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Lantos-Hyde United States Government Tuberculosis Strategy



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ACRONYM LIST

CDC	Centers for Disease Control and Prevention
DOTS	Directly Observed Treatment, Short-course
GDF	Global TB Drug Facility
GHI	Global Health Initiative
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
FTBTF	Federal TB Task Force
HBC	High Burden Country
HHS	Department of Health and Human Services
ISTC	International Standards of TB Care
MDR	Multidrug-Resistant
NGO	Nongovernmental Organization
NIH	National Institutes of Health
NTP	National TB Program
OGAC	Office of the Global AIDS Coordinator
PEPFAR	President's Emergency Plan for AIDS Relief
PMDTB	Programmatic Management of Drug-Resistant TB
TB	Tuberculosis
USAID	United States Agency for International Development
USG	U.S. Government
WHO	World Health Organization
XDR	Extensively Drug Resistant

EXECUTIVE SUMMARY

Global Health Initiative – the Context

Last summer, the Congress approved the Lantos-Hyde U.S. Global Leadership Against HIV/AIDS Act – legislation that I was proud to co-sponsor as a U.S. Senator and now carry out as president. But, I also recognize that we will not be successful in our efforts to end deaths from AIDS, malaria, and tuberculosis unless we do more to improve health systems around the world, focus our efforts on child and maternal health, and ensure that best practices drive the funding for these programs.

– President Obama, announcing the Global Health Initiative, May 5, 2009

Through the Global Health Initiative (GHI), the United States will invest \$63 billion over six years to help partner countries improve health outcomes, with a particular focus on improving the health of women, newborns and children. The GHI is a global commitment to invest in healthy and productive lives, building upon, and expanding, the U.S. Government’s successes in addressing specific diseases and issues. Addressing wide-ranging health needs in partnership with governments, communities and other partners represents an ambitious agenda that can be met only if we work together, aligned toward common goals, with a commitment to fundamentally improve the way we do business.

The GHI aims to maximize the impact the United States achieves for every health dollar it invests in a sustainable way. The GHI’s business model is based on implementing a woman- and girl-centered approach; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; encouraging country ownership and investing in country-led plans and health systems; improving metrics, monitoring and evaluation; and promoting research and innovation.

The GHI will build on the United States’ accomplishments in global health, accelerating progress in health delivery and investing in a more lasting and shared approach through the strengthening of health systems.

The U.S. Government Tuberculosis Strategy

Tuberculosis (TB) is a global health emergency that must be addressed with immediate and aggressive action. This disease is a major worldwide public health threat that kills approximately 1.8 million people each year, the majority of whom are in the lowest income quintile. In addition, more than one-third of the world’s population is thought to be infected with latent TB. While TB is found in almost every country in the world, 80 percent of the estimated cases occur in 22 high-burden countries. Multidrug-resistant TB (MDR-TB), including extensively drug-resistant TB (XDR-TB), threatens to undermine recent progress in controlling the disease.

In response to the urgent need to control the spread of TB, the U.S. Congress passed the 2008 Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act (Reauthorization Act) supporting a substantial increase in U.S. Government (USG) funding for TB treatment and control over a five-year period. The Reauthorization Act requests the development of a USG Global Tuberculosis Strategy. In addition, the Reauthorization Act states that the United States should support the objectives of the Global Plan to STOP TB, including the achievement of the following goals: reduce by half the TB death and disease burden from the 1990 baseline; sustain or exceed the detection of at least 70 percent of sputum smear-positive cases of TB and the successful treatment of at least 85 percent of cases detected in countries with established United States Agency for International Development (USAID) tuberculosis programs; the successful treatment of 4.5 million new sputum smear-positive TB patients under Directly Observed Treatment, Short-course (DOTS) programs

by 2013, primarily through support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and the diagnosis and treatment of 90,000 new MDR-TB cases by 2013, and provide additional treatment through coordinated multilateral efforts.¹ The GHI and the Reauthorization Act provide the framework for the USG TB program's goals and objectives.

As part of the GHI, the goals and projected targets for the USG TB program, 2009–2014, are as follows:

- Contributing to a 50 percent reduction in TB deaths and disease burden from the 1990 baseline;
- Sustaining or exceeding the detection of at least 70 percent of sputum smear-positive cases of TB and successfully treating at least 85 percent of cases detected in countries with established USG tuberculosis programs;
- Successfully treating 2.6 million new sputum smear-positive TB patients under DOTS programs by 2014, primarily through support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and
- Diagnosing and initiating treatment of at least 57,200 new MDR-TB cases by 2014 and providing additional treatment through coordinated multilateral efforts.

This strategy outlines conservative treatment targets based upon the total estimated costs of existing drugs, diagnostic tests and services to diagnose and treat basic TB and MDR-TB. The treatment of 57,200 cases of MDR-TB represents a significant increase compared to the 6,000 cases of MDR-TB that were treated according to international control standards in 2008. These targets could be surpassed substantially with the introduction of new technologies and enhanced donor contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and other TB control programs. We are working with public-private partnerships on the development and introduction of new diagnostics and drugs, and once clinical trials and country-level evaluations are completed, we anticipate that these new tools will help to accelerate TB case detection and shorten treatment duration. In addition, country-level evaluations of more rapid tests for MDR-TB are already underway in numerous countries, and the clinical trials on several new drugs to treat TB are promising. These developments could substantially increase our impact.

The USG will achieve these targets through the following key interventions:

1. *Accelerated detection and treatment of TB in up to 25 countries:* The USG will work to ensure that there is full coverage of DOTS services; laboratory networks are fully functional; effective monitoring and surveillance are in place; the private sector, communities, and nongovernmental organizations are fully engaged; new tools are introduced; and women-centered approaches are used.
2. *Scaled up prevention and treatment of MDR-TB:* The USG will intensify its efforts to combat MDR-TB by expanding diagnosis and treatment, introducing more rapid diagnostic tools, implementing infection control measures, conducting routine surveillance at the country level, and improving access to quality second-line drugs.
3. *Expanded coverage of interventions for TB-HIV co-infection in coordination with USG HIV efforts under the President's Emergency Plan for AIDS Relief (PEPFAR):* In countries with a high burden of HIV/AIDS, the USG will work with PEPFAR programs to ensure that all TB patients are tested for HIV and referred and that the "Three Is" (Intensified TB case-finding, Isoniazid preventive therapy, and TB Infection control) are implemented.
4. *Improvements in health systems:* The USG will accelerate its efforts to strengthen health systems particularly by improving supply chain management systems; strengthening laboratory systems;

¹ Lantos Hyde Reauthorization Act, sec. 302, Assistance to Combat Tuberculosis.

increasing access to tuberculosis services through expansion of partnerships with private- and public-sector providers; and improving overall information management systems. Human resource planning and development will be accelerated as part of integrated efforts in health workforce development.

The achievement of these goals is possible through the consolidated and coordinated efforts of all USG agencies working together. USAID is the lead agency in international TB control. USAID provides bilateral assistance to national TB control programs to support scale-up of the STOP TB Strategy at the country level. USAID works closely with the Office of the Global AIDS Coordinator (OGAC) at the Department of State; OGAC is the lead for the USG response to TB-HIV co-infection as part of PEPFAR. The U.S. Centers for Disease Control and Prevention (CDC) provides technical support and assistance to ministries of health and USG programs for global TB control including both USAID and OGAC. The National Institutes of Health (NIH) leads the international biomedical research effort. This team of USG agencies will collaborate to implement this strategy.

In addition to strengthening health systems as described above, the USG TB program will implement the following development principles as reflected in the GHI.

- *Implement a women- and girl-centered approach:* The USG will improve the detection of TB among women and develop innovative ways to reduce gender barriers to quality TB treatment and care, particularly when implementing models of community DOTS, intensified case finding, and interventions to increase access to services.
- *Increase impact through strategic coordination and integration:* The USG will foster integration with other programs where appropriate and improve coordination among existing USG health agencies and programs, as well as with other USG development programs outside of health (e.g., food security and basic education).
- *Strengthen and leverage key multilateral organizations, global health partnerships and private-sector engagement:* The USG will actively participate in the Stop TB Partnership, coordinate with the Global Fund, and closely cooperate with other key partners such as WHO and the World Bank. The USG cannot achieve these goals alone and remains committed to active engagement with donors and the leveraging of existing donor resources.
- *Encourage country ownership and invest in country-led plans:* The USG will work with National TB Programs (NTPs) at the country level to build local capacity, and provide support that is fully aligned with national strategic plans as well as with the Global Plan and the Stop TB Strategy.
- *Improve monitoring, metrics and evaluation:* The USG will assess outcomes and measure progress toward results by developing indicators, data sources and measurement techniques.
- *Promote research and innovation:* The USG will invest in new tools and approaches that are less labor intensive, more cost-effective, of greater efficacy, and can be delivered closer to the patients, thereby improving case detection and treatment success rates.

I. GLOBAL HEALTH INITIATIVE

Through the Global Health Initiative (GHI), the United States will invest \$63 billion over six years to help partner countries improve health outcomes, with a particular focus on improving the health of women, newborns and children. The GHI is a global commitment to invest in healthy and productive lives, building upon, and expanding, the U.S. Government's (USG's) successes in addressing specific diseases and issues. Addressing wide-ranging health needs in partnership with governments, communities and other partners represents an ambitious agenda that can be met only if we work together, aligned toward common goals, with a commitment to fundamentally improve the way we do business.

The GHI aims to maximize the impact the United States achieves for every health dollar it invests, in a sustainable way. The GHI's business model is based on implementing a woman- and girl-centered approach; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; encouraging country ownership and investing in country-led plans and health systems; improving metrics, monitoring and evaluation; and promoting research and innovation.

The GHI will build on the United States' accomplishments in global health, accelerating progress in health delivery and investing in a more lasting and shared approach through the strengthening of health systems.

II. GOALS OF THE USG TUBERCULOSIS PROGRAM

The U.S. Congress demonstrated its continued firm commitment to tuberculosis (TB) control with the passage in 2008 of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (P.L. 110-293) (herein referred to as the Reauthorization Act) . This Reauthorization Act authorized increased resources for TB control over the next five years and outlined the U.S. Government’s goals and targets for TB control. As stated in the Reauthorization Act, the USG strives to support activities described in the *Global Plan to Stop TB* and will contribute significantly to the global reduction of morbidity and mortality associated with tuberculosis. Section 302 of the Reauthorization Act states that:

“In all countries in which the Government of the United States has established development programs, particularly in countries with high rates of tuberculosis, the United States should support the Objectives of the Global Plan to Stop TB, including through the achievement of the following goals:

- (1) Reduce by half the tuberculosis death and disease burden from the 1990 baseline; and*
- (2) Sustain or exceed the detection of at least 70 percent of sputum smear-positive cases of tuberculosis and the successful treatment of at least 85 percent of cases detected in countries with established USAID tuberculosis programs.*
- (3) In support of the Global Plan to Stop TB, the President shall establish a comprehensive five-year U.S. strategy to expand and improve U.S. efforts to combat tuberculosis globally, including a plan to support –*
 - (A) The successful treatment of 4.5 million new sputum smear-positive TB patients under DOTS programs by 2013, primarily through support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and*
 - (B) The diagnosis and treatment of 90,000 new multidrug-resistant tuberculosis (MDR-TB) cases by 2013 and provide additional treatment through coordinated multilateral efforts.”*

The GHI and the Reauthorization Act provide the framework for the USG TB program’s goals and objectives. As part of the GHI, the goals and projected targets for the USG TB program, 2009–2014, are as follows:

- Contributing to a 50 percent reduction in TB deaths and disease burden from the 1990 baseline;
- Sustaining or exceeding the detection of at least 70 percent of sputum smear-positive cases of TB and successfully treating at least 85 percent of cases detected in countries with established USG tuberculosis programs;
- Successfully treating 2.6 million new sputum smear-positive TB patients under Directly Observed Treatment, Short-course (DOTS) programs by 2014, primarily through support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and
- Diagnosing and initiating treatment of at least 57,200 new MDR-TB cases by 2014 and providing additional treatment through coordinated multilateral efforts.

This strategy outlines conservative treatment targets based upon the total estimated costs of existing drugs, diagnostic tests and services to diagnose and treat basic TB and MDR-TB. The treatment of 57,200 cases of MDR-TB represents a significant increase compared to the 6,000 cases of MDR-TB that were treated according to international standards in 2008. These targets could be surpassed substantially with the introduction of new technologies and enhanced donor contributions to the Global Fund and other TB control programs. We are working with public-private partnerships on the development, licensing, and

introduction of new diagnostics, vaccines and drugs. Once these activities are completed, we anticipate that these new tools will help to accelerate TB case detection and shorten treatment duration. In addition, country-level evaluations of more rapid tests for MDR-TB are already underway in numerous countries, and early clinical trials on several new drugs to treat TB are promising. Trials with new vaccine candidates are also underway and are providing critical information about the development needs of preventive measures for TB. These developments could substantially increase our impact.

In order to achieve these goals and targets, the USG will accelerate implementation of proven, cost-effective interventions designed to prevent the further spread of TB and drug-resistant TB and reduce morbidity and deaths. Building on a strong foundation of support for improved TB programs in a number of countries, the USG will:

1. Accelerate detection and treatment of TB for all patients, including children;
2. Scale up prevention and treatment of MDR-TB;
3. Expand coverage of interventions for TB-HIV co-infection in coordination with USG HIV efforts under PEPFAR; and
4. Improve the overall health systems where we work.

III. OVERVIEW OF GLOBAL TB SITUATION

Tuberculosis is a global health emergency that must be addressed with immediate and aggressive action. This disease is a major worldwide public health threat that kills approximately 1.8 million people each year. The majority of these deaths occur among those in the lowest income quintile. In addition, over one-third of the world's population is believed to have latent TB infection. While TB can be found in almost every country in the world, 80 percent of the estimated cases occur in 22 developing and/or transitioning countries.

Globally, TB was considered to be controlled during the twentieth century until the 1980s, when the world saw a rapid increase in the number of TB cases. Since then, the number of new cases of TB continues to rise globally in absolute terms reaching an estimated 9.4 million in 2008, as a result of population growth.² While the total number of new cases is increasing, the number of cases per capita is falling slightly, suggesting that there is progress toward TB control. Due to coordinated and collaborative efforts, global rates have fallen from 142 new TB cases per 100,000 population in 2004 to 139 cases per 100,000 population in 2008. This trend has been found in all regions with the exceptions of African countries with a high prevalence of HIV³ and Eastern Europe, where rates have changed little.

TB affects women in various ways. According to the World Health Organization (WHO), 500,000 women died and 3.6 million became sick from TB in 2008. TB is the third leading cause of death among women of reproductive age. Once infected with TB, women of reproductive age are more susceptible to developing TB disease than men of the same age.⁴ Despite this, health systems do not reach women with TB effectively; case detection rates are often lower among women, and women may have greater delays in diagnosis, possibly due to difficulties accessing care. Also, when a mother is ill with TB, the family suffers. Women report a decreased availability to spend time on child care, and approximately 30,000 children are forced to leave school each year because of parental TB. Evidence also suggests that TB has many reproductive health implications, causing infertility, and increasing the risk of prematurity, obstetric morbidity, and low birth weight.

The TB epidemic has been further compounded by its complex interaction with HIV/AIDS. TB is the leading cause of death among people with HIV/AIDS in sub-Saharan Africa, and of the 1.8 million annual TB deaths, approximately 500,000 are among persons who were HIV positive. Among new TB cases in 2008, an estimated 1.4 million or 15 percent were HIV positive, with the greatest burden of HIV-positive TB cases found in Africa (78 percent) followed by South East Asia (13 percent). HIV infection is the most significant risk factor for a latent TB infection to convert to active TB and HIV-positive persons are 20 to 40 times more likely to develop TB than an HIV-negative person.

Tuberculosis is more than an individual and public health problem; it is also a disease that has widespread economic effects. The disease threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development. The direct cost to families seeking diagnosis, treatment and care for TB is often high; mean household spending on TB care for items such as transport to the health facilities as well as fees for medications can be as much as 20 percent of total annual household income.⁵ This does not include lost wages and decreased productivity of family members caring for those who are sick. A World Bank study estimated that without the provision of effective TB treatment, the economic cost of TB-related deaths (including HIV co-infection) in sub-

² Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 1

³ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 25

⁴ 2009 Tuberculosis Women and TB Fact Sheet, WHO.

⁵ Laxminarayan, R., Klein, E., Dye, C., Floyd, K., Darley, S., Adeyi, O. Economic Benefit of Tuberculosis Control. The World Bank, Human Development Network, Health Nutrition and Population Team. August 2007, p 1.

Saharan Africa from 2006 to 2015 would be US\$519 billion. However, if these countries offered effective and consistent treatment to TB patients, their economic benefits could exceed their costs nine-fold.⁶

In 2000, the global health community launched the Stop TB Partnership to galvanize support for TB control. The Stop TB Partnership is the lead international body in the global fight against TB, and the U.S. Government is a prominent member of the Partnership. The first *Global Plan 2001–2005* catalyzed governments and donors to address TB collaboratively and established two key global targets: 70 percent TB case detection and 85 percent treatment success rates in new sputum smear-positive pulmonary TB cases,⁷ to be achieved by the year 2005 in the 22 high-burden countries (HBCs)⁸. Between 2001 and 2005, case detection increased from 32 percent to 58 percent and treatment success increased from 82 percent to 84 percent in DOTS⁹ programs globally.

A Call for Action

Building on the achievements of the first *Global Plan*, in January 2006, The Stop TB Partnership launched the *Actions For Life – The Global Plan to Stop TB 2006–2015*, which includes the Millennium Development Goal (MDGs) of halting and beginning to reverse the incidence of TB by 2015, as well as the more ambitious Stop TB Partnership targets of reducing TB prevalence and deaths by 50 percent by 2015 relative to the 1990 baseline. The second *Global Plan* describes the actions and resources needed to combat the epidemic and achieve the above targets. The *Global Plan* also articulates the need for biomedical research in TB as an integral part of a global strategy resulting in modern interventions and new tools to control TB.

The key stakeholders in the Stop TB Partnership recognized that DOTS would not be enough to achieve the targets set forth by the second *Global Plan*. In 2006, the World Health Organization (WHO) and the Stop TB Partnership launched a more robust scientific and technical approach building on DOTS, known as the Stop TB Strategy.

The Stop TB Strategy

1. Pursue high quality DOTS expansion and enhancement
2. Address TB-HIV, MDR-TB and the needs of poor and vulnerable populations
3. Contribute to health system strengthening based on primary health care
4. Engage all care providers
5. Empower people with TB and communities through partnerships
6. Enable and promote research

Since the establishment of second *Global Plan* goals, there has been steady progress in the fight against TB. By the end of 2007, 97 percent of the world's population lived in countries that had adopted DOTS. Globally, case detection in DOTS programs reached 61 percent in 2008, and the treatment success rate was sustained at 87 percent in 2009.¹⁰ India, the world's highest TB-burden country, recently reported research findings documenting a 50 percent decline in TB mortality due to the rapid scale-up of DOTS and implementation of the Stop TB Strategy. Furthermore, for the first time since the introduction of the bacille Calmette-Guérin (BCG) vaccine, which has a very limited effect in reducing the transmission of TB, and the discovery of the currently used TB therapies, new candidate tools including new treatments,

⁶ Economic Benefit of Tuberculosis Control. August 2007, p. 16.

⁷ Sputum smear positive TB cases are the most infectious and therefore the most responsible for transmission of the disease.

⁸ 22 high burden countries (HBCs) account for 80% of the global TB burden.

⁹ Directly Observed Treatment Shortcourse (DOTS) consists of five components: political commitment with increased and sustained funding; case detection through quality-assured bacteriology; standardized treatment, with supervision and patient support; an effective drug supply and management system; and a monitoring and evaluation system, including impact measurement.

¹⁰ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 1

diagnostics, and vaccine candidates, are being developed. These biomedical advances are a critical component of modernizing the diagnostic, preventive and care armamentarium that is currently available for TB and deployed under the DOTS program.

Challenges

Despite this progress, analysis of the global TB trends indicates that implementation of the Stop TB Strategy is slower than needed and many challenges remain. Case detection is lagging in the WHO's Eastern Mediterranean and Africa regions in particular, where case detection rates are only 57 percent and 47 percent respectively. Only three of the 22 HBCs (China, Indonesia, and Tanzania) have achieved or surpassed the targets for both case detection and treatment success thus far.¹¹ While overall treatment success in DOTS programs is 87 percent (2007 cohort), regional disparities reveal alarmingly low rates of treatment success in Europe (67 percent) and Africa (79 percent), due in part to MDR-TB¹² and TB-HIV co-infection.

Compounding the slow progress in improving case detection is the rise of drug-resistant TB. Drug-resistant TB is caused by inadequate or inconsistent treatment. It is a serious and growing problem that threatens to undermine years of progress in TB control. In 2008, there were an estimated 440,000¹³ cases of MDR-TB, and cumulatively to date, 58 countries have confirmed at least one case of extensively drug-resistant¹⁴ (XDR) TB. The MDR-TB cases in India and China combined account for nearly 50 percent of the estimated global burden. Access to good quality services to diagnose and treat drug-resistant TB continues to be insufficient. In 2008, around 6,000 (20 percent) of the 30,000 MDR-TB cases notified to WHO received treatment through programs or projects approved by the Green Light Committee (GLC) – a proportion that is significantly lower than the global targets.^{15,16} Limited laboratory and human resource capacity to diagnose and treat patients and an inadequate supply of quality-assured second-line anti-TB drugs are some of the factors slowing progress in expanding global MDR-TB detection and treatment. Enhanced human resource capacity to ensure completion of treatment and improved therapies and diagnostics that simplify and expedite patient identification will be necessary to meet the targets of the *Global Plan* for both drug sensitive and drug-resistant TB.

Implementation of TB-HIV components of the Stop TB Strategy has not been fully achieved. While the absolute number of TB patients with known HIV status increased to almost 1.4 million in 2008, compared to 1.2 million in 2007, rates of HIV testing remain sub-optimal in Africa (45 percent) and other regions.¹⁷ Insufficient HIV testing among individuals with TB remains a challenge overall. Just 22 percent of TB patients were tested for HIV in 2008, far below the *Global Plan* target of 65 percent for 2008.¹⁸ While the provision of cotrimoxazole preventive therapy to persons with TB-HIV co-infection reached 71 percent globally in 2008, the initiation of antiretroviral (ART) to persons with TB-HIV co-infection continues to lag. Only 32 percent of identified HIV-positive TB patients were started on ART.¹⁹

Other key interventions, such as engagement of private-sector providers and key community stakeholders, have not been scaled up in many countries. Fourteen of the 22 HBCs reported significantly expanded partnerships with private-sector providers to offer TB treatment in 2007, and there is scarce information

¹¹ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, pp. 11-12

¹² MDR TB is a form of TB that is resistant to at least isoniazid and rifampicin, the two most important first line anti-TB drugs.

¹³ Multidrug and extensively drug-resistant TB (M/XDR) – 2010 Global Report on Surveillance and Response, p. 1.

¹⁴ XDR TB is a form of TB that is resistant to isoniazid and rifampicin (MDR-TB) and any fluoroquinolone, and at least one of three injectable aminoglycoside drugs (capreomycin, kanamycin, or amikacin).

¹⁵ The GLC is a technical review committee coordinated by WHO. The GLC reviews and guides programs that treat drug-resistant TB. Programs that receive GLC approval are eligible to purchase second-line anti-TB drugs through a GLC pooled procurement mechanism at substantially discounted prices.

¹⁶ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 12 and 17.

¹⁷ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 13 and 14.

¹⁸ The Global Plan to STOP TB 2006 – 2015: Progress Report 2006 – 2008. p. 33

¹⁹ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 12 and 14.

about the role of community-level initiatives in early identification of TB cases and treatment support.²⁰ Nongovernmental organizations (NGOs) and persons who have been treated for TB are important resources that require further engagement in the detection and treatment of TB.

Lastly, currently available tools that can improve detection of TB (such as liquid culture, line-probe assays, and enhancements to smear microscopy) require a more rapid introduction at the country level. These tools have the potential to improve significantly approaches to TB diagnosis; however, because of limited funding and poor laboratory capacity, these tools are not being adopted quickly enough. Despite some initial advances in the development of new health care interventions, investments in new tools and related infrastructure development and capacity building is insufficient. There is a vital need for new drugs, diagnostics, and vaccines along with training in their use.

According to WHO, it is unlikely that the Stop TB global targets to halve TB prevalence and deaths will be achieved by 2015.²¹ Insufficient resources for scale-up of the Stop TB Strategy at the country level and the limited access to new tools impose challenges to reducing the incidence and prevalence of TB infection and achieving the 2015 goals. Inadequate funding for TB control is an ongoing problem. Among the 118 countries that report TB to WHO, there is an identified funding gap of US\$0.8 billion in 2010.²²

While the challenges described above are daunting, global TB control is achievable. The *Global Plan* and the Stop TB Strategy provide the road map and technical framework to reduce mortality due to TB; these strategies need to be fully funded and implemented. The USG TB strategy outlines a plan for increased USG investments in TB control to address the gaps outlined above based on USG comparative advantages relative to other donors. Through targeted and strategic use of our resources to scale up programs, the USG will contribute to the achievement of TB global targets, including a 70 percent case detection rate, 85 percent treatment success, and 50 percent reduction in TB deaths and disease burden.

²⁰ The Global Plan to STOP TB 2006 – 2015: Progress Report 2006 – 2008, p. 14

²¹ Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 1

²² Global Tuberculosis Control: A short update to the 2009 report. WHO, December 2009, p. 23

IV. USG STRATEGY

To achieve the targets of successfully treating 2.6 million new TB cases and 57,200 cases of MDR-TB, and to also contribute substantially to the goals and objectives of the *Global Plan to Stop TB 2006–2015*, the USG will significantly expand its partnership with up to 25 countries to scale up and enhance their TB programs. The USG, in conjunction with National TB Programs, will achieve national coverage of the following package of interventions:

Key Interventions

1. *Accelerated detection and treatment of TB for all patients*

- a. Full coverage of quality DOTS services, including a reliable anti-TB drug supply and full implementation of infection control measures;
- b. Effective monitoring, evaluation and surveillance of TB;
- c. Active engagement of the private sector, NGOs, and other public-sector entities to control TB;
- d. Active involvement of and support for communities affected by TB; and
- e. Accelerated introduction of new tools for diagnosis and treatment, ensuring their optimal use.

2. *Scaled up prevention and treatment of MDR-TB*

- a. Increase diagnosis and treatment of drug-resistant TB within national TB programs;
- b. Introduction of new and more effective MDR-TB diagnostic tools;
- c. Implementation of infection control measures to prevent the spread of MDR-TB;
- d. Routine surveillance for drug-resistant TB at the country level; and
- e. Improved access to quality-assured second-line anti-TB drugs.

3. *Expanded coverage of interventions for TB-HIV co-infection in coordination with USG HIV efforts under PEPFAR*

- a. Ensure HIV testing for all TB patients and effective referral of those found to be HIV-positive;
- b. Provide TB screening of all HIV patients and referral to TB services for those who are suspected cases of TB; and
- c. Accelerate the implementation of the “Three Is” (Intensified case finding for TB, Isoniazid preventive therapy and TB Infection control) to reduce the burden of TB among those with HIV.

KEY EXPECTED RESULTS:

- Contribute to a 50 percent reduction in TB deaths and disease burden from the 1990 baseline;
- Sustain or exceed the targets to detect 70 percent of new TB cases and successfully treat 85 percent of those cases in countries with established USAID tuberculosis programs;
- Successful treatment of 2,600,000 new smear-positive TB cases under DOTS programs; and
- Diagnosis and initiation of treatment for 57,200 new MDR-TB cases.

4. *Improvements in the overall health systems*

- a. Increase TB diagnosis by scaling up a fully functioning laboratory network with appropriate biosafety provisions;
- b. Strengthen information systems through improved data quality and reporting; and
- c. Increase health worker capacity to provide high quality health services.

Expected Results:

By 2014, USG will:

- Contribute to a 50 percent reduction in TB deaths and disease burden from the 1990 baseline;
- Achieve at least 70 percent case detection rates and at least 85 percent treatment success rates among new TB cases in countries with established USG TB programs;
- Successfully treat 2,600,000 new smear-positive TB cases under DOTS programs; and
- Diagnose and initiate the treatment of 57,200 new MDR-TB cases.

To achieve these targets, the following results will be accomplished in up to 25 countries:

- Implementation of the comprehensive package of TB intervention: quality DOTS, Programmatic Management of Drug Resistant TB, TB-HIV collaborative activities, and engagement of all care providers and communities;
- Routine TB surveillance, including surveillance for drug resistance, will be active;
- International TB infection control standards will have been implemented;
- Laboratory networks will be fully functional, including trained human resources, biosafety measures, adequate equipment and supplies, and routine quality assurance;
- Access to HIV testing and counseling for TB patients will be increased, contributing to the achievement of the STOP TB Partnership's Global Plan target of 85 percent; and
- Improved health system performance including trained human resources, reliable commodity supplies, improved data quality and use of information for decision-making, and strengthened primary health services to deliver DOTS.

At the global level, the USG will continue to support research, technical assistance, and policy development to expand and improve the tools and technologies available for TB. After six years of implementation, the USG efforts are expected to result in:

- Good Manufacturing Practices certification and WHO pre-qualification for at least two suppliers for each second-line anti-TB drug;
- Introduction of one new diagnostic tool; and
- Introduction of one new TB drug.

Strategy Details:

The following narrative describes the intervention package that will be scaled up in up to 25 countries.

1. Accelerated detection and treatment of TB for all patients

The accelerated detection and treatment of TB is a key pillar of the USG TB strategy. Early detection of TB and effective treatment reduces transmission of the disease and slows the emergence of drug

resistance. The USG focus will include the expansion and enhancement of DOTS and other essential elements of the Stop TB Strategy. Particular attention will be given to reaching vulnerable groups, including women and children through community-based approaches and reducing barriers to care and to improving linkages with maternal and child health services.

- *Full coverage of quality DOTS services, including a reliable anti-TB drug supply and full implementation of infection control measures:* The USG will give priority to increasing routine screening and testing for TB and the initiation of treatment for persons who are confirmed to have active TB. Quality improvement measures will ensure adherence to treatment standards, improve cure and treatment completion rates, and increase capacity for pharmaceutical management. Efforts will be expanded to ensure that women are appropriately reached and that gender considerations are integrated into all DOTS programs. Infection control measures will be implemented in health facilities to reduce the risk of disease transmission among patients and laboratory and health workers. Funding to the Global TB Drug Facility (GDF) will support grants to purchase TB drugs to countries in need.
- *Effective monitoring, evaluation and surveillance of TB:* The USG will improve monitoring and evaluation of TB control activities, the quality of data, and the analysis and use of routine information to improve program performance. Surveillance activities will assess epidemiological trends and measure the impact of programs.
- *Active engagement of the private sector, NGOs, and other public-sector entities to control TB:* Health care providers outside of the public health sector will be engaged to help increase access to care and the quality of services. Examples include NGOs, private-sector providers, the informal system, medical schools, professional associations, prisons and hospitals. The International Standards of TB Care (ISTC) will be integrated into all programs.
- *Active involvement of and support for communities affected by TB:* Advocacy, communications, and social mobilization efforts will be supported to raise political commitment for TB control, reduce stigma, and empower people with TB. Community-based approaches will be implemented to identify persons, particularly women, with TB symptoms to facilitate diagnosis and to provide support to TB patients receiving treatment. Mobilization of civil society and NGOs, as well as advocacy activities to increase awareness about TB, will be undertaken.
- *Accelerated introduction of new tools for diagnosis and treatment, ensuring their optimal use:* The USG will assist countries to conduct field tests of new technologies and integrate these technologies into existing programs. Policy development and capacity building will be supported to accelerate introduction of these new tools and to ensure their appropriate use. Examples include use of bleach to enhance smear microscopy, fluorescent microscopy, and rapid methods to detect TB and drug-resistant TB. When they become available, new drugs will be introduced.

2. Scaled up prevention and treatment of MDR-TB

Detection and treatment of drug-resistant TB along with good infection control measures are essential for interrupting the transmission of these more deadly strains of TB. Drug-resistant TB in the high HIV seroprevalent region of sub-Saharan Africa is particularly concerning because of the rapid progression from TB infection to disease among people with HIV/AIDS.²³ Weak or nonexistent infection control measures, combined with congested health facilities and prisons, can create a volatile situation for nosocomial transmission of the disease.

²³ For example, from January 2005 to March 2006, 53 XDR-TB cases were identified in Tugela Ferry, KwaZulu-Natal Province, South Africa, among 221 MDR-TB cases. Among the 53 patients, all 44 tested for HIV were found to be HIV-positive, and 52 (98%) of the patients died within approximately 16 days of diagnosis.

- *Increase diagnosis and treatment of drug-resistant TB within national TB programs:* Services to diagnose and treat drug-resistant TB in accordance with WHO guidelines for programmatic management of drug-resistant TB (PMDTB) will be scaled up. With USG support, the GLC will provide technical assistance to countries to increase capacity to implement PMDTB. The USG will procure second-line drugs if needed, ensure effective forecasting, quantification, and drug management, as well as provide support for routine monitoring and evaluation of PMDTB.
- *Introduction of new and more effective diagnostic tools for MDR-TB:* The USG will support upgrading of laboratory services and biosafety and laboratory capacity building and the introduction of currently available rapid diagnostic tests (not widely used in developing countries) to detect drug-resistant TB cases. New diagnostic tools will be introduced as they become available.
- *Implementation of infection control measures to prevent the spread of MDR-TB:* The USG will support the development of national infection control policies and guidelines, assessment and monitoring of infection control practices, and training and technical assistance to introduce and improve infection control and bio-safety measures in health care settings including clinics and laboratories. Infection control supplies will be procured as needed.
- *Routine surveillance for drug-resistant TB at the country level:* Accurate and available surveillance data are essential for targeting our resources to stem more effectively the spread of drug-resistant TB. The USG will support country-level drug resistance surveillance, particularly in African countries that have limited data on drug resistance. The USG will strengthen the capacity of supranational reference laboratories to provide technical assistance and to monitor the quality of national TB reference laboratories. Continued support will be provided for global anti-TB drug resistance surveillance activities.
- *Improved global access to quality-assured second-line anti-TB drugs:* Currently there is an insufficient global supply of quality-assured second-line anti-TB drugs to meet the needs of MDR-TB treatment programs. Working with the Global TB Drug Facility, the GLC and the WHO pre-qualification project, the USG will provide technical assistance to manufacturers of second-line drugs to help them meet Good Manufacturing Practice standards and to prepare product dossiers for applications to the WHO pre-qualification project.

3. Expanded coverage of interventions for TB-HIV co-infection

HIV/AIDS and TB co-infection presents special challenges to the achievement of global TB control targets and to the expansion and effectiveness of TB control programs. The USG supports implementation of the “Three Is” (Intensified case finding for TB, Isoniazid preventive therapy and TB Infection control) as well as TB-HIV collaborative activities in accordance with the WHO’s TB-HIV policy, and assists countries to strengthen health systems to deliver these interventions. TB-HIV collaborative activities are included in all PEPFAR country plans, and PEPFAR resources for TB-HIV/AIDS activities are essential for the scale-up of this key component of the Stop TB Strategy. TB-HIV activities supported by this strategy will be coordinated with PEPFAR to ensure that the interventions described above are fully covered. Specific implementation will vary country by country. The USG will prepare coordinated TB-HIV plans for both PEPFAR and TB resources.

- *Ensure HIV testing for all TB patients and effective referral of those found to be HIV positive:* The provision of HIV testing to TB patients is essential to ensuring access to HIV care and treatment services. The USG will train health workers responsible for TB services in HIV testing and counseling, and ensure the referral of TB patients to HIV testing services.
- *Provide TB screening of all HIV patients and referral to TB services for those who are suspected cases of TB:* To reduce the burden of TB in persons with HIV, the USG programs will ensure that

persons receiving HIV care and treatment services are routinely screened for TB, and if positive, provided TB treatment. TB treatment services will be strengthened as described above. The USG will ensure effective referrals between HIV and TB services, and support integration of services where feasible. Support will also be provided for cotrimoxazole preventive therapy to co-infected persons.

- *Accelerate the implementation of the “Three Is.”* The USG will provide intensified case finding for TB, promote Isoniazid preventive therapy (to HIV-positive persons who do not have active TB) and implement TB infection control measures in health care and congregate settings.

4. Contribute to health system strengthening

The USG will ensure that our support to TB programs is integrated with overall health sector policies and planning frameworks and strengthens the overall health system. The USG TB program will contribute to improvements in health system performance by building workforce capacity in areas such as problem solving, supervision, management, and planning. A specific focus will be on strengthening laboratory systems, education of health workers in TB diagnosis and management, human resource planning and development, improving the skills of health workers, improving the supply chain system related to the management of TB commodities to minimize stock outs, ensuring effective harmonization and integration of TB commodity management within health logistics systems (when relevant and possible), and improving information systems to help inform decision-making.

- *Increased TB diagnosis by scaling up a fully functioning laboratory network with appropriate biosafety provisions:* The USG will strengthen and expand national, regional, and local laboratories to bring TB diagnostic services closer to the community. Quality assurance systems will be rolled out, and capacity within laboratory and other diagnostic networks organizations will be built.
- *Strengthened health information management systems through improved data quality and reporting:* The establishment of a robust system to monitor and evaluate multiple health indicators is crucial to understanding the trends in and impact of TB control. Thus, the USG will provide support to efforts to improve data management and collection processes and aid in the analysis of that data to inform decision-making.
- *Increased capacity of the health workers to provide high quality health services:* As part of its overall efforts to improve the quality of TB care, the USG will work to build the capacity of health workers through both pre-service and in-service training, supervision, management and support. Attention will be given to ensuring that capacity building for TB is coordinated with system-wide human resource development strategies and plans.

V. ROLE IN THE GLOBAL HEALTH INITIATIVE

The Global Health Initiative (GHI) represents a USG-wide commitment to work with host governments and other multilateral partners and donors to improve global health in a holistic and sustainable fashion. The GHI continues ongoing efforts in infectious diseases and builds upon the successes of PEPFAR, the President's Malaria Initiative and USG-supported tuberculosis efforts while increasing the focus on broader global health challenges. It adopts a more integrated approach to fighting diseases, improving health, and strengthening health systems. The USG TB program will contribute to the core principles of the GHI as described below.

Implement a women- and girl-centered approach: The first principle is that women and girls must be at the center of any global health strategy. Central to the GHI are long-term, systemic changes in the way health programs respond to and incorporate the needs, perspectives and abilities of women and girls. Tuberculosis is among the top three leading causes of death among women in low-income countries, resulting in devastating impacts on the health of families and children. The USG will improve the detection of TB among women and develop innovative ways to ensure the reduction of gender barriers to quality TB treatment and care, particularly when implementing models of community DOTS, intensified case finding, and interventions to increase access to services.

Increase impact by strengthening strategic integration and coordination: The USG has achieved success under its current TB program; however, the program can benefit from better integration and coordination both between health programs and with multilateral organizations. Under the GHI, the TB program will be planned, programmed, and implemented in a more holistic manner, taking into account the multiple health and development needs faced by governments and people. The USG TB program will look for opportunities to foster integration with other programs where appropriate, and improve coordination among existing USG health agencies and programs, as well as with other USG development programs outside of health (e.g., food security and basic education). As part of the GHI, this program will continue to work with the President's Emergency Plan for AIDS Relief (PEPFAR) to ensure that TB-HIV is addressed in a coordinated fashion as discussed above. Beyond PEPFAR, the USG TB program will ramp up its efforts to build on past USG efforts to strengthen the health system and will look for synergies with maternal and child health and other health programs.

Strengthen and leverage key multilateral institutions, global health partnerships, and private-sector engagement: The USG TB program cannot achieve its goals without collaborating with other key donors. The Global Fund is the single most important multilateral source of external funding for TB control in countries, constituting up to 70 percent of external funding in some cases. The USG assists country coordinating mechanisms and national TB programs (NTPs) to prepare proposals for TB grants to the Global Fund. Once grants are awarded, the USG and cooperating agencies will assist NTPs in the implementation of all technical aspects of the grant and to prepare reports and documentation to support Phase Two grant approvals. USAID and PEPFAR, through mechanisms such as the Grant Management Support contract, the TB Technical Assistance Mechanism and other technical partners assist countries by providing technical assistance to address grant implementation bottlenecks and to prepare documentation required prior to grant signing, including procurement and supply management plans, monitoring and evaluation plans, implementation plans, and human resources plans. The USG will also work with other donors such as UNITAID and the World Bank to leverage financial and technical support to expand country-level programs.

Also, a fundamental premise of this USG Strategy will be the use of global health partnerships to translate priorities into action, both within the USG and globally. Partnerships fall into two broad categories: global and regional/country.

Global partnerships are an integral part of the USG's TB strategy, and the USG will continue to participate in and provide support for several activities and initiatives. Active engagement in the Stop TB Partnership is a critical element of the USG program. USAID provides support to the Stop TB Secretariat and is the leading bilateral donor to the GDF and the GLC. Both USAID and CDC are members of the Stop TB Partnership's Coordinating Board. USAID, CDC, NIH and PEPFAR participate in all the Stop TB Partnership's technical working groups that are relevant to the expertise of each agency.

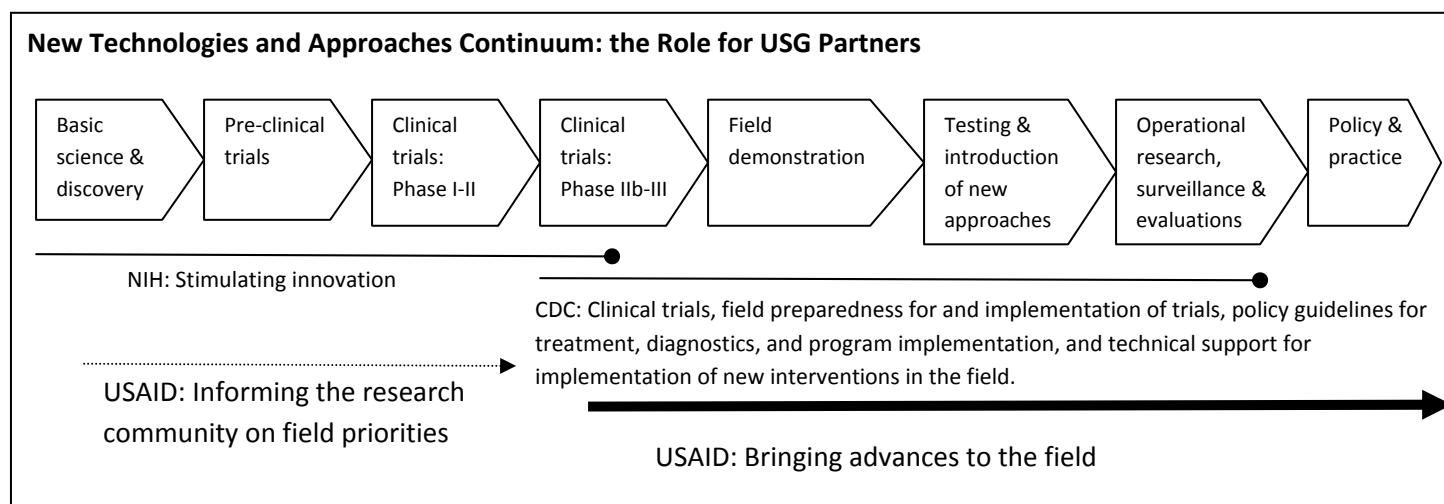
Regional and partnerships are also an important component of this strategy. Regional partnerships enable the USG to support activities tailored to the unique characteristics of specific geographic areas. Through grants to regional institutions and regional initiatives, the USG supports capacity building, fosters cross-country collaboration, and conducts multi-country operations research and pilot activities. Examples include the establishment of Centers of Excellence for MDR-TB that provides technical assistance and training to countries in their respective regions and bi-national partnerships to respond to cross-border TB control issues.

Encourage country ownership and invest in country-led plans: A core principle of the USG's approach to TB is to work with NTPs at the country level and to provide support that is fully aligned with national strategic plans as well as with the *Global Plan* and the Stop TB Strategy. The majority of the annual TB appropriation will be allocated to country-level programs and related activities, including the Global TB Drug Facility, with the remainder of resources to be allocated to core research, policy development, and dissemination of tools. These country-level funds will be used to directly support the NTP strategic plans to expand TB services and to strengthen the in-country capacity. Priority will be given to addressing funding and technical gaps and obstacles to scaling up essential services and interventions.

Build sustainability through health system strengthening: As described above, the USG TB program views health systems strengthening as a fundamental aspect of TB control. To ensure that there is a consistent supply of appropriate first-line and second-line drugs, the USG will tackle pharmaceutical management issues including forecasting, procurement, monitoring of drug supplies, quality assurance, and distribution capacity at both the global and country level. Diagnosis and treatment of TB will be integrated into public health services in all countries. Training related to TB diagnosis, treatment and control will be included in the basic curriculum of all health workers. Supportive supervision and capacity building in data analysis will be provided such that it improves the quality of several primary health care services. Similarly, laboratory services for diagnosis of TB and infection control interventions will be integrated into general health services. Also, capacity will be built in the areas of research, monitoring and evaluation and management. All of these activities will be aimed at supporting the entire health system such that quality and availability of all public health services, including TB services, are improved.

Improve metrics, monitoring and evaluation: Metrics and monitoring and evaluation are essential components of the USG TB strategy to ensure accountability and measurable results. The USG TB program has a long history of utilizing the standardized TB indicators as well as the recording and reporting system promoted by WHO to measure progress toward desired outcomes, targets and goals. Support will also be provided to improve data analysis and evaluation and to enhance the use of data and information to improve program performance. Section VII provides an overview of the USG TB programs monitoring and reporting approach.

Diagram 1. USG partners in TB research



Promote research and innovation: Several exciting new candidate diagnostics, drugs, vaccines and alternative models for DOTS are in the pipeline for TB. These new technologies have the potential to revolutionize how TB is diagnosed, treated and prevented. In addition, new applications of existing tools have the potential to greatly enhance our ability to detect and manage cases. Under this strategy, the USG will invest in new tools and approaches that are less labor intensive, more cost-effective, of greater efficacy and can be delivered closer to the patients, thereby improving case detection and treatment success rates. Building upon NIH's comparative advantage to support fundamental science, new product development, and early stage clinical trials, funding for research under the Reauthorization Act will support subsequent phases of research as relevant tools become ready for field evaluations.

In addition to new tools and approaches, the USG with its partners will play a critical role in assessing program performance, analyzing operational barriers, and in developing and testing approaches to overcome constraints to program implementation. The USG will prioritize operations research on key issues inhibiting implementation and scale-up of services and will evaluate novel and innovative ways to improve the impact of TB diagnosis, treatment and control interventions. Through this constant re-evaluation of implementation efforts, the USG will be able to ensure that barriers are being addressed rapidly and that new ideas are moving from testing to implementation.

Using the results of this operations research, the USG will work with its priority countries to accelerate the uptake and introduction of new tools and approaches. As these candidates are proven to be effective, licensed and put into commercial production, it is vital that country programs adopt them into policy. The USG will work with NTPs to help them develop an evidence-base on the appropriateness of these technologies in their countries, and provide support for the development of policies and guidelines related to their introduction and use.

VI. COUNTRY PLANNING AND SCALE-UP

As additional resources at the levels authorized in the Reauthorization Act become available, the USG will intensify its bilateral programs in up to 25 countries by the end of this six-year strategy or sooner. These countries will benefit from the comprehensive package of interventions described above.

The Current Bilateral Program

The current USG's bilateral TB program provides assistance to 40 countries (see table below).

USG Priority Countries ²⁴
Afghanistan , Armenia,* Azerbaijan*, Bangladesh *, Bolivia, Brazil , Cambodia , Democratic Republic of Congo *, Djibouti, Dominican Republic, Ethiopia *, Georgia,* Ghana, Haiti, India *, Indonesia *, Kazakhstan,* Kenya , Kyrgyzstan,* Liberia, Malawi, Mexico, Mozambique , Namibia, Nigeria *, Pakistan *, Peru, The Philippines *, Russia *, Senegal, South Africa *, Southern Sudan, Tajikistan,* Tanzania , Turkmenistan, Uganda , Ukraine,* Uzbekistan,* Zambia, Zimbabwe

Countries in bold are high-burden TB countries

* Indicates countries that have a high burden of MDR-TB

Intensifying Support in Select Countries

The USG will increase support in up to 25 of the 40 countries listed above. Countries that represent the greatest opportunity to achieve and sustain impact will be designated for increased funding and will receive at least \$10 million per year to implement the package of interventions described above. Other bilateral country programs will continue to receive funding to provide targeted technical assistance to address gaps in implementation of the STOP TB strategy.

The principal criteria for selection of countries to receive the funding increase are:

- High burden of TB cases (among the list of 22 HBCs)
- High burden or prevalence of drug-resistant TB
- High incidence of TB (estimated incidence rates over 100/100,000)
- High HIV/AIDS prevalence (TB-HIV co-infection)
- Lagging case detection and treatment success rates

Other factors – such as political commitment and technical, financial need, and managerial feasibility – will also be considered when funds are allocated.

In FY 2009, India, Indonesia, and South Africa became the first three TB countries to receive funding increases, and their FY 2009 TB funding levels were increased to at least \$10 million annually. In FY10, this list expanded to nine countries, including the Democratic Republic of Congo, Ethiopia, Nigeria, Bangladesh, Russia, and the Philippines. All of these countries are on the list of 22 high-burden countries and also have a high burden of drug-resistant TB. Additional countries will receive funding increases in FYs 2011–2014, depending on the level of resources provided for TB programs.

²⁴ Four top 22 high-burden countries do not appear in the above table. Operational obstacles prevent country level support in Burma, and for China and Thailand, country resources exist. Vietnam may be added to the list of countries where USG assistance is provided if adequate resources become available.

County-level Planning

While all components of the USG strategy are necessary to achieve the objectives, the specific activities will vary by country depending on needs and the local situation. The USG team in each country will develop plans for support in collaboration with the NTP and other partners. These plans will specifically delineate how annual USG resources will be programmed to implement the package of interventions presented in this strategy. All USG supported activities must fit within and contribute to the existing national TB strategic plan; should complement existing donor and domestic resources, including those of the Global Fund; and should be tailored toward the specific needs and gaps of the countries. These plans should address country- and regional-specific issues as well as any staffing and USG management requirements.

VII. IMPLEMENTATION THROUGH THE USG PARTNERSHIP

The achievement of our ambitious goals and implementation of the GHI principles are only possible through the consolidated and coordinated efforts of all the USG agencies working in partnership with the global TB community to combat TB worldwide. The United States Agency for International Development (USAID) is the lead USG agency in international TB control. USAID works closely with the Office of the Global AIDS Coordinator (OGAC) at the Department of State; OGAC is the lead for the USG response to TB-HIV co-infection as part of PEPFAR. A key partner in the USAID response and the PEPFAR program is the U.S. Centers for Disease Control and Prevention (CDC), an agency under Department of Health and Human Services (HHS). CDC leads domestic USG TB control efforts and provides critical technical support to international partners on epidemiology and surveillance (including drug-resistant TB), laboratory strengthening, and clinical/operational research that evaluates promising diagnostic and treatment strategies, and informs the efficient use of new approaches to TB care. CDC also funds the TB Clinical Trials Consortium and the TB Epidemiologic Studies Consortium to fill current TB knowledge gaps in TB diagnostics, TB treatment regimens, case detection, and monitoring. Finally, the National Institutes of Health (NIH) leads the way in improving the biomedical understanding of TB and conducts basic, applied, and clinical research on both drug-sensitive and drug-resistant TB and is heavily involved in the discovery and early development of new drugs, vaccines and diagnostics. All of these agencies are active members of the Stop TB Partnership.

Agency/Initiative	Role in International TB Control
USAID	Supports implementation and scale-up of all components of the Stop TB Strategy through bilateral programs in 40 countries. Works in partnership with national TB control programs. Supports programmatically relevant operations research and late stage clinical trials.
OGAC coordinates the USG agencies involved in PEPFAR (HHS, USAID, Department of Defense, Department of Labor, Department of Commerce and Peace Corps, coordinated by OGAC)	Provides support for services to persons co-infected with TB-HIV in PEPFAR countries. Examples include integration of TB and HIV services, HIV testing for TB patients, TB screening and testing of persons with HIV/AIDS, surveillance and laboratory strengthening.
HHS/CDC	Provides critical technical support to international partners on epidemiology and surveillance (including drug-resistant TB), laboratory strengthening, and clinical/operational research that evaluates promising diagnostic and treatment strategies, and informs the efficient use of new approaches to TB care. Funds the TB Clinical Trials Consortium and the TB Epidemiologic Studies Consortium to fill current TB knowledge gaps in TB diagnostics, TB treatment regimens, case detection, and monitoring.
NIH	Supports domestic and international biomedical research, including fundamental basic research; studies of pathology, epidemiology, and transmission of TB; studies to characterize drug resistance; research on basic, clinical and behavioral aspects of TB-HIV co-infection; identification, pre-clinical development, and clinical evaluation of new drugs, diagnostics, and vaccines; and research training, infrastructure, and capacity-building in resource-constrained countries.

VIII. MONITORING AND REPORTING OUR PROGRESS

The USG will submit an annual report to Congress that describes the results and impact of U.S. foreign assistance on efforts to control TB as required by the Reauthorization Act. Our monitoring will include impact indicators that will be reported on annually as well as other forms of oversight that look at program quality and addresses challenges preventing scale-up. The following key indicators will be reported on in countries with established USG TB programs:

- Progress toward the Stop TB goals of reducing TB deaths and disease burden by 50 percent compared to the 1990 baseline;
- The number of tuberculosis cases diagnosed and the number of cases cured in countries receiving U.S. bilateral foreign assistance for tuberculosis control purposes;
- Case detection and treatment success rates in new sputum smear-positive TB patients under DOTS programs;
- The number of new sputum smear-positive TB patients successfully treated under DOTS programs; and
- The number of persons who have been diagnosed and started treatment for MDR-TB in countries receiving U.S. bilateral foreign assistance for tuberculosis control programs.

The annual report will also include other required information about USG programs, including:

- A description of activities supported with U.S. tuberculosis resources in each country and how these activities contribute to increasing the number of people diagnosed and treated for TB;
- The percentage of the total U.S. assistance provided for direct TB services in each country receiving bilateral foreign assistance for TB control purposes;
- A description of research efforts to combat TB, including new diagnostics, drugs and vaccines supported by U.S. bilateral assistance;
- A description of collaboration and coordination of the USG with the WHO, the Global Fund and other major public and private entities;
- Constraints on implementation of programs posed by health workforce shortages and capacities;
- The number of people trained in TB laboratory diagnosis, treatment and control;
- A breakdown of expenditures for direct patient TB services, drugs and other commodities, drug management, training in diagnosis and treatment, health systems strengthening, research and support costs;
- A discussion of efforts to strengthen health systems as part of TB control; and
- A description of areas where there has been successful integration of TB control programs with other global health programs (HIV, maternal and child health, etc.) as part of the GHI.