US Agency for International Development

Expanded Response to Tuberculosis

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ACRONYMS

ACSM	Advocacy, communication, and social mobilization
ART	Antiretroviral therapy
ATS	American Thoracic Society
CCM	Country coordinating mechanism
CDC	US Centers for Disease Control and Prevention
DHHS	Department of Health and Human Services
DOS	Department of State
DOTS	Directly observed treatment, short course
FBO	Faith-based organization
FSA	Freedom Support Act
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, TB, and Malaria
GLC	Green Light Committee
HBC	High burden countries
HHS	US Department of Health and Human Services
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
IEC	Information, education, and communication
IPT	Isoniazid preventive therapy
ISTC	International Standards of TB Care
IUATLD	International Union against Tuberculosis and Lung Disease
KNCV	KNCV Tuberculosis Foundation
M & E	Monitoring and Evaluation
MDR-TB	Multi-drug resistance tuberculosis
NGO	Non-governmental organization
NIH	National Institutes of Health
NTP	National Tuberculosis Program
OGAC	Office of the Global AIDS Coordinator
PAL	Practical Approach to Lung Health
PEPFAR	President's Emergency Plan for AIDS Relief
PLWHA	Person living with HIV/AIDS
PPM	Public-public and public-private mix
PVO	Private voluntary organization
TB	Tuberculosis
TB CAP	Tuberculosis Control Assistance Program
TBCTA	Tuberculosis Coalition for Technical Assistance
TBTEAM	TB Technical Assistance Mechanism
USAID	U.S. Agency for International Development
WHO	World Health Organization
XDR-TB	Extensively-drug resistant tuberculosis

INTRODUCTION

An estimated one-third – two billion people – of the global population is infected with tuberculosis (TB). Tuberculosis kills more than 1.7 million people per year and is economically devastating to families and communities worldwide. Although TB is a global problem, its geographic distribution is drastically disproportionate. Ninety-five percent of all TB cases and 98% of all TB deaths occur in developing countries. TB is a major killer among women of reproductive age and the leading cause of death in HIVpositive people. Only 22 high burden countries (HBCs) account for 80% of the global TB burden, with half of these countries located in Asia. In Africa, 25 countries have an estimated TB case notification rate greater than 100/100,000, as compared to an estimated case notification rate of 5/100,000 in the United States.

The global resurgence of TB has been fueled by a combination of factors, including increasing human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) prevalence and multi-drug resistance, inadequate investments in public health infrastructure, insufficient political commitment, limited awareness of TB, disparities in access to and quality of health care services, and insufficient investments in new tools, including drugs, diagnostics, and vaccines. The disease threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development.

Significant progress has been made since The Stop TB Partnership (of which USAID is a member) was launched in 2000. The Amsterdam Ministerial Conference on Tuberculosis and Sustainable Development held in March 2000 established global targets of 70% TB case detection and 85% treatment success rates in sputum smear-positive pulmonary TB cases[1] to be achieved by the year 2005 in the 22 HBCs. The first *Global Plan 2001 – 2005* served to catalyze governments and donors to address TB. The number of countries implementing Directly Observed Treatment Shortcourse (DOTS), the most effective strategy available for the treatment and control of TB, increased from 112 in 1998 to 184 in 2006, and one high burden country (Peru) reduced TB incidence sufficiently to graduate from the list of 22 HBCs. India recently reported a 50% decline in TB mortality due to rapid scale up of DOTS and implementation of the Stop TB Strategy.

Building on this momentum, in January 2006, The STOP TB Partnership launched the *Global Plan to STOP TB 2006 – 2015* which includes the Millennium Development Goal target of halting and beginning to reverse the incidence of TB by 2015, as well as the more ambitious STOP TB targets of reducing TB prevalence and deaths by 50% by 2015 relative to the 1990 baseline. The *Global Plan* describes the actions and resources needed to combat the epidemic and achieve the above targets. The World Health Organization (WHO) and other Stop TB partners also launched a more robust technical approach known as the Stop TB Strategy which builds on DOTS. There is strong global commitment to combat TB and to collaboration in that effort: the Partnership has grown

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

to include over 700 members, including endemic countries, donors, non-governmental organizations (NGOs), research organizations, and other institutions.

However, recent analysis of global TB trends and progress in DOTS implementation indicates that progress is slower than needed. Reported global DOTS coverage of 89% masks the reality that many people, even in areas where DOTS is reportedly available, lack true access to DOTS. While overall treatment success in DOTS areas is 84.7% (2005 cohort), regional disparities reveal alarmingly low rates of treatment success in Europe (71%) and Africa (76%), due in part to Multi-Drug Resistant (MDR) TB and TB/HIV-AIDS.

Globally, on average, just 61% of estimated sputum smear-positive TB cases were detected in 2006, and the annual increase in case detection is slowing down. Case detection is lagging in Europe, Africa, and Eastern Mediterranean, where case detection rates are below 53%. Only the Western Pacific region has achieved both case detection and treatment success targets, and only five of the 22 HBCs (Vietnam, China, Myanmar, Indonesia, and Philippines) have achieved the targets for both case detection and treatment success thus far.[2]

Section I: USAID's Commitment

USAID strives to support the implementation of the STOP TB Strategy and contribute significantly to the global reduction of morbidity and mortality associated with tuberculosis. Consistent with the goals set forth in the *Global Plan 2006 – 2015*, USAID's specific goals are:

- By 2015, to halve TB prevalence and deaths in USAID priority countries (see Section III); and
- By 2011, to detect at least 70% of estimated cases and successfully treat at least 85% of those cases in USAID priority countries;

USAID's TB program consists of the following five components, all in accordance with the STOP TB Strategy:

- DOTS expansion and enhancement;
- Scaling up management of MDR-TB and XDR-TB;
- Addressing TB/HIV co-infection;
- Strengthening health systems and human resource capacity; and
- Developing new tools and improved approaches

USAID is the lead USG agency in international TB control programming, except for international HIV/TB programming which is led by The Department of State/Office of the Global AIDS Coordinator through a USG interagency response under the Presiden'ts Emergency Plan for AIDS Relief. The Department of Health and Human Services/The

[2] All data are from Global Tuberculosis Control: Surveillance, Planning, and Financing. WHO Report 2008, Geneva, World Health Organization (WHO/HTM/TB/2008.393).

US Centers for Disease Control and Prevention (CDC) provides critical technical support to global and country-level initiatives.

USAID leads the implementation of the TB Element of the US government's Foreign Assistance Framework[3]. The following table shows the relationship between USAID's five-pronged TB program, the Foreign Assistance Framework and the Stop TB Strategy.

[3] The Foreign Assistance Framework elucidates the seven strategic goals of transformational diplomacy. The TB Element falls under the third goal, Investing in People, defined as helping nations achieve sustainable improvements in the well-being and productivity of their populations (http://www.state.gov/f/c23053.htm).

USAID's TB Program Components	FOREIGN ASSISTANCE FRAMEWORK (TB Element)	STOP TB STRATEGY
1. DOTS expansion and enhancement	**1.2.1**: DOTS expansion and enhancement **1.2.5**: TB care and support	**1. Pursue high-quality DOTS expansion and enhancement** a) Political commitment and increased financing b) Case detection c) Standardized treatment d) Effective drug supply and management system e) M&E system, and impact measurement **2. Engage all care providers** a) Public-public and public-private mix approaches b) International Standards for TB Care **3. Empower people with TB and communities** a) Advocacy, communication and social mobilization b) Community participation in TB care c) Patients' Charter for TB Care
2. Scale up management of MDR & XDR **3. Address TB/ HIV co-infection**	**1.2.4:** Multi drug resistant TB **1.2.3:** Improve management of TB/HIV	**4. Address HIV/TB and MDR-TB and other special challenges** a) Implement collaborative TB/HIV activities b) Prevent and control MDR-TB c) Address high-risk groups and special situations
4. Strengthen health systems and Human Resource capacity	**1.2.2**: Increasing availability of drugs **1.2.7**: Health governance and finance **1.2.8**: Host country strategic information capacity	**5. Contribute to health systems strengthening** a) Actively participate in efforts to improve system-wide policy, HR, financing, management, service delivery, and information systems b) Share innovations c) Adapt innovations from other fields
5. Develop new tools and improved approaches.	**1.2.6**: Development of new tools and improved approaches	**6. Enable and promote research** a) Support research in new diagnostics, drugs, and vaccines b) Program-based OR

USAID contributes to the achievement of STOP TB global targets for treatment success and case detection by focusing on country level support to implement the STOP TB Strategy in priority countries (see Section III).

Section II. USAID's Program

USAID's activities to address the five priority areas are described below.

A. DOTS Expansion and Enhancement

DOTS[4] is a cost-effective and affordable strategy for controlling TB, and 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. Good quality DOTS also slows the emergence and spread of drug-resistant TB. DOTS can be adapted to a variety of different settings and local conditions, and the regimens used are also effective in curing TB in people who are co-infected with HIV.

USAID *supports interventions to increase access to and the quality of DOTS in priority countries* to achieve international targets for case detection (70% of new smear-positive cases detected) and treatment (85% of new sputum smear-positive pulmonary TB cases successfully treated). More specifically, USAID *works with host countries in developing strategic plans and budgets that are consistent with the Stop TB Strategy and Global Plan.* Investments are directed towards promulgating standardized treatment with context specific and patient-oriented supervision; improving TB program management and supervision; personnel training; effective procurement and management of a dependable supply of high-quality TB drugs; expansion and strengthening of high-quality laboratory services, including culture capacity; and routine monitoring of treatment outcomes and overall program performance. USAID also provides technical assistance to prepare proposals to the Global Fund to Fight AIDS TB and Malaria (GFATM) and assist in successful implementation of the GFATM grants and provides funding to the Global TB Drug Facility (GDF) for grants for TB drugs to countries in need.

To complement DOTS expansion efforts through national TB programs, USAID supports initiatives to engage *all health care providers through public-public and public-private mix (PPM) approaches*. Many people initially seek treatment in the private sector. Partnerships with these private and NGO providers help to increase equity, reduce diagnostic delay and to extend the reach of TB services to populations that may have difficulty accessing public sector services. USAID Missions work in consultation with National Tuberculosis Programs and other stakeholders to determine how to best maximize the reach of services given each country's context. Integration of the International Standards of TB Care (ISTC) into PPM activities serves to ensure that PPM activities are consistent with global standards of care. ISTC also serves as a tool to engage professional associations.

[4] DOTS includes the following five components: political commitment with increased and sustained financing; case detection through quality-assured bacteriology; standardized treatment, with supervision and patient support; an effective drug supply and management system; and monitoring and evaluation system, and impact measurement.

USAID also undertakes activities and interventions *to improve the quality of existing DOTS programs* with the goal of achieving better treatment outcomes, reducing diagnostic delay, preventing disease transmission, and slowing the emergence of MDR-TB[5]. Although the case detection rate for new sputum smear-positive cases is 61% among DOTS programs in the 22 HBCs, only eight HBCs reached the target of 70%. Case detection was lowest in the African (46%), European (52%), and Eastern Mediterranean (52%) regions. Furthermore, while overall treatment success under DOTS averaged 84.7%, only ten of the 22 HBCs met or surpassed the 85% target. Unfavorable outcomes (defined as death, treatment failure, and default) were unacceptably high in Europe (24.4%) and Africa (16.9%). Attention is given to ensuring that all those suspected of having TB are correctly diagnosed, that diagnosed patients begin therapy, that clinicians and nurses adhere to program norms or standards, that patients are supported to adhere to treatment regimens, and that outcomes are documented and reported. Training is provided in the correct use of TB registries and in monitoring and evaluation systems to improve data quality, and to enhance the ability of local personnel to analyze and use their data to improve program performance.

USAID continues to support WHO Global TB Monitoring and Surveillance project as a key investment in providing information on the global, regional, and country level TB program and epidemiological situation. The Agency provides technical and financial support for TB prevalence surveys and plays a key role in the standardization of monitoring and evaluation instruments. Existing tools are evaluated and adapted and new tools are developed to assist USAID missions and TB program managers in the use of effective benchmarks for measuring progress and evaluating TB activities throughout the lifecycle of their programs.

Finally, USAID *supports partnerships that empower people with TB and communities including advocacy, communication, and social mobilization (ACSM).* Community participation in TB care is encouraged via implementation of community-based treatment support approaches and advocacy to increase local and national support and resources for TB control. Information, education, and communication (IEC) activities are supported to reduce stigma, raise awareness, increase demand for services, and promote adherence to treatment. USAID also supports advocacy for implementation of the Patients' Charter for Tuberculosis care to enable patients and communities to raise awareness about the rights of people with TB and to strengthen patient-provider relationships.

B. Scale up Management of MDR-TB and XDR-TB

MDR-TB and extensively drug resistant TB (XDR-TB) compromise TB control efforts and threatens years of progress in controlling TB. Resistance is the result of weak TB programs, poor patient adherence to treatment regimens, and irregularly supplied and/or poor quality drugs. The most recent Anti-Tuberculosis Drug Resistance Surveillance in the World report (2007)[6] identified MDR-TB in all regions of the world, with

[5] MDR TB is defined as resistance to at least isoniazid and rifampicin, the two most-important anti-TB drugs.

[6] WHO's Anti-Tuberculosis Drug Resistance in the World, Report No. 4. WHO/IUATLD Global Project on Anti-Tuberculosis Drug Resistance Surveillance, 2007 (WHO/HTM/TB/2008.394).

exceptionally high prevalence in Eastern Europe. WHO estimates that the prevalence of MDR-TB may be as high as one million cases, with approximately 490,000 new cases annually; of these cases, less than 2% are treated in accordance with WHO guidelines. In addition, CDC[7] reported the presence of XDR-TB in all regions of the globe, with the highest rates in Eastern Europe. In June 2007, WHO identified 25 priority countries[8] based on estimated MDR-TB and XDR-TB burden.

MDR/XDR-TB is a serious concern because drug-resistant TB is more difficult and expensive to diagnose and cure, contributing to continued disease transmission and higher death rates. Diagnosis of MDR-TB requires laboratory capacity to perform culture and drug sensitivity testing. Second line drugs used to treat MDR-TB are often toxic and poorly tolerated by patients. The duration of treatment is longer than for drug susceptible TB and the cost of treating MDR-TB is 10 to 100 times greater than the cost of treating drug-susceptible TB, which has implications for both health budgets and patient access to care. While cure rates as high as 50-60% among MDR-TB cases are possible, successful outcomes depend greatly on good quality TB control programs. MDR-TB and XDR-TB in sub-Saharan Africa is particularly concerning because of the high HIV prevalence, and the rapid progression from TB infection to disease among people with HIV/AIDS.[9] Weak or non-existent infection control measures, combined with congested health facilities, can create an explosive situation for nosocomial transmission of the disease.

USAID has supported activities to address MDR-TB since the inception of its TB program in 1998. USAID's strategic priorities to address MDR-TB and XDR-TB are fully consistent with WHO's Global MDR-TB and XDR-TB Response Plan 2007. Seventeen of the 25 priority countries for MDR-TB defined by WHO are among USAID priority countries. USAID *supports both the full integration of the diagnosis and treatment of MDR-TB into DOTS programs* and measures to improve the quality of services to prevent further emergence of resistance. USAID supports country-level drug resistance surveys and the biannual Global Report on TB Drug Resistance. USAID has supported the Green Light Committee (GLC)[10] since it was established. The Agency's assistance enables the GLC to provide technical assistance to GLC applicants and GFATM grant recipients. Attention is given to capacity building for management of second-line anti-TB drugs and to improving good manufacturing practices of second line drug manufacturers to help expand the supply of quality assured second line drugs. In addition, USAID supports the expansion and strengthening of laboratory services through activities such as establishing supranational reference laboratories and fostering partnerships with regional Centers for Excellence. Finally, USAID supports technical

[7] March of 2006 issue of Morbidity and Mortality Weekly Report
[8] WHO, Global MDR-TB and XDR-TB Response Plan 2007-2008.
[9] 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.
[10] The GLC is a technical review committee that functions under the auspices of the STOP TB Partnership that reviews and guides programs to treat drug resistant TB. Pilot projects that receive GLC approval are eligible to purchase second-line anti-TB drugs through a GLC pooled procurement mechanism at substantially discounted prices.

assistance, interventions and capacity building to improve infection control and research to improve approaches for monitoring and managing drug resistant TB.

C. Address TB HIV co-infection

HIV/AIDS and TB co-infection also presents special challenges to the expansion and effectiveness of DOTS programs and the STOP TB Strategy. TB accounts for one-third of AIDS deaths worldwide and is one of the most common causes of morbidity in people living with HIV/AIDS (PLWHA). Currently, about 33 million people are HIV-infected and at least one-third are also infected with TB. The dual epidemics of TB and HIV are particularly pervasive in Africa, where HIV has been the single most important factor contributing to the increasing incidence of TB over the last ten years. In some countries of sub-Saharan Africa, up to 70% of patients with active TB disease are also HIV-positive[11]. The dual epidemics are of growing concern in Asia, where two-thirds of TB-infected people live and where TB now accounts for 40% of AIDS deaths. Eastern Europe and the Former Soviet Union have the fastest growing HIV epidemic in the world, and a factor that could exacerbate problems with the MDR-TB epidemic in these regions. The overlap of TB/HIV co-infection with MDR-TB and XDR-TB presents a tremendous challenge and threatens progress in controlling both TB and HIV/AIDS.

Persons co-infected with HIV and TB are 30 times more likely to progress to active TB disease. Infection with TB enhances replication of HIV and may accelerate the progression of HIV infection to AIDS. Fortunately, TB treatment for HIV-positive patients under DOTS is just as effective as it is for people who are HIV-negative. In addition, clinical trials have shown that prophylaxis using anti-TB drugs can prevent or decrease the likelihood of TB infection from progressing to active TB disease in an HIV-infected person, making it an important intervention for increasing the length and quality of life of HIV-infected people, with benefits to their families and communities.

Within the USG, PEPFAR takes the lead in funding and implementation of TB/HIV co-infection activities, however USAID's TB activities are closely coordinated with PEPFAR. Given the importance of TB/HIV as part of a comprehensive TB program, USAID supports some specific TB/HIV activities within the Agency's TB programs and closely coordinates efforts with PEPFAR. Specifically, USAID supports the three-fold strategy established in 2004 by WHO: to enhance collaborative efforts between TB and HIV/AIDS programs; to decrease the burden of TB in PLWHA; and to decrease the burden of HIV in TB patients[12]. To address the first strategy, USAID *supports coordination of TB and HIV/AIDS services* by improving collaboration among both programs, host countries and donor agencies, NGOs, and research institutions; developing training programs for TB specialists/programs managers on HIV counseling and testing and management of co-infected patients; strengthening the links between TB services to HIV testing and HIV care services; and exploring the use of alternative

[11] Corbett E.L., Watt C.J., Walker N., Maher D., Williams B.G., Raviglione M.C., Dye C. The Growing Burden of Tuberculosis: Global Trends and Interactions with the HIV Epidemic. *Archives of Internal Medicine*. 2003; 163:1009-21.

[12] WHO's *Interim Policy on Collaborative TB/HIV Activities.* WHO Report 2004, Geneva, World Health Organization (WHO/HTM/TB/2004.330).

service delivery approaches, such as community and home-based care, and involving faith-based organizations in such approaches. Such coordination is essential in ensuring early diagnosis, appropriate referral, and prompt, quality care for each disease.

To *decrease the burden of TB in people living with HIV/AIDS*, USAID assistance is designed to support improvements in TB prevention, screening, and treatment through links with facilities providing antiretroviral (ART) treatment services. In 2006, *only* 0.9% of HIV-positive patients were screened for TB. Such a low rate of screening for TB among PLWHA as well as the difficulties associated with diagnosis of TB in persons with HIV/AIDS contributes to delayed diagnosis of TB. USAID supports programs that strengthen and expand HIV surveillance to improve the quality of data on co-infection and epidemiological trends. USAID also supports programs that promulgate WHO standards in the provision of isoniazid preventive therapy (IPT) to HIV/AIDS patients with latent infection to prevent progression to active disease in accordance with national policies. Infection control measures in clinical settings where patients with HIV/AIDS and TB mix are also supported.

Finally, USAID supports programs and operations research that seek to decrease the burden of HIV in TB patients. Support is provided to increase access to HIV-testing and counseling and establish a system of referrals with HIV/AIDS programs and by training TB program personnel in HIV testing. Based on WHO recommendations, USAID supports programs that promote the use of co-trimoxazole preventive therapy in adults and children living with HIV/AIDS and ARVs in eligible TB patients. USAID supports pilot service delivery models for reaching co-infected patients, monitors and analyzes the effectiveness of such models, and documents these experiences.[13]

D. Strengthen health systems and human resource capacity

Effective TB control programs require a well-performing health system and trained personnel. USAID supports tracking of financial resources for TB, policy dialogue to ensure that TB control programs are a priority in health sector policies, and integration of TB control activities into health system reforms. Technical assistance and training are undertaken to ensure effective TB commodity procurement and supply management. *USAID supports all aspects of human resource capacity development*, including training of all cadres of health care providers and managers, epidemiologists, and community-based workers and volunteers. Capacity building includes the core elements of DOTS and TB control, as well as areas that contribute to overall system strengthening such as problem solving, supervision, management and planning. These measures facilitate effective program expansion, improve program performance, and enhance the ability of program managers and supervisors to address problems in program implementation. Attention is given to integration of the Stop TB Strategy into pre-service training in schools of Public Health, Medicine and Nursing, and other Allied Health Professions. USAID supports the development of human resource plans for TB programs, information systems to track the deployment and training of personnel responsible for TB control activities, and the adaptation, translation and dissemination of training materials. The

[13] USAID will support these activities through combined funding from the HIV/AIDS and TB programs.

Practical Approach to Lung Health (PAL) is integrated into primary care to improve the diagnosis and management of persons suspected of having TB.

E. Develop new tools and improved approaches

New or improved tools to increase TB case detection and to improve TB treatment are urgently needed. A lack of access to accurate and reliable diagnostic services precludes or delays identification and treatment of cases, leading to continued disease transmission and poor patient outcomes. In addition, the current arsenal of drugs requires long treatment durations and is sub-optimal for curing MDR-TB and XDR-TB patients.

USAID supports research in a number of areas critical for improving the performance and public health impact of country-level TB programs while mitigating the risks of drug resistance. Research aims include reducing diagnostic delay, reducing the duration and improving the efficacy of treatment, preventing disease, and increasing access to the components of the STOP TB Strategy. Investment priority is given for research that will change policy and practice within three to five years. Examples include: (1) field evaluations of new/adapted diagnostic tools and translational research to support continual updating of the diagnostic algorithm recommended globally; (2) clinical trials to evaluate patient management and treatment efficacy; (3) research to evaluate infection control strategies; (4) operational research and epidemiological studies to identify and overcome constraints to implementing current or introducing new tools and approaches; (5) evaluation research to monitor the impact of new tools and approaches; and (6) late-stage clinical trials of 3 new drugs that may shorten the duration of treatment and be useful in the management of drug-sensitive and resistant disease.

USAID brings its field presence to bear on the TB research agenda, informing the research community about the field-based needs and priorities, enabling field-based trials of new technologies, and moving the results of research into policy and practice in the field. In this light, USAID has a comparative advantage to contribute to research at the stage where it has direct and near-term implications for country level TB programs; e.g. clinical trials at stage IIb for drugs, stage III and beyond for vaccines, field demonstrations of new technologies and implementation approaches, and operations research to improve program performance.

USAID collaborates with U.S. government and other partners to ensure seamless and non-duplicative support to the continuum of research, drawing on the comparative advantages of each agency. Once promising developments are ready to be tested in the field and moved into policy, USAID has a clear role in supporting and coordinating their introduction. With its field presence and active role in the Stop TB Partnership, USAID is well-positioned to assist national TB programs to evaluate the potential benefits of these new technologies and to inform global policy related to diagnostic strategies.

Section III. Where We Work

USAID's TB efforts are primarily concentrated in 38 countries (see table below) to maximize impact and focus financial resources, technical assistance from USAID/Washington and its partners, and staffing. Twenty of these countries are designated as Tier One, which have higher priority for funding than countries in Tier Two. These priority countries (or sub-regions of these countries) were selected based on the following criteria:

- High burden of TB cases;
- High incidence of TB (case notification rates over 100/100,000);
- High HIV/AIDS prevalence (TB/HIV co-infection);
- Prevalence and/or potential for drug resistance; and
- Lagging case detection and treatment success rates

In addition to the criteria above, other factors – such as political commitment and technical and managerial feasibility – are considered in selecting countries where USAID provides assistance. Beginning in FY08, countries with high TB prevalence and/or potential for drug resistance and lagging case detection and treatment success rates will receive increased funds.

Category	**Countries**[14]
Tier 1 (20)	Afghanistan, Bangladesh, Brazil, Cambodia, Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Nigeria, Pakistan, The Philippines, Russia, South Africa, Tanzania, Uganda, Ukraine, Zambia, Zimbabwe
Tier 2 (18)	Angola, Azerbaijan, Bolivia, Dominican Republic, Georgia, Ghana, Haiti, Kazakhstan, Kyrgyzstan, Malawi, Mexico, Namibia, Peru, Senegal, Southern Sudan, Tajikistan, Turkmenistan, Uzbekistan

In addition to the countries noted above, USAID supports the Europe and Eurasia Regional Bureau, Latin America and the Caribbean Regional Bureau, Africa Regional Bureau, and Regional Development Mission to implement regional and sub-regional activities.

Section IV. Program Approach

A. Focus on the country level and support National Tuberculosis Control Programs

USAID's comparative advantage is the Agency's field presence in developing and transitional countries, as well as the technical and programmatic expertise of its personnel. A core principle of USAID's approach to TB is to support National TB Programs (NTPs) at the country level and to provide support for the national strategic

[14] A number of the top 22 high-burden countries (i.e., Burma, China, Thailand, and Vietnam) do not appear in the table of priority countries for USAID. While all of these countries have substantial burdens of TB (and in many cases MDR-TB and HIV/AIDS also), there are currently significant legal and/or operational obstacles to providing country-level USAID support for TB control. If a particular country situation should change so that these obstacles are no longer present, USAID will consider adding that country to the priority list provided adequate funds are available.

plans of NTPs including the STOP TB Strategy. The Agency expects to continue allocating approximately 80% or more of the annual TB budget to country level programs and activities including the Global TB Drug Facility, with the remainder of resources allocated to core research, development and dissemination of tools, and advocacy activities. Tier One countries will receive the highest priority for funding as well as for technical assistance provided by USAID Washington staff; technical staff will coordinate closely to ensure that both Tier One and Tier Two countries receive technical assistance as required. Illustrative support will include guidance on mission strategic plans, program design and activities, integration of new tools and approaches, development of monitoring and evaluation plans, and monitoring and evaluation visits. Through a variety of contracts, grants and cooperative agreements, USAID provides technical assistance to country level programs.

B. Invest in global, regional, and national partnerships

Partnerships are a cornerstone of USAID's expanded response to TB. USAID's approach is to coordinate efforts and investments, provide technical input, strategically support key activities and areas of mutual interests, and ensure that USAID's strategic concerns are addressed. USAID and USAID-sponsored programs coordinate with other donors and partners to enhance programmatic synergy, and to leverage financial and technical inputs to increase program impact. Partnerships fall into three broad categories: financial, technical/programmatic, and advocacy. Within and across these categories, global, regional, and country (local) activities are supported.

Global partnerships are an integral part of USAID's program and consist of USAID participation and support for several activities and initiatives. Active engagement in the Stop TB Partnership is a critical element of USAID's program. USAID provides support to the Stop TB Secretariat, is a member of the Stop TB Coordinating Board, and participates in all of the Stop TB working groups. USAID also provides support to the GDF to ensure availability of quality TB drugs and access to complementary technical assistance in pharmaceutical management. USAID coordinates with multilateral and bilateral donors and foundations. Finally, USAID collaborates and coordinates with the Department of State (DOS), PEPFAR, and other U.S. Government agencies, including the Department of Health and Human Services, particularly the CDC and the National Institutes of Health (NIH).

Regional partnerships are also an important component of USAID programs and enable the Agency to support activities tailored to the unique regional and cultural characteristics of specific geographic areas. Through Stop TB Regional Partnerships, grants to regional institutions, and regional initiatives, USAID supports regional technical advisors and trainings, information dissemination and networking activities, operations research, and pilot activities. For example, USAID has established Centers of Excellence for MDR-TB that provide technical assistance and training to countries in their respective regions.

At the *country level*, USAID missions take the lead in establishing partnerships and coordinating their activities with NTPs and other donors. Illustrative activities include coordinated planning and strategy development, synchronized monitoring and evaluation

activities, support for proposal development to the GDF and GFATM, and involvement in national level interagency coordinating committees and STOP TB partnerships.

C. Ensure success of GFATM grants

The Global Fund is the single most important source of external funding for TB control in countries constituting up to 70% of external funding in some cases. USAID works on several fronts to ensure that GFATM TB grants are secured and effectively implemented. USAID assists Country Coordinating Mechanisms (CCMs) to prepare proposals to the GFATM. Once grants are awarded, USAID missions and cooperating agencies assist countries to implement all technical aspects of the STOP TB Strategy, and to prepare reports and documentation to support Phase Two grant approvals. The Agency and our partners assist countries by providing technical assistance to prepare various plans required prior to grant signing, including procurement and supply management plans, monitoring and evaluation plans, implementation plans and human resources plans. Finally, USAID's support helps ensure that best practices in various aspects of the STOP TB Strategy are identified, disseminated, and promoted to GFATM CCMs at the country level.

E. Strategic Engagement with PEPFAR

USAID activities to address TB and HIV-AIDS co-infection are closely coordinated with PEPFAR. Since 2004, an inter-agency collaboration between USAID and the U.S. Government agencies involved with PEPFAR has accelerated efforts to combat TB/HIV. PEPFAR has placed special emphasis on 15 focus countries and TB/HIV resources are used for the integration of TB and HIV collaborative activities; HIV testing for people with TB and TB screening, diagnosis, and treatment for PLWHA; improving TB infection control; and TB/HIV and MDR-TB and XDR-TB surveillance, supply chain management; and laboratory support. In the ten[15] countries with overlapping PEPFAR and USAID TB support, USAID TB programs strengthen TB services for the general population while PEPFAR programs prioritize care for individuals co-infected with TB and HIV. Members of USAID's TB team are actively engaged in PEPFAR's HIV-TB working group and in the annual review of PEPFAR Country Operational Plans.

Section V. How We Measure Our Achievements

USAID's Monitoring and Evaluation activities are fully consistent with the global TB monitoring and reporting system promoted by WHO. Country level programs collect and analyze standard indicators to demonstrate achievements and to identify areas requiring more attention to reach targets.

USAID promotes the use of standard indicators and includes TB indicators in the Foreign Assistance Reform Foreign Assistance Coordination and Tracking System, including:

[15] The ten countries are Ethiopia, Haiti, Kenya, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Uganda, and Zambia.

TB burden: The burden of TB is measured by monitoring the number of all new TB cases notified by health facilities every year per 100,000 population. This indicator is calculated and reported annually as part of routine surveillance system, with most countries reporting this information to WHO.
Standard Indicator: Case notification rate in all new cases
Case detection: Monitoring of case detection measures the capacity of the health system to identify new sputum smear-positive (SS+) cases. This indicator is most appropriately monitored at the national level (except in countries with large populations). Most countries report this indicator annually to WHO.
Standard Indicator: Case detection rate in new SS+ cases

Treatment outcomes: Successful treatment of SS+ pulmonary TB cases is an important outcome indicator of TB programs. National level routine monitoring and evaluation systems collect and report treatment cohort analyses semi annually, with most countries reporting this information to WHO on an annual basis.

USAID reports on program results and progress, as part of the Agency Annual Progress Report, the Annual Report to Congress on USAID Child Survival and Health Programs, and other reports such as the Freedom Support Act (FSA) report.