs (ART) will be affected by the change in strategy and that very few HIV patients coinfected with TB will be affected.

The CDC also provides indirect support to the FMOH's surveillance of disease through its Field Epidemiology Training Program (FETP) trainees, who come from specific departments within the FMOH. We were told that the FETP has not yet trained anyone from the NTLP because TB is not considered an emerging disease.[72] However, TB epidemiology has its unique challenges, including the ongoing emergence of drug-resistant TB, and training FMOH staff under this program would be an important opportunity to improve the FMOH's capacity to collect, analyze, and use TB data.

The Global Fund is another key donor to Ethiopia's TB program, as it provides about $10.6 million annually to Ethiopia for TB control, primarily focused on drug procurement and supply. The Global Fund is widely regarded by both the United States and Ethiopian government as a strong, collaborative partner. USAID Ethiopia staff has monthly calls with Global Fund staff to facilitate coordination and avoid duplicating efforts.

Ethiopia's TB Control and Elimination Resource Gap

Based upon the impact of TB on Ethiopia's mortality, health, and productivity, increased investment in TB control is warranted by both the Ethiopian government and donors, as shown in Table 3. The WHO estimates a $39 million TB budget gap for Ethiopia in 2015.[73] The strong donor support from the United States and Global Fund notwithstanding, Ethiopia's current gap in resources for TB control will hold back the country's long-term ability to successfully eliminate TB.

Based upon Ethiopia's considerable TB burden, increased investment in new approaches to TB control is warranted by both the government and donors. As noted, even with the current suboptimal case-detection rate of 60 percent, there are already challenges in meeting TB diagnostic and treatment demands. Anticipated increases in the case-detection rate, while clearly desirable for disease control, will lead to an increase in the clinical TB caseload and subsequently will require greater health facility resources. In addition, because each case of MDR-TB is far more costly to treat adequately than

[72] Interview with senior CDC staff, U.S. Embassy, Addis Ababa, October 26, 2015.
[73] WHO, *Global Tuberculosis Report 2015*, 95.

Table 3. Annual Funding Allocations by the Government of Ethiopia and External Donors for HIV/AID, Malaria, and Tuberculosis

	Funding Source and Amount (US$ millions)					
Disease	**External Donors**	**Ethiopian Government**	**Total**	**Proportion of National Health Expenditure (percent)**	**Estimated Annual Deaths**	**Total Expenditures per Estimated Death (US$)**
HIV/AIDS	256	43	299	18.7	23,000 (2014)	13,000
Malaria	190	17	207	14.7	213–19,000 (2013)	11,000
Tuberculosis	26	6	32	3.1	32,000 (2014)	1,000

Source: UNAIDS, http://www.unaids.org/en/regionscountries/countries/ethiopia.

(a) 2013 malaria mortality data and estimates are from WHO, *World Malaria Report 2015*; only 213 malaria deaths were actually reported, but there is a wide range for estimated deaths. The peak (19,000) estimate was used to make the "per death" calculation. See World Health Organization, Ethiopia Country Profile, http://www.who.int/malaria/publications/country-profiles/profile_eth_en.pdf.

TB death estimate (from WHO's Ethiopia Tuberculosis Profile) do *not* include TB-related HIV deaths.

drug-sensitive TB cases, identification of greater numbers of patients with MDR-TB will raise the TB resource requirements even more quickly.

The large global funding gap for research and development of new TB vaccine, diagnostic, and treatment tools also affects Ethiopia.[74] The recent global End TB Strategy calls for an annual $2 billion budget for intensified research and innovation. However, only $677 million was available in 2013, leaving a shortfall of $1.32 billion.

Although Ethiopia and the other high-burden countries cannot be expected to address this need alone, Ethiopia has been making a significant research and development contribution through the work of its Tuberculosis Research Advisory Committee (TRAC),[75] a voluntary network of government, academic, and professional organizations that advises NTLP on priorities for domestic (Ethiopian) TB research. In fact, operational research is a particularly strong suit for Ethiopia, with more than 110 medical journal articles published using the terms "tuberculosis AND Ethiopia" in calendar year 2015 alone. Ethiopia is also participating in the global STREAM study to evaluate newer drugs used in shorter treatment regimens for MDR-TB.[76] The data from the study will be used for drug registration, which requires a much greater level of rigor and scrutiny that will ultimately help strengthen Ethiopia's capacity for future clinical trials. If any of these new regimens are proven effective and approved for use, Ethiopian physicians involved in the trial can use their experience to facilitate the implementation of these regimens into the NLTP. The successful development of shorter, safer, and more effective TB drug treatment would also reduce the programmatic costs associated with care (e.g., fewer visits for patient visits, more time for health workers to focus on other diseases, fewer laboratory tests) and prevention (e.g., less TB transmission to others by current patients).

The United States can play a strong leadership role in closing the global R&D gap, both by providing more of its own resources and by using health diplomacy to urge other countries to contribute more. The recently announced and White House-sponsored National Action Plan for Combating Multidrug-Resistant Tuberculosis[77] may be an initial step in the right direction.

Discussion and Recommendations

The Ethiopian government has made major progress over the past 20 years in tackling the spread and treatment of TB. Government officials at all levels recognize that TB is still an enduring national challenge requiring additional specific attention; are aware of

[74] Several sets of earlier U.S. and global recommendations to address this gap have never been adequately funded or implemented.
[75] WHO, "A global action framework for TB research," 2015, Box 3, 28.
[76] A. J. Nunn et al., "Evaluation of a standardized treatment regimen of antituberculosis drugs for patients with multi-drug-resistant tuberculosis (STREAM): study protocol for a randomized controlled trial," *Trials* 15 (September 9, 2014): 353. USAID is supporting the first study of this nature and scope in Ethiopia.
[77] The White House, "Obama Releases National Action plan for Combating Multidrug Resistant Tuberculosis," December 22, 2015, https://www.whitehouse.gov/the-press-office/2015/12/22/fact-sheet-obama-administration-releases-national-action-plan-combating.

the multiple shortcomings in the current national response(s)[78]; and are committed to essential, priority programmatic goals. Ethiopia's partner countries, other international organizations, private-sector investors, and Ethiopian government ministries beyond the FMOH need to understand that investing in additional TB control efforts in Ethiopia will have important economic benefits.

In this regard, senior Ethiopian officials have a great sense of ownership of this process and feel comfortable having a strong leadership role in it. The following recommendations are provided in this context.

Recommendations to address these challenges include the following.

To the U.S. government:

1. *Make it a priority to help increase total TB control resources available to the Ethiopian government.*

The United States has humanitarian, political, and health reasons to continue its leadership role in support of improved TB control globally and in Ethiopia. Given the gravity of Ethiopia's TB situation, including its impact on the national economy and the slowly but steadily growing challenges of MDR-TB and XDR-TB, the U.S. government should consider options for increasing the resources available to Ethiopian government TB control activities.

These options should include: 1) strong encouragement to the Ethiopian government to increase the amount of public and private domestic resources devoted to TB control; 2) U.S. political and technical support for Ethiopian government approaches to other international and bilateral donors; and 3) U.S. government exploration of potential additional U.S. resources in support of related goals, for example, bilateral USAID resources, additional PEPFAR resources, and the new U.S. Action Plan for Multidrug-Resistant TB (or other U.S. programs or resources addressing antimicrobial drug resistance).

2. *Ensure through careful monitoring that PEPFAR's ongoing transition (PEPFAR 3.0) does not inadvertently create adverse consequences on Ethiopia's TB control programs.* Although TB/HIV coinfection and codisease are less common problems in Ethiopia than in many other countries, changes in U.S. support levels related to that country's control of TB or HIV may have unintended consequences. Because program funding levels for PEPFAR and other U.S. health and development support are likely to change over time and to ensure that support for TB services is not inadvertently compromised in the process, the U.S. country team should carefully monitor the impacts of such changes on national, regional, and local TB epidemiology and on the effectiveness of U.S.-supported (and other) TB control programs. U.S. country team members should encourage senior officials at the FMOH to raise any such concerns with their U.S. counterparts.

[78] These shortcomings include the ongoing failure to identify many people with active TB, including those Ethiopian patients infected with MDR-TB and XDR-TB. These latter groups and their providers also face the consequences of treatment with regimens that have severe side effects and limited efficacy.

3. *Enhance U.S. investments globally in research and development for TB in order to provide new, safe, and effective treatment regimens that can be scaled up in developing countries such as Ethiopia.*

Ethiopia's complex TB situation highlights the need for the U.S. government to continue playing a major role in addressing the global research and development (R&D) funding gap in order to help provide Ethiopian and other global TB patients and their providers with safer and more effective treatment regimens. Just as safe, well-tolerated, and highly effective regimens have been critical to the success of HIV/AIDS interventions in Ethiopia and globally, new treatment regimens are desperately needed for patients with drug-resistant TB in Ethiopia and globally. Clearly, the U.S. government cannot be solely responsible for addressing these needs. As a way of stimulating new contributions from potential donor countries and institutions, health diplomacy should be used judiciously to publicize implementation of the recently announced National Action Plan for Combating Multidrug-Resistant TB.

To the government of Ethiopia:

1. *Explore all possible domestic and international funding sources to help address current shortages.*

Because resource shortages are clearly an important obstacle to improving TB control, all possible existing sources of additional TB program funding should be explored. These include additional domestic government resources, expanded public-private partnerships, and exploration of additional resources from the Global Fund or other international organizations, other governments, and foundations and philanthropies. The goal is to increase the amount of domestic resources allocated for direct TB control and for other TB-related programs to a level commensurate with the magnitude and severity of the country's TB problem. External support for Ethiopia's TB control activities will be needed for some time. However, because successfully attracting external resources for public health programs is often more likely when domestic resource allocations are increasing, a greater allocation of domestic health resources to TB control activities would be particularly helpful.

2. *Engage Ethiopia's Field Epidemiology Training Program (FETP) in MDR-TB control.* Including MDR-TB as one of the emerging diseases addressed by the FETP and its trainees is a step that would both educate Ethiopia's future public health leaders about MDR-TB and provide extra human resources to address epidemiologic and public health aspects of MDR-TB.

3. *Accelerate efforts to address the multiple TB program gaps.* Multiple TB program service gaps need to be addressed as quickly as possible to increase the numbers of Ethiopians who are correctly diagnosed with active TB disease, identified as having drug-sensitive or drug-resistant TB, notified, started on appropriate treatment, supported until treatment completion, monitored for treatment side effects, and cured. Similar gaps occur in the contact investigation process.

In particular, the following are some high-priority gaps around TB services that need to be addressed:

a. Improving case-detection rates, involving operational research to identify more effective strategies as well as improvements in public awareness, health worker numbers and training levels, numbers and capacity of laboratories, and radiology (X-ray) support.

b. Ensuring that TB treatment is based on drug sensitivity test (DST) results.

c. Ensuring completion of TB treatment.

d. Improving data management to better inform program decision-making nationally and at local levels.

e. Avoiding stockouts of appropriate TB drugs and laboratory supplies.

4. *Monitor—and encourage further progress in reducing—the financial burden of TB on Ethiopian families.* The most recent health expenditure data indicates that households are incurring 36 percent of all national health expenditures on TB. Reducing TB's financial burdens on affected families should be an important national public health goal.

Appendix. Tuberculosis in Ethiopia-born U.S. Residents: Health Security Implications for the United States

Tuberculosis is a current health security threat for the United States. The ongoing global transmission of drug susceptible and drug-resistant TB, including specifically in Ethiopia, directly impacts the United States. Two-thirds of the 9,421 TB cases reported in the United States in 2014 resulted from infection by individuals born outside the United States. Over 80 percent of MDR-TB cases in the United States are reported among foreign-born residents never previously treated for TB, meaning they result from ongoing airborne transmission of MDR-TB strains acquired before they arrived in the United States. Persons born in the African region accounted for 570 U.S. cases in 2014, with 140, the largest group of them, being from Ethiopia.[79]

U.S. residents from Ethiopia rank eighth in foreign-born TB cases. The majority of Ethiopian-born U.S. residents with reported TB were screened prior to arriving in the country, but likely had latent TB that progressed to active TB over time in the United States. For example, surveillance data from the Centers for Disease Control and Prevention (CDC) from 2010–2014 show that of the TB cases reported among Ethiopian-born persons residing in the United States, 61 percent included a documented visa status, meaning that the individuals were screened for TB before entering the United States.[80] Over the past five years, 72 percent of Ethiopian-born U.S. TB cases were tested for drug resistance, and 2 percent were classified as having MDR-TB. The cost of treating drug-susceptible TB and MDR-TB in the United States, including hospitalizations, are $17,000 and $134,000, respectively.[81]

Investing in Ethiopia's TB efforts will directly protect U.S. domestic interests. It will prevent Ethiopians from bringing the disease to the United States (and other countries), reducing the domestic U.S. burden of disease. Long-term investments in TB prevention and control are also cost effective, particularly as drug resistance looms on the horizon and threatens to undermine decades of progress.

[79] Centers for Disease Control and Prevention (CDC), *Reported Tuberculosis in the United States, 2014* (Atlanta, GA: CDC, September 2015). http://www.cdc.gov/tb/statistics/reports/2014/pdfs/tb-surveillance-2014-report.pdf.
[80] Personal communication, Dr. Thomas Navin, chief, Surveillance, Epidemiology & Outbreak Investigations Branch, Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, November 30, 2015.
[81] S. Marks et al., "Treatment practices, outcomes, and costs of multidrug-resistant and extensively drug-resistant tuberculosis, United States, 2005–2007," *Journal of Emerging Infectious Diseases* 20, no. 5 (2014): 812–21, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4012799/.

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