



United States Government
Global Tuberculosis Strategy

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COVER PHOTO: Anibya in Indonesia has a type of TB known as multi-drug resistant tuberculosis. (Photo by John Rae, the Global Fund)

ACRONYMS & ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
DOS	Department of State
DR-TB	Drug-Resistant TB
FDA	Food and Drug Administration
FY	Fiscal Year
GDP	Gross Domestic Product
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GNP	Gross National Product
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
LTBI	Latent Tuberculosis Infection
MDR-TB	Multi-Drug Resistant Tuberculosis
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NSP	National Strategic Plan
PEPFAR	President's Emergency Plan for AIDS Relief
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis
Xpert	Xpert [®] MTB/RIF



A mother and child take part in
a TB Reach Event in Cambodia
(Photo by RESULTS)

VISION

The U.S. Government and the global community share a vision of a world free from tuberculosis (TB), as set forth in the World Health Assembly's Post-2015 Global TB Strategy.¹

To achieve this vision and end all deaths due to TB, the U.S. Government will work with its partners around the world to **reach** every person with TB, **cure** those in need of treatment, and **prevent** the spread of disease and new infections.

¹ http://www.who.int/tb/post2015_strategy/en/

CONTEXT

The vision of a world free from TB is ambitious yet achievable. Great progress toward this goal has been made in the last 25 years. Since 1990, the global community has reduced the number of deaths from TB by 45 percent, reduced TB prevalence by 41 percent, and reduced annual TB incidence from 151 to 126 per 100,000. Since 2000, 37 million people have been cured of TB. The World Health Organization (WHO) began systematic collection of data on drug-resistant TB (DR-TB) treatment initiation in 2008. Since then, approximately 319,000 individuals with DR-TB were started on appropriate treatment² — 97,000 in 2013 alone.

Despite this substantial progress, much work remains to eliminate TB as a global health threat. TB is the second-leading cause of death from infectious disease in the world with one person dying of TB every three minutes.³ 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. Furthermore, the rapid emergence of DR-TB has the potential to reverse 20 years of progress in mitigating the devastating effects of TB. Each year, an estimated 9 million people develop TB, and 1.5 million people die from the disease. There are more than 500,000 cases of TB among children each year. In addition, multi-drug resistant TB (MDR-TB), a strain of TB resistant to at least two of the most effective TB drugs, is estimated to develop in almost half a million people each year. More than 100 countries have reported a case of extensive drug-resistant TB (XDR-TB), resistant to nearly all drugs available to treat it. TB is a global health security threat because of the

large number of people affected by the disease and the disease being spread by air. The urgent need to address MDR-TB was explicitly recognized in September 2014 in the Presidential Executive Order “Combating Antibiotic-Resistant Bacteria,”⁴

Effectively addressing TB is an important element of the U.S. Government’s efforts to improve global health and reduce poverty. TB disproportionately affects the poor and individuals who are already immunocompromised. More than 95 percent of TB cases and deaths occur in developing countries, with 80 percent of estimated TB cases occurring in 22 “high-burden” countries. Unfortunately, TB can be a cause as well as a consequence of poverty. The economic impact of TB, including the loss of income among those who are sick, as well as their caretakers, can devastate individuals and their families, and is estimated to decrease gross domestic product (GDP) by 4 to 7 percent in some countries.⁵

The currently recommended treatment regimens for drug-susceptible⁶ TB are effective and affordable, with an individual success rate of more than 85 percent when administered correctly and completely. However, when treatment is not completed appropriately, drug resistance can develop, making cases more difficult and costly to treat. WHO reported in 2014 that only 48 percent of individuals diagnosed with DR-TB were successfully treated.⁷

2 All Data in this paragraph is derived from WHO
3 <http://www.who.int/mediacentre/factsheets/fs104/en/>

4 <http://www.whitehouse.gov/blog/2014/09/18/new-executive-actions-combat-antibiotic-resistance-and-protect-public-health>

5 <http://www.tballiance.org/why/economic-impact.php>

6 Drug-susceptible refers to patients who do not have evidence of infection with strains resistant to rifampicin (i.e. not rifampicin-resistant or multidrug-resistant TB). WHO, 2014. Source: http://apps.who.int/iris/bitstream/10665/79199/1/9789241505345_eng.pdf

7 http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf?ua=1

The U.S. Government must continue to ramp up efforts to improve the quality of diagnosis, care, and treatment of TB to prevent the development of DR-TB, and develop new tools to address this deadly epidemic. Fortunately, most people developing active TB can be identified and cured using widely available diagnostic tools and treatment regimens. However, without proper treatment, up to two-thirds of people with TB will die.

Approximately one-third of the world's population is infected with the *mycobacteria* that causes TB.

While individuals 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. Approximately 10 percent of individuals with latent TB will develop active TB; the risk increases dramatically among individuals whose immune systems are weakened through disease, such as HIV and AIDS, diabetes, or malnutrition. For example, among individuals co-infected with HIV, approximately 30 to 50 percent with latent TB will develop active disease.

TB BY THE NUMBERS

SUCCESSSES

- 37 million lives saved through TB diagnosis and treatment during 2000–2013
- 45 percent decline in TB mortality since 1990
- 41 percent decline in TB prevalence since 1990
- 108 countries rolling out new diagnostics (Xpert® MTB/RIF) using concessional rates
- 50+ companies involved in the development of TB diagnostics
- 10 new or re-purposed anti-TB drugs in late phases of clinical development
- 2 new drugs approved for treatment of DR-TB under specific conditions
- 15 vaccine candidates in clinical trials
- 48 percent of notified TB patients with a documented HIV test result in 2013 (76 percent in the African Region)
- Increased rates of ART for diagnosed TB patients to 70 percent

CHALLENGES

In 2014:

- 9 million people developed active TB
- 3 million cases were not diagnosed or notified to public health programs
- 1.5 million individuals died from TB, including 360,000 people living with HIV and AIDS (1/4 of all HIV-related deaths were due to TB)
- 30 percent of TB patients known to be HIV-positive people were not started on ART
- 550,000 children developed TB
- 480,000 people developed DR-TB
- 97,000 of those with DR-TB started on appropriate treatment
- 210,000 people died from DR-TB

U.S. GOVERNMENT LEADERSHIP IN COMBATING TB GLOBALLY

The U.S. Government is a leader in the global fight against TB. Between 2010 and 2014, the U.S. Government invested more than \$2.8 billion to combat TB globally, including more than \$1.2 billion through the U.S. Agency for International Development (USAID) bilateral program; more than \$930 million through the U.S. Government's contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); and more than \$730 million through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funding for TB-HIV. This strategy describes activities that will be implemented and targets that will be achieved using these funding streams, in close collaboration with host countries. The U.S. Government specifically includes those agencies that have been appropriated these funding streams.

The U.S. Government is the largest bilateral donor in the global TB effort, supporting TB programs in more than 50 countries with the highest TB burdens through USAID, and supporting patients with and at risk of HIV-associated TB in more than 32 countries through PEPFAR. The U.S. Government has contributed more than \$10.6 billion to the Global Fund since 2004, making it the world's largest single donor, and this investment is a vital component of the U.S. Government's response to the TB epidemic – leveraging our bilateral resources and expanding the geographic reach of our bilateral programs. Approximately 18 percent of this contribution has supported TB programming in more than 100 countries; the remainder supports HIV and AIDS, malaria, and health system strengthening grants, and the Global Fund's operating expenses. Global Fund grants and U.S. Government bilateral TB activities complement one another to address both financial and technical

gaps identified in the national strategic plans (NSPs) developed by National TB Programs in recipient countries. Through our technical assistance programs, the U.S. Government helps affected countries use Global Fund resources to achieve the TB-related goals specified in their NSPs and to contribute to global targets.

Nonetheless, the U.S. Government cannot and should not attempt to tackle the TB epidemic alone and is committed to supporting sustainable national efforts to curb the TB epidemic in the countries in which we work. In fact, the bulk of funding for national TB programs comes from the domestic budgets of affected countries. The U.S. Government works closely with partner countries, global institutions, and other financiers to ensure that resources are used optimally, and supports individual country governments to build national capacity to combat TB rather than creating external, parallel systems.

The U.S. Government is also a leader in infectious diseases research. In its 2014 report, the Treatment Action Group estimated that global investments in TB research and development were \$676.7 million in 2013.⁸ U.S. Government investments accounted for approximately 36 percent of this total, with an overall investment of \$310.3 million from the following agencies: National Institutes of Health (NIH), including National Institute of Allergy and Infectious Diseases (NIAID), National Heart, Lung and Blood Institute, and other Institutes and Centers (\$270 million); USAID (\$20.4 million); U.S. Centers for Disease Control and Prevention (CDC) (\$16.1 million); PEPFAR (\$2 million); the U.S. Food and Drug Administration (FDA) (\$1.2 million); and the National Science Foundation (\$0.6 million).

⁸ http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201410/TAG_2014_TB_Funding_Report.FINAL.pdf



A TB education exercise on treatment support takes place in Nigeria. (Photo by FHI 360)

Together, the U.S. Government's investments in international TB control and TB research have reaped phenomenal health dividends. Internationally, the U.S. Government has documented a 43 percent decrease in TB-related mortality and a 42 percent decrease in TB prevalence in U.S. Government-supported countries since 1990. These declines in TB prevalence and mortality have contributed substantially to overall global declines in TB prevalence and mortality.

This TB Strategy (2015–2019) lays out how the U.S. Government will direct and coordinate its investments in the global fight against TB between 2015 and 2019 to achieve even greater global health progress. Our efforts to combat TB internationally save and improve the lives of millions of people around the world and help protect American citizens from TB both at home and abroad.

STRATEGIC FRAMEWORK

The U.S. Government strongly supports WHO's *Global Strategy and Targets for Tuberculosis Prevention, Care and Control after 2015*⁹ (The End TB Strategy), a global consensus document. This WHO strategy emphasizes the need to:

1. Integrated, patient-centered care and prevention
2. Bold policies and supportive systems
3. Intensified research and innovation

The U.S. Government is further committed to ensuring our investments are coordinated with the investments of national health programs and the Global Fund to increase their impact and sustainability.

To save lives and alleviate suffering from TB, the U.S. Government will further intensify its efforts to identify and invest in programs and policies that have the greatest potential to end the epidemic.

The U.S. Government will focus efforts in the following areas:

- Supporting countries with the highest TB, DR-TB, and/or TB-HIV burdens
- Leveraging interagency strengths and innovative approaches
- Supporting multilateral and international global programs, policies, and research for TB prevention, care, and treatment

SUPPORTING COUNTRIES WITH THE HIGHEST TB, DR-TB, AND/OR TB-HIV BURDENS

To maximize the impact of our bilateral investments, the U.S. Government will focus its efforts on national TB and AIDS control programs in countries

most affected by TB. The following factors will be considered in the selection of countries: TB burden; DR-TB burden; TB-HIV burden; Global Fund TB Grant support; and country ability to finance TB services.

The U.S. Government will work in partnership with each country to identify and provide high-quality, patient-centered care and treatment to individuals with active TB and those most at risk of developing active TB, taking into account each country's unique epidemiologic profile, local capacity, and national and international investments. The U.S. Government will work closely with supported countries to develop, implement, and track the success of comprehensive, sustainable national TB strategies and programs. This support includes helping countries to identify and address gaps in their TB programs and adopt new, evidence-based practices and policies. Consistent with WHO's End TB Strategy, the U.S. Government will work to:

- Improve access to high-quality, patient-centered TB, DR-TB, and TB/HIV services
- Prevent TB transmission and disease progression
- Strengthen TB service delivery platforms
- Accelerate research and innovation

All U.S. Government-supported activities will be coordinated with relevant ministries (e.g., health, social welfare, justice, and defense), national TB and HIV programs, private sector and community partners, and Global Fund TB Grant implementation efforts. The U.S. Government will work through local partners wherever practical to increase local relevance, ownership, and sustainability.

⁹ <http://www.who.int/tb/strategy/en/>

LEVERAGING INTERAGENCY STRENGTHS AND INNOVATIONS

The U.S. Government's international TB activities are led by USAID through its bilateral and multilateral programs. PEPFAR is the lead for international TB-HIV efforts. USAID ensures close coordination among all U.S. Government agencies implementing international TB activities with U.S. foreign assistance and other funds through an interagency Global TB Working Group. U.S. Government agencies involved in this interagency collaboration include: USAID, PEPFAR, CDC, NIH, and the Department of Defense (DOD). Each agency contributes to the overall effort according to its individual mandate and strengths.

As lead for the U.S. Government's response to the global TB epidemic, USAID supports TB programs and health systems in the countries and regions most affected by the TB epidemic. USAID tracks progress toward agreed-upon targets and adjusts areas of focus and activities as needed. USAID works to increase access to high-quality patient-centered TB diagnosis, treatment, and care for patients with TB or DR-TB. USAID also implements a range of PEPFAR-funded TB-HIV programs.

As lead for the U.S. Government's international HIV and AIDS efforts, PEPFAR leads the response to HIV-associated TB as outlined in PEPFAR's 2012 Blueprint "Creating an AIDS-free Generation" and in the 2014 "PEPFAR 3.0, Controlling the Epidemic: Delivering on the Promise of an AIDS-free Generation." High rates of HIV testing among TB patients are being sustained in many of the countries where PEPFAR works. In countries with a high burden of HIV-associated TB, PEPFAR has also played a critical role in providing life-saving

TB-HIV services. PEPFAR support for TB-HIV service delivery is implemented through USAID, CDC, the Health Resources and Services Administration (HRSA), DOD, and the Peace Corps.

CDC plays a vital role in the global TB effort through its leadership for developing and strengthening international surveillance and laboratory networks, technical support to ministries of health and national TB programs, and operational research activities. CDC also implements PEPFAR-funded TB-HIV care and treatment programs.

NIH leads the U.S. Government's efforts in TB biomedical research, conducting and supporting research and product development domestically and internationally. NIH supports research on TB and TB-HIV in adults and children and invests in the discovery and development of new drugs, vaccines, and diagnostics. Within NIH, NIAID is the lead institute for TB research. Although NIH does not provide foreign assistance, the knowledge gained through NIH's research informs and greatly improves the U.S. Government's global TB efforts.

DOD also plays an important role in the U.S. Government's international TB efforts. Through its laboratories in high-burden TB countries, DOD supports and monitors the quality of TB diagnostic services and supports operational research.

A lab technician tests tuberculosis samples at a lab in Bandung's Public Health Laboratory in Indonesia. (Photo by USAID)



SUPPORTING MULTILATERAL AND INTERNATIONAL GLOBAL PROGRAMS, POLICIES, AND RESEARCH FOR TB PREVENTION, CARE, AND TREATMENT

Given the global scope of the TB epidemic, the U.S. Government works closely with and supports international partners who have competencies and capacity in addressing the TB epidemic. This expands our geographic reach, leverages investments of other donors, and advances the development and global adoption and adaptation of new policies and metrics.

The U.S. Government strongly supports and is the largest donor to the Global Fund, which provides almost 66 percent of all donor funding for TB.¹⁰ This investment in the Global Fund is an essential

component of the U.S. Government's response to the global TB epidemic, and bilateral USAID TB programs complement and support TB programs financed through Global Fund TB grants. We are committed to helping countries achieve their national TB goals and targets including effective use of domestic resources and Global Fund grants.

The U.S. Government also works closely with international partners in a broad range of activities. WHO's Global TB Programme and the Stop TB Partnership are two of our most important partners in this effort. Collaborative activities include monitoring and measuring the TB epidemic; setting international TB goals; contributing to normative guidance; building laboratory infrastructure; helping countries develop and fund national TB strategies; supporting TB drug distribution networks; and providing technical assistance to countries to increase the coverage and quality of TB services.

¹⁰ http://www.who.int/tb/publications/global_report/gtbr14_main_text.pdf?ua=1

MEASURING SUCCESS

In implementing this TB Strategy (2015–2019), the U.S. Government seeks to:

- Reduce TB incidence by 25 percent compared to 2015 levels
- Successfully treat at least 13 million TB patients
- Maintain treatment success rates of 90 percent for individuals with drug-susceptible TB
- Initiate appropriate treatment for at least 360,000 individuals with drug-resistant TB
- Provide antiretroviral therapy (ART) to 100 percent of the people diagnosed with HIV and active TB

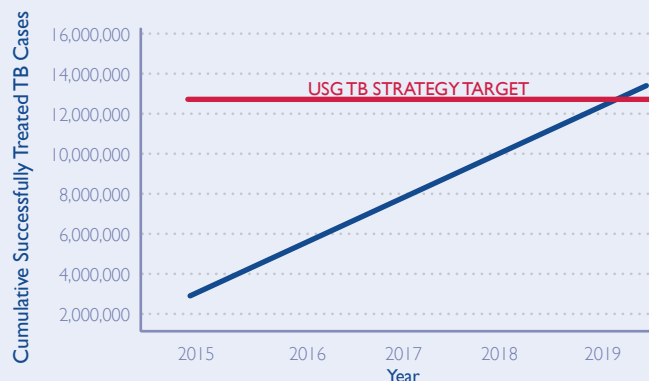
Achievement of these targets is essential for contributing to the WHO milestones for 2020 and 2030, as well as the ultimate goal of eliminating TB as a public health problem by 2050. (See table on page 13)

The U.S. Government will track a variety of indicators in supported countries that are linked to programmatic activities and relevant to our ultimate goal of ending TB-related mortality. USAID will regularly report on key outcome indicators in the subset of countries that receive TB funds during 2015–2019. Indicators will include those that measure TB incidence, TB mortality, the number of TB patients successfully treated, and the number of DR-TB patients initiating second-line treatment. PEPFAR resources will contribute to the percentage of individuals with HIV-associated TB initiating ART. A system for monitoring and improving the quality of care and treatment services will be implemented, and the data produced will be locally available, frequently analyzed, and used to inform new policies, approaches, and program design.

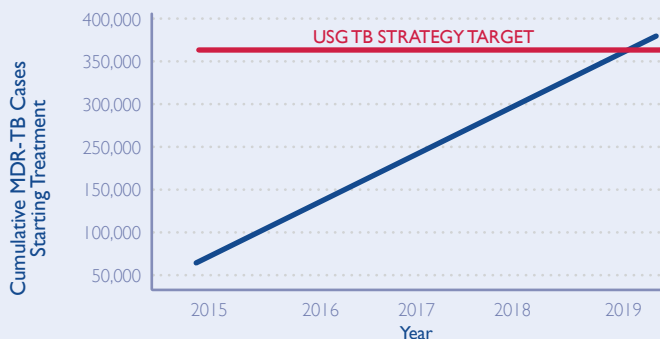
In calculating the targets to be achieved by implementing this strategy, the U.S. Government took into account current estimates and recent trends

in TB data, using the most updated information available in the WHO Global TB Database. The U.S. Government also considered nationally and internationally developed targets, such as those for TB incidence and mortality detailed in the WHO End TB Strategy¹¹ and adopted by the World Health Assembly in May 2014, and the targets for ART initiation set in the PEPFAR 90-90-90 strategy.¹² USAID used the countries that received U.S. Government TB funding in Fiscal Year (FY) 2014 as the basis for setting targets for 2015–2019.

Successfully treated TB cases in USAID-supported countries, 2015-2019



MDR-TB patients initiating second-line therapy in USAID-supported countries, 2015-2019



11 http://www.who.int/tb/post2015_strategy/en/

12 <http://www.unaids.org/en/resources/documents/2014/90-90-90>

U.S. Government Strategic Framework – Medium- and Long-Term Outcomes

<p>IMPACT</p>	<p>A World Free of TB</p>			
<p>LONG-TERM OUTCOMES</p>	<p>Reduce TB incidence rate by 90% by 2035 Reduce TB mortality rate by 95% by 2035</p>			
<p>MEDIUM-TERM OUTCOMES (By 2019)</p>	<p>Reduce TB incidence rate by 25% Maintain treatment success rates of 90 percent for individuals with drug-susceptible TB Successfully treat at least 13 million TB patients Initiate treatment for 360,000 drug-resistant patients Provide ART for 100% of TB-HIV infected patients</p>			
<p>OBJECTIVES</p>	<p>Improve access to high-quality, patient-centered TB, DR-TB, and TB/HIV services</p>	<p>Prevent TB transmission and disease progression</p>	<p>Strengthen TB service delivery platforms</p>	<p>Accelerate research and innovation</p>

TECHNICAL INTERVENTIONS

OBJECTIVE I. IMPROVE ACCESS TO HIGH-QUALITY, PATIENT-CENTERED TB, DR-TB, AND TB/HIV SERVICES

To reach our ultimate goal of a world free of TB, we must work with the global community to achieve universal access to high-quality, patient-centered services for TB, DR-TB, or TB-HIV. Universal access to TB services is defined as the availability of TB prevention, diagnosis, and treatment services to every individual who resides in a country. Access should not result in undue financial hardship for the affected individual or his or her household. Also, affected communities should be involved and engaged in the design and distribution of services.

To achieve this objective, we must identify and address potential challenges to access, including geographic coverage of healthcare facilities offering TB services, hours of operation, cost of TB services, and social stigma. The U.S. Government will help countries supported through our bilateral TB programs to develop national and sub-national approaches that ensure populations at high risk of TB have access to TB services in local facilities.

Improved access to TB services will be achieved through the development and implementation of three interventions:

- Support for an enabling environment including social support packages
- Expansion and strengthening of a comprehensive, high-quality diagnostic network
- Development of a patient-centered care and treatment approach

A. ENABLING ENVIRONMENT

An important component to achieve universal access to TB services is the creation of an enabling environment that promotes and encourages the identification of all individuals with symptoms associated with TB; rapid, accurate evaluation for and diagnosis of TB; and early initiation and successful completion of TB treatment. Specific activities will vary by country, community, and affected populations to address local epidemiology and social structure and be developed in a manner that strengthens healthcare facilities and support services to successfully reach and cure those affected by TB. U.S. Government efforts to create and support enabling environments will focus on improving the attitudes and behaviors of providers, communities, leaders, and individuals to facilitate appropriate TB care and treatment and reduce stigma in all care settings.

The U.S. Government will support a package of activities in each country based on national priorities including:

1. Identification and elimination of barriers to accessing TB services by those most at risk for TB
2. Services provided according to national guidelines by all care providers to all those at risk
3. Integration of patient-centered approaches into existing TB services to improve service quality and accessibility across all care providers
4. Engagement of leaders, representatives of key populations, and both public and private health providers in encouraging and supporting early and active case finding and care to enhance treatment completion

Workers participate in a practical exercise on Xpert data in Kazakhstan. (Photo by KNCV)



B. COMPREHENSIVE, HIGH-QUALITY DIAGNOSTIC NETWORK

Universal access to TB care is dependent upon the existence of a comprehensive and high-quality TB diagnostic network that includes microscopy, culture, drug susceptibility testing, and the use of molecular and radiological assessments at appropriate, accessible points of care. Strong laboratory networks are needed and must be adaptable and able to incorporate new, efficient, and effective technologies as they become available. Diagnostic services should be easily available and affordable to all individuals and tailored to the needs and characteristics of the

population or community served (e.g., urban slums, mines, workplaces, schools, prisons). A particular focus should be on improving diagnosis for TB in children. Diagnostic networks should integrate all public and private laboratories from the community to the national level into a quality-assured system.

The U.S. Government will intensify support for laboratory accreditation as one means of assuring high-quality TB diagnostic services. Efficient and effective utilization of TB diagnostic tools will be guided by appropriate diagnostic algorithms for TB and DR-TB. These algorithms should be designed to incorporate new tools as they become available.

The systems will ensure that patients in HIV clinics and other healthcare settings are regularly screened for TB and have access to appropriate diagnostic testing and rapid follow-up on test results. Laboratory systems will be strategically linked to treatment sites and facilities to facilitate the rapid initiation of treatment and reporting of results to clinicians to enable timely and effective treatment, minimize patient discomfort, optimize utilization, and prevent attrition. Network logistics and transport systems will function smoothly and seamlessly to maximize the forecasting, procurement, collection, and transport mechanisms.

Through its bilateral and multilateral investments, the U.S. Government will support the development and maintenance of comprehensive, high-quality diagnostic networks. A particular focus of the U.S. Government's Global TB Strategy will be to ensure that private laboratories and services for TB, DR-TB, and TB-HIV screening use the same quality assurance mechanisms as laboratories within the public health system and are linked to a larger, comprehensive laboratory network. The U.S. Government will support country and local efforts to rationalize diagnostic networks and the implementation of new technologies to optimize the identification of TB cases and make the best use of available resources. The U.S. Government will further support strong monitoring and evaluation systems, so countries can identify weaknesses in their systems and provide support where most needed.

C. PATIENT-CENTERED CARE AND TREATMENT

Every individual deserves high-quality TB, DR-TB, and TB-HIV care and treatment that optimizes his or her chance of success. Patient-centered care and treatment puts the individual at the center of all activities and strives to meet his or her specific needs. It requires an ongoing and in-depth partnership between healthcare providers and the patient and his or her family and community, to

identify and address a full range of individual needs and preferences.

Consistent with the WHO's End TB Strategy, the U.S. Government will support a patient-centered approach to TB services in which individuals with TB and their families participate in the design and implementation of care and treatment services in an attempt to identify, avoid, and remove barriers. The U.S. Government will support the collection, analysis, and use of quality-assured data and technologies, such as mobile devices and geographic information services, to ascertain the best locations for new care and treatment sites and/or existing sites that should be strengthened, so appropriate services are widely and easily accessible. The U.S. Government will also support the integration of TB, DR-TB, and HIV diagnosis and treatment services within all appropriate healthcare settings to maximize efficiency, uptake, and successful outcomes. This will include the integration of TB services within maternal and child health settings, as well as TB screening and TB infection control in the scale-up of lifelong treatment for HIV-infected pregnant women and children. Ideally, the integration of services should extend to the management of other co-morbidities (e.g., malnutrition, diabetes mellitus, smoking, chronic obstructive lung disease) as justified by the local epidemiology, to facilitate a true patient-centered approach to comprehensive care.

TB care and treatment services should also include access and referral to supportive services such as counseling, social services, nutrition, and economic strengthening interventions (e.g., income-generating activities). The U.S. Government will support the provision of TB services tailored to the needs of the population/community served to address the epidemic. Such services should be made widely available in a variety of settings, including urban slums, workplaces, schools, mines, and prisons, and be provided free of charge or at a cost that does not cause unnecessary financial burden to the user. As new tools and evidence become available, the

U.S. Government will assist in their rapid deployment to improve the care, treatment, and support of individuals with TB, DR-TB, and TB-HIV. The U.S. Government will also support the implementation of robust monitoring and evaluation systems that enable countries to monitor and continually improve the quality of TB care and treatment services.

OBJECTIVE 2. PREVENT TB TRANSMISSION AND DISEASE PROGRESSION

Without intensified action to prevent the transmission of TB to uninfected individuals and without efforts to prevent the progression of latent TB infection (LTBI) to active disease, global TB targets will not be met. The U.S. Government recognizes that the best way to prevent TB is through early and accurate diagnosis and effective treatment of active TB. Until a vaccine that prevents infection and/or progression to active disease is available, the U.S. Government will support early and effective TB diagnosis and treatment as the primary focus of TB prevention efforts.

The U.S. Government will support a range of prevention activities, including:

- Strengthening targeted screening for active TB among high-risk individuals and groups
- Improving infection control interventions to prevent transmission in congregate settings
- Screening for and treatment of LTBI to reduce the risk of progression to active TB among individuals with or at greatest risk to develop TB

A. TARGETED SCREENING FOR ACTIVE TB

Innovative strategies are necessary to screen and evaluate individuals who are at high risk for active TB, including contacts of persons with infectious TB and those living in social circumstances in which there is a high prevalence of TB. Systematic

screening of individuals in these groups can improve early detection of active TB, early initiation of TB treatment, and the likelihood of successful treatment, all of which will decrease transmission to others and ultimately lower TB incidence, prevalence, and mortality rates. Systematic screening, when accompanied by prompt diagnosis and treatment, leads to reduced TB transmission by shortening the period during which an individual with TB is infectious – treatment as prevention. Accordingly, the U.S. Government will focus TB prevention efforts to find the missing cases through:

1. Improving contact investigation and follow-up interventions and treatment
2. Screening high-risk individuals and individuals in high-risk congregate settings
3. Identifying individuals with LTBI who have specific risk factors for progression to disease
4. Identifying individual and community-level risk factors and socioeconomic determinants that need to be addressed to prevent TB transmission in a specific population

B. INFECTION CONTROL

The foundation of TB infection control and prevention is early and rapid diagnosis of active TB cases and prompt initiation of treatment, so patients with TB quickly become non-infectious and are cured. As outlined previously, this is a key element of the U.S. Government's Global TB Strategy. The U.S. Government will support the implementation of key infection control activities, including:

1. Administrative and environmental/engineering controls
2. Use of personal protective equipment
3. Healthcare worker surveillance, screening and preventive measures
4. Broader community interventions aimed at interrupting the chain of transmission in high-risk settings or among high-risk populations

The U.S. Government will support the implementation of infection control recommendations at national, facility, community, congregate, and household settings and will tailor advocacy and communication efforts to these different levels. These efforts will include a concentration in high HIV burden settings including HIV clinics serving immunocompromised patients. In order to better understand the contribution of specific infection control measures to overall TB prevention and care and improve our programming, we will work with partners to develop, implement, and monitor outcome indicators for infection control measures and use the information gained to refine infection control policies, programs, and guidelines.

C. MANAGEMENT OF LATENT TB INFECTION

There is a strong evidence base supporting the treatment of persons with LTBI to prevent progression to active TB disease, especially for children and persons with HIV infection or other immunosuppressive conditions. Individuals with LTBI constitute an important reservoir of not only active TB, but also potential TB transmission. If someone with LTBI progresses to active TB, he or she will not only require services to address personal health issues, but also will likely become an agent for transmission of TB within his or her community. This cycle will continue for decades unless the risk of progression from LTBI to active disease is mitigated through improved LTBI detection, treatment initiation, and adherence; alleviation of the underlying clinical and population risk factors for progression; and/or a post-exposure vaccine. The U.S. Government will work with National TB Programs and National HIV Programs to determine which LTBI strategies should be prioritized, based on local epidemiology, high-risk populations, and care settings.

Despite the importance of addressing LTBI, many challenges to implementation of LTBI programs remain. There is no reliable gold standard to diagnose LTBI, and the decision to treat individuals with LTBI is largely based on a combination of imprecise tests, identification of risk factors for progression to active disease, and a determination of whether the benefits of treatment outweigh the risks, such as side effects. As a result, coverage and adherence to LTBI treatment is poor. The U.S. Government's Global TB Strategy will work with countries to support targeted introduction and implementation of adherence and management strategies for the treatment of individuals with LTBI.

OBJECTIVE 3. STRENGTHEN TB SERVICE DELIVERY PLATFORMS

TB services are implemented and delivered at all levels of the health system from primary to tertiary. The national health system is the platform through which TB prevention, diagnosis, and treatment activities are introduced, expanded, and strengthened. It is, therefore, clear that the quality of this system has a direct impact on the provision of high-quality, patient-centered TB services. Although the U.S. Government's Global TB Strategy is not designed or able to address entire health systems, our efforts focus on strengthening key service delivery platforms for TB service delivery. We will assist countries to identify populations at high risk of TB and support improvements to the health settings in which they seek care. This will require a multi-sectoral approach and engagement of a range of partners including not only traditional government health agencies, but also affected communities and community organizations and the private sector – for-profit and non-profit. Through these partnerships, the U.S. Government will focus on strengthening drug policy and management, monitoring and evaluation systems, and human

resource development. There is inherent overlap and linkages between the objectives as each contributes to the others.

The U.S. Government's work to strengthen TB service delivery platforms will focus on:

- Increasing political commitment and leadership
- Improving and expanding comprehensive partnerships and informed community involvement
- Strengthening drug and commodity management
- Improving quality data, surveillance, and monitoring and evaluation
- Developing human resources

A. POLITICAL COMMITMENT AND LEADERSHIP

Scaling up sustainable interventions for TB care and treatment requires high-level political commitment and adequate financial and human resources. Central coordination under the national government's stewardship is essential. In supported countries, the U.S. Government will support government-led processes to develop NSPs for combating TB, as part of a comprehensive national health sector plan. NSPs should take into consideration the country's TB epidemic and its health system structure and functions, including procurement and supply systems, resource availability, regulatory policies, and private sector and community engagement. NSPs should be ambitious and comprehensive and include a budgeted operational plan, monitoring and evaluation framework, and technical assistance scheme. The U.S. Government will support country-led implementation, governance, and management of national strategic plans. Specific areas of focus will include:

1. The development of policy frameworks
2. Support for adequate resource allocation and resource management

3. Evidence-based analysis and decision-making
4. Integration of insurance programs as well as social protection and poverty alleviation strategies

B. COMPREHENSIVE PARTNERSHIPS AND INFORMED COMMUNITY INVOLVEMENT

The U.S. Government believes that National TB Programs must involve affected communities and actively partner with civil society organizations and private stakeholders if they are to reach their potential. Accordingly, the U.S. Government will support national partnerships and coordination bodies that ensure appropriate representation and capacity or ability to strengthen programs.

The U.S. Government will facilitate sustainable partnerships across the health and social sectors and between these sectors and affected communities to develop a robust response to the TB epidemic. Efforts to fully utilize the unique skills and capabilities of civil society and other local organizations will be made so that TB programs can incorporate and harness the dynamism of them, especially in their work to reach vulnerable populations; mobilize communities; channel information in accessible and user-friendly formats; create demand for high-quality, patient-centered TB services; frame effective delivery models; and address other determinants of the TB epidemic. Partnerships with a range of organizations will be actively explored to ensure strong country led approaches.

The U.S. Government will also work closely with supported countries to reinforce successful implementation of Global Fund TB grants. We will use our technical and programmatic expertise to help countries develop strong Global Fund grant applications and implementation strategies to maximize the impact of Global Fund resources for TB.

C. DRUG AND COMMODITY MANAGEMENT SYSTEMS

An uninterrupted supply of effective, affordable, and quality-assured TB drugs is a vital element of every national TB program. The U.S. Government will continue to support country efforts to develop reliable procurement and distribution systems for all essential TB medicines and supplies. These systems should ensure that TB medicines and supplies reliably reach all relevant health facilities. To this end, the U.S. Government will help National TB Programs plan, procure, distribute, and maintain adequate drug stocks. The U.S. Government will further encourage countries to make TB medications available free of charge to all TB patients, not only because many patients are poor and find medicines difficult to afford, but also because treatment has benefits that extend to society. For example, cure prevents transmission to others, decreases overall health system costs, and minimizes reduction in gross national product (GNP) and individually affected household incomes.

The U.S. Government will also work to improve the appropriate utilization of TB drugs globally and at country level. Among other activities, we will support the development, implementation, and monitoring of legislation governing the use of TB drugs by all providers. The U.S. Government will introduce and strengthen pharmacovigilance systems that monitor adverse drug reactions to all TB medicines, especially new drugs and/or regimens that are introduced. We will also work to expand and improve the use of fixed dose combinations and other tools, such as patient kits. Lastly, the U.S. Government will support maintenance of a global supply of affordable, quality-assured TB medicines to ensure that all countries and their citizens are able to access life-saving drugs.

D. QUALITY DATA, SURVEILLANCE, AND MONITORING AND EVALUATION

TB surveillance systems to track notifications and deaths, coupled with a strong monitoring and evaluation system to gauge progress and identify areas for improvement, are critical components of a National TB Program. The U.S. Government will work with supported countries to develop and improve systems to track TB disease burden in high-risk settings and among high-risk groups, accurately monitor trends, and quickly detect any resurgence of TB, so corrective actions can be implemented. In addition, supported countries and partners will institute upgrades to their routine monitoring systems using standardized methods based on data of documented quality; these surveillance systems will also be better able to monitor progress towards NSP targets.

The U.S. Government strategy will strengthen TB case notification and vital registration systems, including integration of case management and surveillance systems, improvements in the use of data for decision-making and in monitoring and evaluation, and in the introduction and expansion of regulatory enforcement. As appropriate, and in line with NSPs, the U.S. Government will also support the introduction and scale-up of case-based and/or patient-based electronic recording and reporting systems to improve TB surveillance. As appropriate and needed, the U.S. Government will continue to invest in national and global surveys and other data gathering to inform programs and policies.

E. HUMAN RESOURCES DEVELOPMENT

One of the most neglected but most important components of a successful TB program is the recruitment, development, and retention of qualified, skilled, and caring personnel. The development

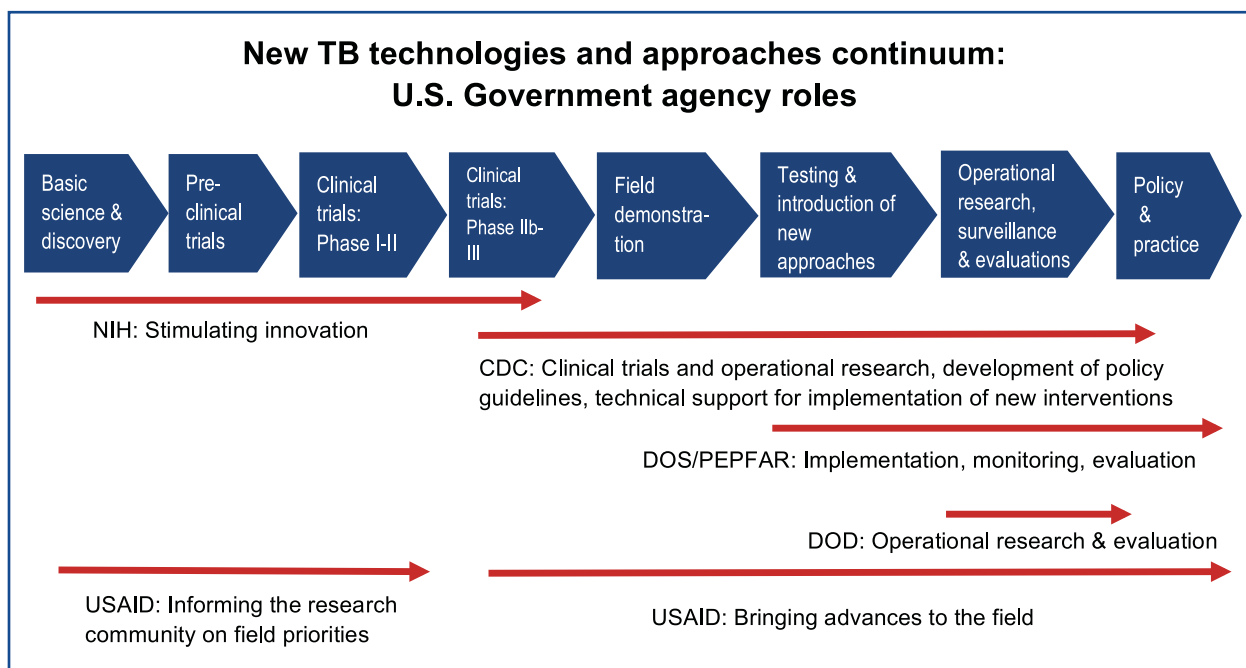
and management of human resources is critical to providing high-quality, patient-centered TB care. The ability of a country to meet its health goals depends largely on the knowledge, skills, motivation, dedication, and appropriate deployment of the workers responsible for organizing and delivering health services. Many countries, however, lack sufficient human resources to deliver even the most basic of health interventions for a variety of reasons, including limited education and training capacity; migration of health workers within and across countries; mismatched skills and needs at the facility level; and demographic disparities. The U.S. Government will work with countries to develop and improve human resources for combating TB by:

1. Developing and implementing national policies and plans for improving human resources for health

2. Integrating disease management at the primary health facility level
3. Promoting task shifting to increase the efficient and effective use of existing human resources
4. Developing comprehensive approaches to pre-service and in-service clinical training, especially among those serving poor and neglected populations

OBJECTIVE 4. ACCELERATE RESEARCH AND INNOVATION

Global progress in the development and introduction of new tools and approaches for TB has been slow. However, biomedical research, largely supported through the NIH, has made great strides in our understanding of TB and the pathogen that causes it, and the translation of research funding into the



development of new drugs, vaccines, and diagnostics. Nevertheless, new tools are not yet widely available and further progress requires a two-pronged approach. Specifically, the U.S. Government will:

1. Continue support for fundamental research the development of new tools and approaches for detecting, treating, and preventing TB
2. Augment its efforts to improve program impact and introduction of new tools through operational and implementation research

Given the limited global resources currently focused on TB research, the U.S. Government will work to leverage existing research sites, programs, and study capacity of U.S. Government agencies, as well as those of our domestic and international partners, to examine critical TB questions and potential ways to translate research findings into program practice. In addition, efforts to strengthen the pathway from biomedical investigations to implementation need to be intensified. The successful interventions will be rapidly introduced and scaled up to ensure access to benefit those most in need of the new tools and practices. The U.S. Government will convene and support research partnerships at all levels (global to community, public, and private) to improve the likelihood of successful introduction and broad implementation of useful scientific advancements.

U.S. Government agencies collaborate on the development, testing, roll-out, and assessment of new tools and approaches to combating TB. The figure on page 21 demonstrates how various agencies work together to bring research findings to the field.

A. NEW TOOLS/APPROACHES TO PREVENT, DETECT, AND TREAT TB MORE EFFECTIVELY

The U.S. Government is committed to supporting the development and uptake of new, more effective

tools and approaches to preventing, detecting, and treating TB. Over the next five years, the U.S. Government will:

1. Support the development, introduction, and implementation of shorter, less toxic, and more effective treatment regimens for drug-susceptible TB and DR-TB in adults and children
2. Collaborate with national and international partners, including WHO, on the introduction of new drugs for adults and children into existing or new treatment regimens approved at the national level
3. Promote the evaluation of biomarkers to diagnose TB infection and TB disease and to monitor disease progression and treatment outcomes
4. Support studies to evaluate the accuracy and feasibility of promising diagnostic tools for TB and DR-TB in adults and children with an emphasis on point-of-care products
5. Evaluate the programmatic impact of new tools
6. Examine the effectiveness of new and existing treatment regimens for LTBI
7. Support the development of TB vaccines to prevent TB disease

B. PERFORMANCE AND POLICY IMPROVEMENTS THROUGH IMPLEMENTATION RESEARCH

To improve TB program performance in each of the areas outlined in this strategy, the U.S. Government will continue to examine and evaluate the implications and outcomes of scalable interventions as they are rolled out in “real world” settings. The U.S. Government will also evaluate the cost-effectiveness of interventions to optimize TB service delivery, prevent new infections, and improve large-scale implementation. Research activities will be tailored to country contexts and will target improvements at the programmatic level.

LOOKING AHEAD

Through concentrated efforts in each of the key technical areas outlined in this strategy, the U.S. Government will continue to lead the global effort to reverse the TB epidemic. The U.S. Government will reach, treat, and cure more people with active TB, and prevent new cases through these interventions. With continued strong support from the U.S. Congress, sustained U.S. Government technical and programmatic leadership, and active engagement with affected countries, communities, and multilateral partners, the U.S. Government will successfully treat at least 13 million TB patients and reduce TB incidence by 25 percent by 2019. This will put the world on track to reach the globally agreed-upon targets for 2035, provide critical treatment to the poorest populations of the world, and ultimately eliminate TB as a global health threat.

