ENDING THE TUBERCULOSIS EPIDEMIC
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ACRONYMS AND ABBREVIATIONS

AIDS Acquired Immunodeficiency Syndrome
ART Antiretroviral Therapy
CDC Centers for Disease Control and Prevention
CPT Co-trimoxazole Preventive Therapy
DOTS Directly Observed Treatment, Short Course
FAST Finding Actively, Separating, and Treating TB
FY Fiscal Year
GDF Global Drug Facility
GHP Global Health Programs
GeneXpert GeneXpert® MTB/RIF
Global Fund Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV Human Immunodeficiency Virus
INH Isoniazid
IPT Isoniazid Preventive Therapy
LTBI Latent TB infection
M&E Monitoring and Evaluation
MDR-TB Multidrug-Resistant Tuberculosis
NAP National Action Plan for Combating Multidrug-Resistant Tuberculosis
NIH/NIAID National Institutes of Health’s National Institute of Allergy and Infectious Diseases
PEPFAR President’s Emergency Plan for AIDS Relief
PLHIV People Living with HIV/AIDS
PMDT Programmatic Management of Drug-resistant TB
SDG Sustainable Development Goal
STREAM Standardized Treatment REgimen of Anti-tuberculosis drugs for patients with Multi-drug-resistant tuberculosis
TB Tuberculosis
USAID U.S. Agency for International Development
WHO World Health Organization
XDR-TB Extensively Drug-Resistant Tuberculosis

Cover: More than 2000 students from a Cirebon boarding school in Indonesia celebrated World TB Day on March 24, 2015. Photo by USAID.
This report is required pursuant to PL. 110-293, the Tom Lantos and Henry J. Hyde US Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Authorization Act of 2008, Sec. 302(g). The United States (U.S.) Government is committed to ending the tuberculosis (TB) epidemic by 2030. This is an ambitious goal: each year, TB kills more people than any other infectious disease. Nevertheless, with smart investments and continued innovation, we can eliminate TB as a public health threat.

In Fiscal Year (FY) 2015, the U.S. Agency for International Development (USAID), the lead U.S. Government agency for international TB programming, supported high-quality screening, diagnosis and treatment services for millions of people affected by TB and multidrug-resistant tuberculosis (MDR-TB). With investments of $242 million focused primarily in 23 countries with bilateral TB funds, the U.S. Government achieved the following results in collaboration with each country’s programs: more than 3.7 million TB cases detected and diagnosed; more than 2.8 million people provided with TB treatment, and more than 70,000 people with MDR-TB started on appropriate treatment. USAID’s FY 2015 investments contributed to an estimated 48 million lives saved from 2000-2015, including people co-infected with HIV/AIDS, leading to a 22 percent decline in TB mortality and a 21 percent decline in TB incidence globally since 2000.

USAID is the largest bilateral donor for TB in the world. USAID works through strategic partnerships with the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund), National TB Programs, technical assistance organizations and civil society to find and cure all TB patients and stop TB transmission through a patient-centered approach aimed at alleviating suffering and saving lives. USAID’s comprehensive approach includes support for: increasing access to high-quality TB services, preventing TB transmission and disease progression, strengthening TB service delivery platforms, and accelerating research and innovation. USAID focuses its bilateral TB program in 23 countries with high burdens of TB, MDR-TB and TB/HIV co-infection and supports a total of 54 countries through targeted technical assistance and support for Global Fund grants. In 2015, USAID focused particular effort on increasing TB detection and diagnosis and on combating MDR-TB.

Improved TB detection and diagnosis is vital to the global effort to end TB. Each untreated person with active TB can infect an estimated 10-15 people within their community each year. Conversely, every person with TB who is successfully diagnosed and treated is one fewer person transmitting TB in a community. The World Health Organization (WHO) estimated that in 2015, approximately 60 percent of all TB cases were undiagnosed and/or untreated. To address this challenge, USAID invested in improved case detection methods, using new tools and approaches to improve screening and diagnosis. For example, USAID strengthened TB and MDR-TB diagnostic services by training healthcare workers, improving screening, and scaling-up the use of GeneXpert MTB/RIF® (GeneXpert) technology.

Combating MDR-TB is also vital to ending the TB epidemic by 2030, as drug-resistant strains of TB are both difficult and expensive to cure. In 2015, an estimated 380,000 people developed MDR-TB. In recognition of the threat this poses to the last 20 years of progress in reducing TB mortality and incidence, USAID focused particular attention on strengthening countries’ MDR-TB programs and on developing and rolling out new and improved ways to treat MDR-TB. In 2015, USAID partnered with National TB Programs, private sector companies, and other key stakeholders to introduce bedaquiline, a new, life-saving MDR-TB drug in 35 countries with active Global Fund TB grants, which also receive Global Fund technical assistance support from USAID. USAID also supported ongoing research into ways to improve MDR-TB treatment and care regimens.

USAID works closely with other U.S. Government agencies in combating TB and MDR-TB. In December 2015, the White House launched the National Action Plan to Combat MDR-TB (NAP) with three overall goals: 1) combating MDR-TB domestically; 2) combating MDR-TB internationally; and 3) accelerating research and innovation. USAID has been tasked with continuing to lead the U.S. Government’s international efforts to address MDR-TB as a public health emergency through Goal 2, with the Centers for Disease Control and Prevention (CDC) taking the lead on Goal 1 and the National Institutes of Health’s National Institute of Allergy and Infectious Diseases (NIH/NIAID) leading Goal 3. USAID, CDC and NIH/NIAID have worked together over to coordinate plans for achieving the objectives of the NAP, including agreement on roles and responsibilities and pathways for implementation of the NAP.

USAID is committed to reaching every person with TB, curing those in need of treatment, and preventing new TB infections, as outlined in the U.S. Government Global TB Strategy (2015-2019). By combating TB, USAID is making smart investments that save lives and contributing to the U.S. Government’s broader effort to end extreme poverty.

USAID supports the National Action Plan (NAP) and works in collaboration with the U.S. Government’s international efforts to address TB. USAID’s comprehensive approach includes support for: increasing access to high-quality TB services, preventing TB transmission and disease progression, strengthening TB service delivery platforms, and accelerating research and innovation. USAID is committed to reaching every person with TB, curing those in need of treatment, and preventing new TB infections, as outlined in the U.S. Government Global TB Strategy (2015-2019). By combating TB, USAID is making smart investments that save lives and contributing to the U.S. Government’s broader effort to end extreme poverty.
GLOBAL CONTEXT

TB is a curable, preventable disease. Through concerted effort, the global community has succeeded in reducing TB incidence by 21 percent and TB mortality by 22 percent since 2000. The WHO Global TB Report, released on October 13, 2016, confirms that the Millennium Development Goal target of halting and reversing TB incidence was successfully met and that significant progress has been made to reduce TB incidence and mortality. At the United Nations Sustainable Development Summit in September 2015, President Obama pledged U.S. Government support for a new set of Sustainable Development Goals (SDGs) and targets, including a goal of ending the TB epidemic by 2030. Achieving this ambitious goal will require continued global action, investment, and innovation.

Despite recent progress in reducing TB mortality and incidence, millions of people still suffer and die from TB each year. TB kills more people than any other infectious disease, and has surpassed HIV as the leading cause of death from an infectious disease. In 2015, there were 10.4 million new cases of TB and 1.8 million deaths due to TB; these increases are due to the availability of better notification and survey data from high burden countries in 2014, for example, India. Among people living with HIV, TB is the leading cause of death. Finding TB cases and putting TB patients on appropriate treatment early in their illness remains challenging; in 2015, only about 60 percent of new and relapse cases were detected and notified to National TB Programs. Of the TB cases that were detected, more than 40 percent were diagnosed only by their symptoms and never received further testing or laboratory confirmation of their diagnosis.

Recent progress in combating TB is threatened by the rise in drug-resistant strains, namely MDR-TB and extensively drug-resistant TB (XDR-TB). In 2015, an estimated 580,000 people developed MDR-TB. This increase in the estimated number of cases is due to the availability of better data on the overall burden of TB in India, as well as improved drug resistance surveillance. Worldwide, only about one in five MDR-TB cases are properly diagnosed and started on appropriate treatment. Less than half of those who start treatment are cured. Another major challenge is the ongoing TB/HIV epidemic, particularly in sub-Saharan Africa. Globally, about 15 percent of all individuals with TB with known HIV status are HIV positive; in Africa, TB/HIV co-infection among TB patients tested for HIV is 36 percent.

The economic and social impact of TB is devastating in high-burden countries. TB can decrease a nation’s gross domestic product by an estimated four to seven percent, and can impose severe financial hardships on TB patients and their families. A WHO systematic review found that on average TB patients and households lose the equivalent of 50 percent of their annual incomes due to incapacitation, health care and related costs. By combating TB, USAID is saving lives and contributing to its broader development goals of ending extreme poverty and building a healthy, strong, and productive workforce.

USAID’S GLOBAL TB PROGRAM:
SAVING LIVES AND ENDING THE EPIDEMIC

To achieve the ambitious goal of ending the TB epidemic, USAID is working with partners to reach every person with TB, cure those in need of treatment, and prevent the spread of disease and new infections.

USAID leads the U.S. Government’s global TB care efforts, focusing on 23 priority countries with high burdens of TB, MDR-TB, and TB/HIV co-infection. USAID achieves results by strengthening National TB Programs and improving the quality and reach of TB services in countries with the greatest need. USAID also leverages the U.S. Government’s significant investment in the Global Fund by providing technical assistance to support implementation of Global Fund TB grants. In FY 2015, this support for Global Fund activities was provided to a total of 54 countries, including the 23 countries that receive USAID bilateral TB funds. In each country, USAID coordinates its efforts with the National TB Program, the Global Fund, and technical assistance partners.

In FY 2015, USAID made significant progress towards the targets set forth in the U.S. Government’s Global TB Strategy and the National Action Plan to Combat MDR-TB (NAP). TB incidence in the 23 countries with bilateral USAID TB funding has fallen by 19 percent since 2000 and 3 percent from 2014 to 2015, which is more than double the average global rate of 1.4 percent reported by WHO in 2016. TB mortality has fallen by more than 30 percent since 2000 in these 23 countries, less than the overall global decline of 42 percent, which is likely due to the high rates of drug-resistant TB and TB/HIV co-infection in the settings where USAID works. In USAID supported countries, more than 2.8 million people were treated successfully for TB, with a treatment success rate of 88 percent.4 In addition, more than 70,000 people with drug resistant TB began second line therapy, a 13 percent increase from 2014. Among those with TB/HIV co-infection, almost 80 percent began antiretroviral therapy compared with 73 percent the previous year.

To improve TB detection and reach more of the estimated 4.1 million individuals with TB who lack access to high quality care or are never reported to National TB Programs, USAID focused FY 2015 efforts on supporting comprehensive, quality-assured TB diagnostic networks and on strengthening routine surveillance and reporting systems to ensure that all diagnosed cases were officially notified. USAID supported the expansion of screening and diagnosis within health facilities and community-based services, which leads to improved TB detection and initiation of appropriate treatment. Through better TB education, targeted screening, and services, such as specimen transport and treatment adherence support at the community level, USAID is saving lives and reducing the risk that patients will spread TB to their friends and families.

During 2015, USAID invested $242 million for TB programs focused on four key technical areas that are vital to effectively addressing the global TB epidemic:

• Improving Access to High Quality, Patient-Centered TB Services;
• Preventing TB Transmission and Disease Progression;
• Strengthening TB Service Delivery Platforms; and
• Accelerating Research and Innovation.

4 The TB treatment success rate for 2015 was affected by changes in TB notification in India in 2014 that were not accounted for in the country’s analysis of treatment outcomes in 2015. Using the data provided to WHO with these extra cases, the treatment success rate for USAID supported countries was 74 percent. However, USAID has used the actual number of TB patients for whom treatment outcomes were reported (the most accurate and internationally acceptable calculation) to determine the treatment success rate in TB priority countries, which yields a result of 88 percent.
ACCELERATING ACTION ON MDR-TB

MDR-TB is one of the most common drug-resistant infectious diseases in the world, with more than half a million people falling ill each year. According to the O’Neill Commission Review of Antimicrobial Resistance, without accelerated action and investment, MDR-TB could kill up to 2.5 million people each year.1

On December 22, 2015, the Obama administration released the National Action Plan for Combating Multidrug-Resistant Tuberculosis (NAP), declaring its commitment to tackling MDR-TB at home and abroad and challenging the global community to accelerate efforts to halt the spread of MDR-TB. Developed by an interagency working group, the NAP identifies three key goals: 1) strengthening domestic capacity to combat MDR-TB; 2) strengthening international capacity to combat MDR-TB; and 3) accelerating MDR-TB-related research and development. The NAP further identifies a set of targeted interventions that the U.S. Government will pursue to achieve these goals. The NAP also articulates a comprehensive strategy to mobilize political will and additional financial and in-kind commitments from bilateral and multilateral donor partners, private-sector partners, and governments of all affected countries.

Accelerated action to combat MDR-TB is needed urgently. The WHO estimates that there were 580,000 cases of MDR-TB in 2015, an increase of 100,000 (20 percent) from the previous year, largely due to improved data from India. Only about one in five of these estimated MDR-TB cases were detected, placed on treatment and reported. Furthermore, only half of the MDR-TB cases detected are successfully treated, with many patients either dying or lost to follow up at some point during the treatment period. MDR-TB treatment regimens are expensive, only moderately effective, and involve thousands of pills and hundreds of injections with severe side effects, including hearing loss, psychosis, and kidney damage.

Recent innovations in MDR-TB diagnosis and treatment are providing new hope to those affected by the disease. Until recently, people with suspected MDR-TB had to wait weeks to receive their test results and had relatively few options for treatment. Now, diagnostic tests such as GeneXpert enable patients to receive accurate TB and MDR-TB test results within just a few hours and patients can be started on life-saving treatment immediately. USAID is providing on-the-ground support and technical assistance to strengthen recipient countries’ MDR-TB treatment programs and health systems.

Additionally, recognizing that the currently available drugs and lengthy treatment for MDR-TB are the major causes of poor treatment outcomes, USAID has invested in research into ways to shorten the length of treatment and evaluate the safety and efficacy of new TB and MDR-TB treatment drugs and regimens. These regimens are expected to reduce toxic side effects, promote better adherence, and lead to better treatment outcomes. USAID’s support for research on the shortened MDR-TB drug regimen continued throughout 2015 and a new regimen was approved and endorsed by the WHO for roll out in 2016. Through partnerships with technical assistance providers, research institutions, and National TB Programs, USAID is accelerating progress against drug-resistant TB.

1 http://amr-review.org/sites/default/files/160518_Final_paper_web%20cover.pdf#page=63
IMPROVING ACCESS TO HIGH QUALITY, PATIENT-CENTERED TB SERVICES

With USAID support, countries with a high burden of TB are expanding access to high-quality TB services, including TB and MDR-TB diagnosis, treatment, care, and prevention. In FY 2015, over 3.7 million TB cases were notified to national TB programs in the 23 countries with USAID bilateral TB funding and more than 2.8 million people successfully completed treatment.

In the Philippines, USAID is assisting people living in isolated, rural villages with getting screened and tested for TB by working with partners to establish remote “smearing stations” in 249 locations around the country. These stations collect and prepare sputum samples from patients with TB symptoms and send the samples to rural health facilities for examination and diagnosis. This program has expanded access to TB services in the Philippines, facilitating the diagnosis and treatment of TB patients in rural areas.

E N A B L I N G E N V I R O N M E N T S

People suffering from TB face many challenges in accessing TB services including cost, distance, and stigma and discrimination. In 2015, USAID worked with country partners to create positive enabling environments, supporting efforts to increase the availability and affordability of TB services and combat TB-related stigma and discrimination, particularly in areas serving high-risk populations.

PATIENT-CENTERED CARE

TB prevention practices, diagnostic processes, and treatment regimens are highly effective when followed correctly. However, strict adherence can be time-consuming, inconvenient, and expensive, all of which reduce patient adherence. To improve TB outcomes, USAID is working with National TB Programs to develop and implement patient-centered TB services. Patient-centered care is defined by the Institute of Medicine as “care that is respectful of and responsive to individual patient preferences, needs, and values and [ensures] that patient values guide all clinical decisions.” In the context of TB, patient-centered care focuses on the patient’s right to actively participate in decisions and activities related to their TB diagnosis and treatment. Patient-centered care models forge a partnership between patient and provider, resulting in the best quality of care based on individual needs, increasing treatment adherence and ultimately leading to better treatment outcomes.

In Ukraine, USAID is working to improve MDR-TB treatment outcomes by supporting patient-centered models of care, including community-based treatment for MDR-TB patients. By providing MDR-TB patients with access to treatment where they live, USAID is improving treatment adherence and saving lives. During the last four years, USAID has worked with the National TB Program to improve the quality of care received by TB and MDR-TB patients in several oblasts (regions) of Ukraine. With USAID support, treatment success rate among new, bacteriologically-confirmed patients in the Kherson region has increased from 50 percent in 2011 to 81 percent in 2015. Anastasia, an MDR-TB patient supported through USAID’s program, testifies: “I am determined to complete my treatment now that I can receive my anti-TB medicines just in the village where I live.”

In Tanzania, USAID is working to improve patient outcomes and treatment adherence through regular supervision and support for ambulatory MDR-TB programs. USAID sponsors quarterly visits during which staff from regional and local health facilities review the quality of ambulatory MDR-TB treatment services, patient support systems, and data collection systems. They review patient records to monitor clinical improvement or deterioration and the prevalence of side effects, and they visit patients in their homes to provide adherence counseling and advice on the management of side effects. During June – September 2015, the supervisory team visited 124 (98 percent) of MDR-TB patients. Of this total, 26 patients were found to have interrupted their treatment; 18 of these patients resumed treatment following the team’s visit.

USAID is working with country partners to expand access to TB services by improving enabling environments, strengthening diagnostic networks, and supporting patient-centered TB care.

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Trained village health workers from the remote village of Paloc, Maragusan, Philippines, prepare sputum samples. A medical technologist will examine the samples in the nearest rural health unit. Photo by USAID.

DIAGNOSTIC NETWORKS

Approximately one out of every three people suffering from TB are missed by the health system—many are never diagnosed or treated, while others are diagnosed, but never registered for treatment or notified to their National TB Program. Many of these people die from TB, while others endure long, difficult periods of illness. Reaching these “missing” TB cases is vital from both a humanitarian and a public health perspective. In 2015, USAID expanded its support for the development of comprehensive diagnostic networks, which include the full screening-diagnosis-care and treatment cascade, to find more of the 4.1 million “missing” TB cases.

The vast majority of “missing” TB cases involved 10 countries: Bangladesh, China, Democratic Republic of the Congo, India, Indonesia, Mozambique, Nigeria, Pakistan, South Africa, and Tanzania. Nevertheless, all high TB burden countries face severe challenges in detecting, accurately diagnosing, and reporting TB cases. USAID, in partnership with the Global Laboratory Initiative, National TB Programs and national TB reference laboratories, is supporting country-specific implementation of vital diagnostic network components and informing global policy through best practices and evidence. Countries in Africa face significant challenges in establishing and implementing high quality TB diagnostic networks: around 40 percent of all undiagnosed TB cases are in Africa and many African countries have relatively weak infrastructure and health systems that preclude the rapid uptake of newer TB testing technologies.

In India, USAID is accelerating access to high quality TB diagnosis for children in four major cities (Delhi, Hyderabad, Chennai and Kolkata) through a network of four laboratories and 272 referral facilities. By offering upfront GeneXpert testing to 15,347 presumptive TB patients during September 2014 to September 2015, a total of 1,253 (eight percent) TB cases were detected, of which 104 (eight percent) were diagnosed with rifampicin resistance.

In 2015, USAID expanded access to rapid MDR-TB diagnosis by building sustainable capacity within Uzbekistan to routinely use GeneXpert testing platforms, troubleshoot errors, and keep instruments running consistently. As a result, the National TB Program can now provide accurate TB diagnoses within two hours and start patients on appropriate treatment the same day. Improvement of the country’s laboratory capabilities will contribute to improved patient outcomes and, ultimately, reduced TB and MDR-TB transmission. As part of USAID’s support to Uzbekistan’s diagnostic network, laboratory specialists, including Dr. Otamurod Kahramon, have acquired the expertise to run and maintain the GeneXpert instruments—a skill that will translate to future molecular diagnostic technologies and innovations both for TB and other diseases of public health importance.
PREVENTING TB TRANSMISSION AND DISEASE PROGRESSION

The best way to prevent TB transmission and disease progression is through early detection and treatment of TB disease. Worldwide, over two billion people are infected with the mycobacteria, which causes TB. While people with latent TB infection (LTBI) are not ill and cannot transmit TB, they may harbor the infection throughout their lives and are at risk of developing active (symptomatic and transmissible) TB disease during their lifetime. People who are malnourished, live in crowded conditions, or whose immune systems are compromised by medical conditions such as HIV and diabetes, are at the highest risk for developing active TB. People with active TB who are not placed on treatment pose a serious risk to close contacts such as family, friends, and colleagues – with the potential to infect an average of 10-15 other people per year. People with LTBI contribute to the global TB epidemic as infection progresses to disease in the subset with weakened immune systems or other vulnerable conditions. LTBI must be addressed in order to truly end the TB epidemic.

Since people with LTBI are not contagious, and TB patients on effective therapy quickly become non-infectious, screening and early treatment are key to stopping the spread of TB. The under-detection and under-diagnosis of TB and MDR-TB significantly hinders global efforts to limit TB transmission. USAID is working to address this by improving screening and diagnosis of high-risk individuals who may have undetected and untreated TB or inadequately treated MDR-TB. As defined in the U.S. Government’s Global TB Strategy, USAID’s TB prevention efforts focus on supporting:

- Education and targeted screening of high-risk individuals and groups;
- Rapid diagnosis and treatment of TB and MDR-TB patients;
- Infection control measures in group settings such as clinics and prisons; and
- The identification and management of latent TB infection.

In Cambodia, USAID is working to reduce TB transmission and disease progression among the elderly through targeted screening and testing of this high-risk population. During June-September 2015, USAID screened over 3,000 elderly Cambodians, of whom 59 percent had at least one symptom suggestive of TB. Of these patients, two percent were confirmed to have TB and an additional three percent were referred for further evaluation. This project confirmed data from the national prevalence survey indicating that the elderly are a key population in Cambodia that should continue to be targeted for TB screening. USAID also supported the National TB Program in implementing enhanced facility-based TB screening for all patients in five TB Referral Hospitals. With USAID support, over 132,000 patients were screened for TB from January to September 2015.

The risk of TB transmission is especially high in health care settings when health care workers and patients come into contact with people who have unsuspected TB disease, are not receiving adequate treatment, and have not been isolated from others. The “FAST” strategy for Finding, Actively Separating and Treating TB was developed with USAID support as a focused approach to TB infection control in health care facilities. In 2015, USAID conducted situational analyses of TB infection control implementation in both Burma and Malawi. Both countries will update their guidelines to incorporate new approaches such as the FAST strategy and new tools for example for monitoring and benchmarking compliance with TB infection control standards.

STRENGTHENING TB SERVICE DELIVERY PLATFORMS

In the countries where USAID has a presence, TB services are typically provided through national and/or private health systems and facilities. Many countries with high burdens of TB, MDR-TB, and TB-HIV co-infection have relatively weak health systems, which reduces their ability to provide high quality TB services and contributes to the development of and spread of MDR-TB.
USAID is committed to supporting the implementation of national TB strategic plans and programs and to building capacity at all levels of the TB service delivery system. During 2015, USAID focused its efforts to strengthen TB service delivery platforms on increasing political and financial support for health systems, improving partnerships and community engagement, strengthening drug and health commodity management systems, improving TB surveillance and monitoring and evaluation systems, and developing human resources for health.

PRIVATE SECTOR ENGAGEMENT

USAID is working with partners to increase community and private sector engagement in the development and delivery of TB services. Overall, the private health sector is an important component of health services as patients often seek health care services from individual or institutional private health-care providers.

In Ethiopia, the private health sector has grown significantly; over the past two years, private facilities diagnosed and treated more than 18,000 TB patients, with public-private mix treatment sites now detecting 10–15 percent of all TB cases reported nationally. In 2015, through an innovative and integrated project promoting collaboration with the private sector across all sectors of health services, USAID’s implementing partner equipped 170 private clinics in Ethiopia to identify and refer patients with presumptive TB, increasing their capacity to screen and detect TB cases.

TB remains a major public health problem in India. The country has the largest number of TB cases in the world — over a quarter of the global TB and MDR-TB burden. Each year, more than two million people in India develop active TB and over 300,000 people die from it. Launched in April 2015, the USAID-sponsored Call to Action for a TB-Free India has sparked new partnerships and united stakeholders in India by leveraging local political, intellectual, financial and material resources to work together to end TB in India. The Call to Action will increase participation and investment in the National TB Control Program by promoting national leadership on TB, advancing public understanding of, and reducing stigma and discrimination associated with TB, and generating support from research institutions to accelerate progress against TB.

TB AND HIV

The U.S. Government and the global community are working to end both the TB and the HIV/AIDS epidemics; these efforts are inextricably linked. TB is the leading cause of death among people living with HIV and AIDS and is responsible for approximately one quarter of all HIV-related deaths. Of the approximately 37 million people living with HIV (PLHIV), more than one-third are also infected with TB.

Working in nearly 100 countries around the world, USAID and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) are providing life-saving TB and HIV prevention, care, support, and treatment services. With U.S. Government support and investment over the past decade, countries have scaled up collaborative TB/HIV activities, resulting in an estimated 5.8 million lives saved from 2005 to 2014. Additionally, TB deaths among PLHIV have fallen by more than 30 percent since 2004.

USAID and PEPFAR are working with country partners to increase coordination between TB and HIV programs and services; start 100 percent of TB/HIV co-infected patients on antiretroviral therapy (ART) by 2019; and provide people living with HIV who are at high risk of contracting TB with ART and isoniazid preventive therapy (IPT) to reduce their risk of developing TB disease. This work will significantly reduce TB-related mortality among people living with HIV and contribute to the U.S. Government’s goal of ending the TB and AIDS epidemics by 2030.

Government of Malawi Minister of Health, Peter Kumpalume, along with district and national officials, visited the TB awareness and information booths at the World TB Day celebrations in Malawi. Photo by USAID.
Nurse Sister Theresa Kitandwe hands out a patient’s daily MDR-TB medication at the drug-resistant TB ward at the Mubende Regional Referral Hospital in western Uganda. Photo by USAID.

THE DEVASTATING HUMAN AND ECONOMIC IMPACT OF TB

TB disproportionately affects the poor. Of the over 10 million people who develop active TB every year, nearly 95 percent are in developing countries. Crowded living conditions, poor ventilation, lack of access to clean water and sanitation, malnutrition, and co-infection with other diseases – especially HIV/AIDS – all contribute to an increased susceptibility to TB. Low-income populations often lack access to health care facilities, which can delay the diagnosis of TB by weeks or months, leading to preventable deaths and perpetuating the spread of TB.

Individuals who contract TB and their families often suffer severe economic consequences even when health services are provided free-of-charge. The average TB patient loses three to four months of work due to their illness; MDR-TB patients are typically out of work for even longer. The impact of the illness is particularly devastating since TB often strikes individuals in their economic prime (ages 15-64), with family members who depend upon their incomes. Many families affected by TB are forced to sell their limited assets to cover the costs of TB treatment or meet their basic needs in the face of a family member’s lost income. Children whose parents contract TB may be pulled out of school to support the family, thus perpetuating the cycle of poverty by jeopardizing the child’s education and future employment opportunities.

TB is both a cause and a consequence of poverty — a vicious cycle. USAID seeks to end TB. The World Bank estimates that combating TB yields a 10-to-1 economic benefit globally. Through smart investments in TB prevention and care, USAID is saving lives and promoting economic growth in support of the SDGs and the Obama Administration’s commitment to ending extreme poverty by 2030.

MULTILATERAL PARTNERSHIPS: THE GLOBAL FUND

The U.S. Government is the largest donor to the Global Fund, which is in turn the largest global financing mechanism for TB care and treatment. In order to increase the impact of the Global Fund’s investments in TB care, USAID provides technical assistance focused on leveraging and maximizing the Global Fund’s resources in countries with the highest TB funding and disease burden.

In 2015, USAID continued to support the development, management, oversight, and implementation of Global Fund TB grants in 54 countries. USAID worked closely with country partners to ensure their Global Fund grants supported and improved access to the most important TB, MDR-TB, and TB/HIV prevention, diagnosis, treatment, and care services. USAID also provided on-the-ground technical support since the Global Fund is, by design, a funding mechanism that does not offer in-country presence or broad technical expertise. In this context, USAID works with country partners to strengthen their Global Fund grant management and implementation capacity. In 2015, USAID funded in-country TB Global Fund advisors in 16 countries in addition to providing support through USAID’s bilateral program and targeted technical assistance. These advisors, embedded within National TB Programs, assist program staff implement national TB strategic plans and Global Fund grants. In some countries, the TB advisors have contributed to the development of Global Fund concept notes and provide continued mentoring and support to National TB Programs to ensure their TB grants are successful.

USAID actively engages with partners to identify and address challenges and opportunities for TB programming and the successful implementation of Global Fund grants to ensure that the TB community benefits as much as possible from the Global Fund’s strategic Investing to End Epidemics. In 2015, USAID contributed to this strategy through an extensive consultation process and in close collaboration with global partners. USAID strongly supports the operationalization of the Global Fund strategy through providing technical and programmatic assistance.

USAID, in coordination with PEPFAR and other U.S. Government agencies, continues to map existing technical support and future needs for all countries with high TB burdens and works in close collaboration with implementing partners and other technical assistance partners, such as the Stop TB Partnership, WHO, and other bilateral donors, to plan and coordinate Global Fund technical assistance to ensure there is no duplication of efforts. Strong coordination with multilateral partners has enabled USAID to better understand the challenges that must be addressed in reducing the global TB burden and ending the TB epidemic.
DRUG AND COMMODITY MANAGEMENT

In order for TB programs to succeed, patients must have reliable access to affordable, quality-assured, and effective TB medicines and diagnostic commodities. USAID is assisting countries with high TB burdens to forecast their need for TB drugs and commodities and strengthen their procurement and distribution systems.

In 2015, USAID continued to support the roll out of an electronic forecasting, quantification, and early warning tool designed to improve procurement processes, ordering, and planning for TB treatment. This downloadable desktop tool transforms complicated calculations into a user-friendly dashboard that displays key information for managing medicines.

In the Philippines, for example, drug shortages had been a challenge in the past. Since this system was introduced in 2014, the country has not experienced any TB drug stock-outs, ensuring that patients have continuous access to lifesaving medications.

USAID also continued to be a major supporter of the Global Drug Facility (GDF), the largest global supplier of TB medicines and diagnostics, to ensure a stable supply of TB and MDR-TB drugs at a reduced cost. The GDF is the largest global supplier of TB medicines and diagnostics. Since 2001, the GDF has ensured a stable, affordable supply of quality-assured treatments of both drug-susceptible and drug-resistant TB globally, benefiting over 137 countries with over $1.44 billion of TB commodities procured. GDF has created a new market for second line drugs that was nonexistent before 2009, and since 2011, has tripled global second line drug supply security and products. GDF also offers technical assistance when required to facilitate the forecast, quantification and ordering of TB medicines.
Since 2012, there has been a gradual decline in the cost of MDR-TB treatment regimens of close to 50 percent, with some second line drugs reduced by 70 percent. Access to high quality, affordable TB treatment is a huge barrier to stopping the spread of TB. Through the GDF, USAID is able to reach more patients, provide vital technical assistance to National TB Programs and projects, and provide treatment to those who need it the most.

**MONITORING AND EVALUATION**

In order to effectively combat TB in all its forms, program managers and funders must have good information on their local epidemic. This requires robust monitoring and evaluation systems. In 2015, USAID worked with country partners to track their TB epidemics, programs, and impact. Through investments in routine data collection and analysis systems, periodic epidemiological assessments, prevalence surveys and specialized inventory studies, USAID is supporting National TB Programs to more accurately determine the true burden of disease and identify and address data quality issues, all of which facilitates better allocation of resources and planning.

In 2015, USAID assisted Ukraine’s National TB Program with completing its transition from an inefficient, paper-based registry and reporting system to a USAID-developed electronic recording and reporting system, a web-based tool that enables the program to manage all TB-related data through a single, integrated, electronic system. As of August 2015, a total of 185,760 TB cases were entered into this system and the consistency between paper-based and electronically generated reports was approximately 99 percent.

In Ghana, USAID helped the National TB Program using the results of a TB prevalence survey to evaluate its TB response. The evaluation informed and enabled a discussion among key stakeholders, including the National TB Program, USAID, WHO, and the Global Fund, leading to a full reprogramming of the Ghanaian Global Fund grant in 2015, with the goal of better focused and aligned program interventions leading to decreased incidence and higher impact.

In Zimbabwe, USAID is supporting local officials use TB data to inform and improve their TB program. Until recently, health care workers recorded information in patient registers without compiling data for broader analysis. As a result, health care workers were often unaware of their facilities’ strengths and challenges. Local data was collected quarterly by a District TB Coordinator who compiled case notification and treatment outcome data by hand. These systems made it difficult for district health managers to identify and address challenges. To address this issue, USAID helped the National TB Program develop a national guide on TB data collection, analysis, and use and implement it in both primary and central health care facilities. The new guide has improved data collection and use and has enabled districts to identify high- and low-performers and target support and resources more effectively.

**ACCELERATING RESEARCH AND INNOVATION**

With 1.7 million people dying from TB each year, the world urgently needs new TB drugs, diagnostics, and preventive measures. USAID supports TB research and innovation with the goal of increasing the effectiveness of existing tools and developing revolutionary new technologies to transform the way TB is diagnosed, treated, and prevented.

USAID has a long history of supporting rigorous research programs that lead to bold innovations in health and development. USAID’s support for research on the efficacy of new tools and approaches to TB care, including the use of GeneXpert for TB diagnosis optimization and evaluation of molecular diagnostic technologies and the introduction of new MDR-TB treatment regimens, have led to dramatic improvements in global TB care.

In 2015, USAID concentrated its support for TB-related research in the following areas:

- TB prevention, including TB transmission and treatment of LTBI;
- TB treatment, including the development and evaluation of new MDR-TB treatment regimens; and
- Operational research for improving TB program performance and the management of TB/HIV co-infection.

GeneXpert machine for rapid TB diagnostics was donated by the USAID Strengthening TB Control in Ukraine project to the Kryvyy Rih TB facility in 2015. The project settled the equipment and provided re-training for the laboratory specialists. Since then, the onset of TB treatment in Kryvyy Rih accelerated in four times. Photo by USAID.
The TB community needs new tools and approaches for reducing TB incidence. In the absence of a vaccine, USAID is promoting the treatment of LTBI. However, there are still questions about which LTBI treatment regimen is most likely to significantly and permanently reduce the chance of disease progression. To answer that question, USAID is supporting the implementation of a randomized clinical trial that will evaluate and compare the efficacy and safety of a three-month regimen of weekly doses of rifapentine and isoniazid (INH) given periodically to people living with HIV. USAID is also supporting research into TB transmission within communities given increasing evidence that most of the new MDR-TB cases are a result of ongoing transmission in the community. In 2015, USAID started funding studies to determine the patterns and factors associated with TB transmission with the aim of developing and evaluating interventions that could be used to reduce TB transmission and, ultimately, TB incidence.

In 2015, USAID continued to fund the STREAM study—the first randomized clinical trial to evaluate the efficacy, effectiveness, and safety of shortened MDR-TB treatment regimens. The STREAM study is evaluating the efficacy of a nine-month MDR-TB treatment regimen as compared to the traditional, more than 20-month treatment regimen. In addition to the evaluation of the nine-month MDR-TB treatment regimen comprised of pills and injectable drugs, the trial has added two new arms to include bedaquiline, the newly approved TB drug, in order to evaluate a six-month treatment regimen and a nine-month all-oral treatment regimen. The new phase of this clinical trial started enrollment in 2015. The STREAM trial will also serve as a registration trial for bedaquiline and will, therefore, play a major role in the overall scale-up and uptake of this new, life-saving drug. USAID is further investing in the development and testing of novel drug compounds and drug combinations through the Global Alliance for TB Drug Development. One of these, the Nix-TB study, is the world’s first clinical trial on an XDR-TB drug regimen that treats TB using pills only, instead of both pills and injections. The Nix-TB regimen consists of a combination of three drugs aimed at curing XDR-TB in six to nine months. If successful, the injection-free regimen could transform XDR-TB treatment, with patients being cured through relatively short, simple, and effective regimens. Importantly, the regimen being tested could also reduce the complexity and cost of the treatment to a fraction of what it is today, facilitating the global implementation of XDR-TB treatment in resource-poor nations.

In order to improve TB detection techniques, USAID, through the US Global Development Lab, is partnering with APOPO, a Belgian non-governmental organization, to develop and test an innovative “scent detection” technology through giant pouched rats (“HeroRATs”). In 2015, HeroRATs in APOPO’s Tanzanian laboratories screened over 40,000 sputum samples, successfully identifying more than 1,150 TB-positive samples that had been missed initially by conventional diagnostic techniques.

Looking ahead, USAID is working with WHO and other partners to define a research agenda for the future that will contribute to the elimination of TB by 2030.
CONCLUSION

USAID focuses its efforts on working with partners to save lives and reduce poverty through its global TB program. USAID’s investments in global TB are contributing to the UN Sustainable Development Goals and are aimed at the ambitious target of eliminating TB at the global level. In 2015, this investment contributed to the notification of 3.7 million TB cases to National TB Programs and more than 2.8 million successfully treated cases. Additionally, more than 70,000 individuals with drug-resistant TB initiated second line therapy.

Despite this tremendous progress, continued investment and innovation are needed to end the TB epidemic. USAID is committed to working actively with country, international, and private sector partners to achieve a TB-free world.
APPENDIX I:
FY 2015 HIGHLIGHTS FOR USAID PRIORITY COUNTRIES

This section highlights selected achievements from USAID’s country-based projects. These projects focus on strengthening national TB and MDR-TB strategies and programs and on piloting innovative approaches for later expansion by domestic and Global Fund financing. USAID’s TB funds are fully leveraged by other financing sources and increase the impact of these other resources.
AFGHANISTAN
In 2015, USAID worked with local officials to improve TB infection control practices in health care facilities and community settings, expanding effective TB infection control measures to 185 health facilities across all 15 provinces, redesigning infection control systems in 45 health facilities, and training 250 health workers in TB infection control.

BANGLADESH
In 2015, USAID worked with Bangladesh’s National TB Program to improve its MDR-TB treatment program. USAID supported the scale-up of the nine-month MDR-TB treatment regimen nationwide and assisted with the introduction of bedaquiline in MDR-TB treatment regimens, enrolling 37 patients on this life-saving medicine. USAID also supported the improvement of GeneXpert machine maintenance at 38 TB testing sites, supporting the recalibration, repair, or replacement of non-functional machines. This contributed to a 37 percent increase in the number of presumed MDR-TB cases tested between the third and fourth quarter of 2015.

BURMA
In 2015, USAID provided technical assistance for the successful finalization of Burma’s new TB national strategic plan. In addition, USAID supported a TB Infection Control assessment and National Laboratory Assessment that were shared with the National TB Program and led to clear follow-on plans and activities, including the training of 70 health workers in TB counselling, infection control, and DOTs.

CAMBODIA
USAID worked with Cambodia’s National TB Program to reduce childhood TB. In 2015, USAID provided the identification of at risk children and provision of preventive therapy (IPT) to 1,287 children under five years of age. USAID further referred 361 children for TB testing. Of this total, nine percent were diagnosed with TB and started on treatment. USAID also trained 70 health workers in TB counseling, infection control, and investigation. During July – September 2015, these health workers identified 5,291 close contacts of 618 TB index patients. Of these close contacts, almost 300 young children were identified and provided with IPT to prevent TB disease.

DEMOCRATIC REPUBLIC OF CONGO
In 2015, USAID trained former and current TB patients to serve as “TB Ambassadors,” educating individuals in hard-to-reach communities about TB and assisting how people with TB symptoms access diagnosis, treatment, and care. From April to September 2015, the TB Ambassadors visited 15,687 households, educated 72,527 people about TB, and referred 9,389 persons with TB symptoms for further screening.

ETHIOPIA
In 2015, USAID assisted the National TB Program to finalize and disseminate a roadmap for combating childhood TB. USAID also worked to improve access to accurate TB diagnosis, including through the procurement and distribution of 32 microscopes in two regions with high TB prevalence and the training of 330 laboratory staff in microscopy techniques and quality assurance.

INDIA
In 2015, USAID worked with local officials to improve diagnosis of childhood TB in four major cities: Delhi, Hyderabad, Chennai, and Kolkata. By offering free GeneXpert testing to all presumptive pediatric TB cases, USAID assistance increased the number of children tested for TB in these cities from 1,000 per month at the beginning of FY 2014 to 1,700 per month at the end of 2015. Of the 15,347 children tested, 1,253 (eight percent) were diagnosed with TB, of whom 104 were further diagnosed with MDR-TB.

INDONESIA
In 2015, USAID worked in partnership with the Ministry of Health and the Global Fund to expand MDR-TB diagnosis and treatment centers nationwide. USAID assisted in the procurement and installation of GeneXpert machines in 42 high-priority sites in 2015 and trained staff in their use. This contributed to a 19 percent increase in the number of GeneXpert tests conducted in FY 2015, as compared to FY 2014. USAID also worked to increase TB case detection by introducing bi-directional TB-diabetes mellitus screening protocols in North Sumatra, South Sulawesi, and Central Java.

KENYA
In 2015, USAID supported Kenya’s National TB and Leprosy and Lung Disease Program to provide financial and social support for half of all MDR-TB patients in the country to complete treatment and has supported the installation of an additional 46 GeneXpert machines across the country, increasing the overall coverage to 76 machines.

KYRGYZ REPUBLIC
In 2015, USAID worked with the National TB Program to develop a plan for the introduction of new MDR-TB drugs, including bedaquiline. USAID provided assistance to secure bedaquiline through a compassionate use waiver, laying the groundwork for MDR-TB patients to be started on this new, life-saving drug in mid-2016, and supported the National TB Program to create a vigorous pharmacovigilance program to ensure the quality of TB drugs used in the country.

MALAWI
USAID supported the National TB Program to improve access to reliable, effective TB treatment and care by increasing the number of TB registration and treatment sites from 59 in 2010 to 277 in 2015. USAID also supported the creation of community-based treatment programs for MDR-TB patients and implement a national programmatic management of drug-resistant TB (PMDT) policy to track patients’ side effects, a prerequisite for the introduction of new MDR-TB drugs. This has contributed to a decrease in MDR-TB mortality from 33 to 25 percent for the 2009 and 2011 cohorts, respectively.

MOZAMBIQUE
In 2015, USAID supported Mozambique’s National TB Reference Laboratory to obtain the highest level of international accreditation for technical competence and quality management, making it one of the few public medical laboratories in Africa to achieve international accreditation. This will enhance Mozambique’s capacity to provide advanced TB diagnoses, conduct second-line drug-resistance testing, and support Mozambique’s network of TB diagnosis sites.
NIgerIA
In 2015, USAID worked to improve access to TB services in hard-to-reach communities such as Bateriko in the Cross River State. USAID worked with local business leaders and residents to renovate and re-open the primary health center in Bateriko, which had been inactive for over 40 years. The health center is now providing TB and MDR-TB testing, treatment and care. USAID also established a toll-free TB call center that provides basic TB information to callers in English and four other major languages and assisted the National TB Program to review and improve its training materials on MDR-TB care and the programmatic management of drug-resistant TB.

PHILIPPINES
USAID is working with the National TB Program to reduce the MDR-TB treatment default rate to less than five percent in 2016. In 2015, USAID concluded an intensive study of the issue, which found the primary factors leading to MDR-TB treatment default to be alcohol abuse and patients’ perceptions of the severity of side effects such as vomiting. This finding led the National TB Program to change its clinical management to MDR-TB patients to better address these factors. USAID also supported the National TB Program in developing guidelines for the use of bedaquiline, laying the groundwork for this introduction of this new, life-saving MDR-TB drug.

SOUTH AFRICA
USAID is working with partners to ensure all MDR-TB patients in South Africa have access to appropriate treatment. With USAID support and an increased focus on decentralized treatment initiation, 96 percent of confirmed MDR-TB patients in the Eastern Cape were started on treatment, 89 percent in KwaZulu-Natal, and 100 percent in the Western Cape. With USAID support, the Eastern Cape reported a 95 percent patient retention rate through the implementation of mobile health technology. In 2015, USAID assisted South Africa’s National TB Program to identify the most effective placement of 309 GeneXpert machines, achieving national coverage. USAID also assisted with the bedaquiline application process.

SOUTH SUDAN
In 2015, USAID assisted South Sudan to improve TB detection and treatment adherence by training 72 “community mobilizers” to find TB patients who drop out of treatment programs and encourage them to restart appropriate treatment. By establishing a network of motorcycle riders to transport samples between laboratories, USAID also supported South Sudan’s expanded use of GeneXpert from 18 tests in June 2015 to 220 tests in September 2015. USAID also improved access to TB services for Internally Displaced Persons in Juba by integrating TB services into the camp’s primary health care system and training healthcare workers and laboratory technicians on TB case detection, diagnosis, and care. With USAID’s support, TB case notification increased from 27 in 2014 to 82 cases in 2015.

TAJKISTAN
Building on its success in the Raish Valley in FY 2014, USAID established out-patient TB and MDR-TB treatment and care programs in 18 new areas in the Sogd Oblast in FY 2015. Local communities are supporting these programs by exempting TB and MDR-TB patients from property taxes and monthly electricity, water, and garbage disposal costs for the duration of their treatment.

TANZANIA
In 2015, USAID worked to improve MDR-TB patient outcomes and treatment adherence through regular supervision of out-patient MDR-TB treatment programs and support for their patients. USAID sponsored quarterly visits to MDR-TB treatment sites, during which health workers reviewed the quality of MDR-TB services. The teams also visited patients in their homes to provide adherence counseling and advice on the management of side effects. During June – September 2015, the teams visited 124 (98 percent) of MDR-TB patients. Of this total, 21 percent patients were found to have interrupted their treatment; 18 of them resumed treatment following the team’s visit.

UGANDA
In 2015, USAID assisted Uganda’s National TB Program to improve its MDR-TB guidelines, establish guidelines for the use of bedaquiline in MDR-TB treatment, and facilitate the introduction of bedaquiline for 20 patients per year.

UKRAINE
In 2015, USAID worked to improve treatment adherence and outcomes by supporting patient-centered models of care, including ambulatory treatment for MDR-TB patients. By enabling MDR-TB patients to receive treatment where they live, USAID is supporting improved increased treatment adherence and success. USAID is also working to reduce MDR-TB transmission in health care settings by assisting facilities to establish and maintain appropriate infection control measures.

UZBEKISTAN
In 2015, USAID trained TB laboratory staff on the use of GeneXpert machines in TB and MDR-TB diagnosis, enabling Uzbekistan’s National TB Program to provide accurate TB diagnoses within two hours and start patients on treatment within a single day. USAID also trained 12 laboratory specialists on the proper maintenance of the GeneXpert machines, reducing disruptions and delays in TB diagnostic services.

ZAMBIA
In order to more effectively combat MDR-TB in Zambia, USAID provided support to the National TB Program to develop national MDR-TB guidelines, revise MDR-TB recording and reporting tools, and identify the most effective placement of 15 GeneXpert machines purchased through a Global Fund grant for TB and MDR-TB diagnosis.

ZIMBABWE
In 2015, through USAID assistance, Zimbabwe scaled up its use of GeneXpert in TB and MDR-TB diagnosis, contributing to a 6 percent increase in MDR-TB case detection. USAID supported the installation of 30 GeneXpert machines in key districts and hospitals and trained 828 health care workers on TB screening and referral practices.