

US Agency for International Development

Expanded Response to Tuberculosis

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ACRONYMS

AEEB	Assistance for Eastern Europe and the Baltics
ALA	American Lung Association
ANE	Bureau for Asia Near East
ARV	Anti-retro viral
ATS	American Thoracic Society
CBO	Community-based organization
CDC	Centers for Disease Control and Prevention
CIDA	Canadian International Development Agency
DfID	Department for International Development
DHHS	Department of Health and Human Services
DOS	Department of State
DOTS	Directly observed treatment, short course
E & E	Bureau for Europe and Eurasia
FBO	Faith-based organization
FSA	Freedom Support Act
GAP	Global AIDS Program
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, TB, and Malaria
GLC	Green Light Committee
HAART	Highly active anti-retroviral therapy
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
IUATLD	International Union against Tuberculosis and Lung Disease
JICA	Japan International Cooperation Agency
KNCV	KNCV Tuberculosis Foundation
LPA	Legislative and Public Affairs
M & E	Monitoring and Evaluation
MDR TB	Multiple drug resistance - tuberculosis
NGO	Non-governmental organization
OE	Operating expenses
PLWA	Person living with AIDS
PPC	Policy and Program Coordination
PVO	Private voluntary organization
QA/QI	Quality assurance/quality improvement
SIDA	Swedish International Development Agency
SOTA	State-of-the-art
TB	Tuberculosis
TBCTA	Tuberculosis Coalition for Technical Assistance
VCT	Voluntary testing and counseling
WHO	World Health Organization
WHO/AFRO	WHO/ Africa Region

INTRODUCTION

Tuberculosis (TB) kills approximately two million people per year. Of the estimated two billion people infected with tuberculosis, eight million develop the disease annually. TB is a major killer among women of reproductive age and is the leading cause of death in HIV-positive people, accounting for one third of AIDS deaths worldwide. Just 22 high burden countries (HBCs) account for 80% of the global TB burden, with half of these countries located in Asia. In Africa, 19 countries have an estimated TB case notification rate greater than 100/100,000, as compared to an estimated case notification rate of 6/100,000 in the United States. It has been projected that Africa will have the highest burden of TB from the year 2005 and beyond.

The global resurgence of TB has been fueled by increasing HIV/AIDS prevalence, inadequate investments in public health systems, and emerging TB drug resistance. The disease threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development. Ninety-five percent of all TB cases and 98% of all TB deaths occur in developing countries.

Much progress has been made since The Stop TB Partnership (of which USAID is a member) was launched in 1998. 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 cases¹ to be achieved by the year 2005 in the 22 HBCs, and served to catalyze governments and donors to address TB. The Stop TB partners and countries have endorsed The Directly Observed Treatment, Short-Course² strategy as the most effective strategy available for the treatment and control of TB. The number of countries implementing DOTS increased from 112 in 1998 to 155 in 2001 and one high burden country (Peru) reduced TB incidence sufficiently to graduate from the list of 22 HBCs. The Partnership has grown to include over 200 donors, non-governmental organizations (NGOs) and other institutions, which demonstrates the strong global commitment to combat TB and to collaboration in that effort.

However, recent analysis of global TB trends and progress in DOTS implementation indicates that without an accelerated plan for DOTS expansion and program strengthening, these global targets will not be achieved for many years to come. Reported global DOTS coverage of 61% 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 82% (2000 cohort) about 39% of the world's

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

² The DOTS Strategy has five components: political commitment; passive case detection among patients seeking care at health facilities and diagnosis using sputum smear microscopy; standardized short-course treatment with direct observation of therapy at least in the initial phase; assurance of an uninterrupted supply of high-quality drugs; and standardized recording/reporting with systematic evaluation of treatment outcomes.

population resides in non-DOTS areas where treatment success averages just 67%. Globally, just 43% of estimated sputum smear positive TB cases were detected. Gains achieved in cases registered in DOTS areas are about the same as the loss from cases detected in non-DOTS areas suggesting that DOTS expansion to date has not resulted in the desired level of case detection. At the current rate of progress, the global target of 70% case detection will not be reached until 2013. Finally, only one of the 22 high burden countries (Vietnam) has achieved the recommended targets for both case detection and treatment success thus far.³

Section I: USAID's Commitment

USAID's goal is to contribute significantly to the global reduction of morbidity and mortality associated with tuberculosis. In order to achieve this goal, USAID's objective is to enhance the capacity of developing and transitional countries to achieve global targets of 70% case detection and 85% treatment success rates among sputum smear positive pulmonary TB patients by preventing and curing active TB. Specifically, USAID will provide financial and technical support to:

- Expand and strengthen DOTS programs;
- Increase and strengthen human resource capacity;
- Develop and disseminate new tools and approaches; and
- Adapt DOTS to address special challenges.

Section II. What We Will Achieve

USAID will contribute to the achievement of STOP TB global targets for treatment success and case detection by focusing on country level support to DOTS programs. The Agency will also support operations research and the development of new tools and approaches.

At the country level, expected achievements will vary depending on the level and type of financial and technical support provided. USAID will assist countries to:

- Increase the treatment success rate to 85% at the national or sub-national level;
- Increase case detection rates to 70%.

In addition to the targets above, USAID assistance will contribute to:

- Increased and improved human resource capacity to support DOTS at all levels – host countries, US partners and globally;
- Progress in the development and dissemination of new tools and approaches (includes diagnostics, treatment, operations research, TB and HIV/AIDS co-infection, and management of patients with multi-drug resistant TB); and

³ All data are from "WHO Report 2003, Global Tuberculosis Control" Communicable Diseases, WHO, Geneva

- Improved quality, availability and use of reliable data on TB and DOTS program performance, both globally, and in selected countries.

Section III. What We Will Do

A. Expand and strengthen DOTS

DOTS is a cost-effective and affordable strategy for controlling TB. In general, if implemented appropriately, DOTS programs should achieve treatment success among at least 85% of sputum smear positive pulmonary TB patients; DOTS can also limit 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 will *support interventions to increase the availability and access to DOTS in priority countries* (see Section IV below) to achieve international targets for case detection (70% of infectious cases detected) and treatment (85% of infectious cases successfully treated). More specifically, investments will be made to improve the ability of health systems to deliver sustainable DOTS programs, including: patient management including supervision of treatment; TB program management and planning skills; training personnel; strengthening laboratories; effectively procuring, delivering, and managing a dependable supply of high-quality TB drugs; educating communities on TB and appropriate care-seeking behaviors; and routinely monitoring treatment outcomes and overall program performance. Given the importance of political commitment and resource mobilization for program sustainability, USAID will assist countries to prepare national five-year plans and budgets for DOTS expansion, and to prepare proposals to funding sources such as the Global Fund to Fight Against AIDS, TB and Malaria (GFATM) and the Global TB Drug Facility (GDF).

To complement DOTS expansion efforts through national TB programs, USAID will *support approaches to expand involvement of private providers, private voluntary organizations (PVOs) and non-government organizations (NGOs)* in DOTS to help extend access to, and quality of, TB services. Partnerships with these groups can extend the reach of DOTS programs to marginalized or difficult to reach populations (e.g., HIV-infected, poor, minorities, migrants, just-released prisoners, and mobile populations) who often have limited access to TB services due to geographic and financial obstacles, and issues of stigma and discrimination. Coordination of in-country staff, resources, and activities will be undertaken in order to maximize impact and avoid duplication.

In addition to supporting DOTS expansion, it is equally important to strengthen existing DOTS programs to achieve better treatment outcomes, prevent disease transmission, and slow the emergence of multi-drug resistant (MDR) TB⁴. In the 22 HBCs, the case detection rate for sputum smear positive cases is 31% in DOTS programs, far below the global target of 70%. Despite the fact that DOTS programs consistently out-performed

⁴ MDR TB is defined as resistance to at least isoniazid and rifampicin, the two most-important anti-TB drugs.

non-DOTS programs in terms of treatment success, in some high burden countries such as Pakistan and South Africa, high treatment default rates of 17% and 12% (2000 cohort in DOTS areas) respectively, contribute to disease transmission and potentially to the development of TB drug resistance. Other countries have difficulty with following up after diagnosis. Other countries have difficulty insuring that patients start treatment soon after being diagnosed with TB. Furthermore, while overall treatment success under DOTS averaged 82%, this global figure masks large variation in regions such as Africa where the treatment success was just 73%.⁵

USAID will undertake *activities and interventions to improve DOTS program performance in USAID priority countries*. Attention will be given to ensuring that diagnosed patients begin therapy, patients on treatment, as well as clinicians and nurses providing treatment and care adhere to program norms or standards, and treatment outcomes are documented and reported. Training will be 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 for improving programs and to influence policies. USAID will continue to support the 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 will play a key role in the development and standardization of monitoring and evaluation instruments through a global working group led by WHO. Existing tools will be evaluated and adapted, and new tools will be 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. In countries where drug supply problems affect DOTS program performance, USAID will strengthen TB drug forecasting, procurement, inventory control, and/or distribution to ensure that reliable supplies of quality TB drugs are available.

Finally, support will be provided for operations research to assist countries in understanding local factors that contribute to weak or poor program performance and to identify appropriate corrective interventions.

B. Increase and strengthen human resource capacity

DOTS expansion and strengthening requires an adequate and well-trained workforce. Currently, the needs for such an effective TB workforce outstrip the supply of trained personnel at all levels of service delivery. To address this problem, *USAID will support all aspects of human resource capacity development*, including training for physicians, nurses, laboratory technicians, program managers, epidemiologists, community outreach workers, social workers, and pulmonary specialists. In addition to training in the core elements of DOTS and TB control, capacity building in areas such as problem solving, supervision, management and planning will be provided. These measures will facilitate effective program expansion, improve program performance, and enhance the ability of program managers and supervisors to address problems in program implementation. Attention will be given to increasing and strengthening the training and technical capacity

⁵ All data from The WHO Report 2003 Global Tuberculosis Control.

of academic institutions such as Schools of Public Health, Medicine and Nursing, and other Allied Health Professions. Specialized training in areas such as operations research, drug management, treatment of MDR TB and TB-HIV/AIDS co-infection, and infection control will also be provided as indicated. USAID will support the development, adaptation, translation and dissemination of training materials that address DOTS and related skill areas described above. USAID will also provide drug management training for DOTS Plus for MDR-TB pilot sites approved by the Green Light Committee in a variety of regions.

C. Develop and disseminate new tools and approaches

USAID's investment in global TB control includes support for focused research in a number of areas critical for accelerating global DOTS expansion and improving DOTS program performance. A number of partners are currently funding research aimed at the development of new TB drugs and improved TB vaccines. To complement these investments, USAID will work with its partners and focus its support on the development, evaluation, and introduction of tools and approaches that are appropriate for use in low-resource countries, have the potential for significant public health impact, and have traditionally been under funded by the public and private sectors.

New or improved tools to increase TB case detection are urgently needed, as lack of access to accurate and reliable diagnostic services precludes or delays identification and treatment of cases leading to poor patient outcomes and disease transmission. In addition, there is a critical need for investment in operational research aimed at developing new or improved approaches to increase access, quality and effectiveness of TB control services in both the public and private sectors.

USAID will support *the development of new and improved diagnostics* appropriate for use in developing and transitional countries that are accurate, rapid, affordable, uncomplicated, appropriate to developing and transitional countries, and functional in a variety of settings (including areas of high HIV prevalence). Examples of current investments include support for the development of a rapid, point-of-care test to detect active TB disease, efforts to strengthen clinical trial capacity for the evaluation of new diagnostics, and the development of improved methods for smear microscopy. To this end, USAID is also investing in WHO's TB Diagnostics Initiative to improve access to well-characterized reference materials for diagnostic tool development and to strengthen clinical trial capacity for the evaluation of new diagnostic tools.

USAID will also support *the development of new drug treatment regimens and new drugs* that are easier to use, safer, lower in cost, and less labor intensive to administer. Current projects include research on fixed-dose combinations of TB drugs, intermittent and shorter treatment regimens, and the use of newly approved antibiotics. These products have the potential to improve DOTS programs through decreased operational costs, lower overall health expenditures and improved patient adherence, leading to higher cure rates and fewer cases of drug resistance. Clinical trials to assess the efficacy of proposed regimens will be supported.

Finally, USAID will support *operations research to improve the management and delivery of TB control interventions*. Examples of priority research areas include: (1) approaches to improve access, quality and effectiveness of DOTS programs (including laboratory services); (2) the development of effective strategies to address the HIV-TB co-epidemics; (3) social, economic and behavior research related to issues such as stigma and poor nutritional status; (4) health policy and systems research, including strategies to improve of public-private partnerships to ensure the harmonization of public-sector DOTS programs and the private sector, NGOs, and communities in TB control; (5) approaches to combat the expansion of MDR TB; and (6) communication strategies to improve program performance and demand for services.

D. Adapt DOTS to address special challenges

HIV/AIDS and MDR TB present special challenges to the expansion and effectiveness of DOTS programs. USAID's response to each of these challenges is described below.

HIV/AIDS and TB co-infection: Currently, about 42 million people are HIV-infected and almost 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; currently in many African countries more than 50% of patients with active TB disease are also HIV-positive. The dual epidemics are also 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 could particularly exacerbate problems with the MDR TB epidemic in the region of Eastern Europe and the former Soviet Union.

Persons infected with both HIV and TB are 30 times more likely to progress to active TB disease. Recent studies have shown that 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.

The objectives of USAID assistance in this area are to actively improve the coordination and harmonization of TB and HIV/AIDS interventions and programs to increase access to TB services (including TB screening and prophylaxis) for people infected with HIV, and increase access to HIV testing and other services for people infected with TB.⁶ In addition, USAID will increase the knowledge base, quality and availability of information on TB/HIV co-infections.

⁶ USAID's HIV/AIDS programs will be principally responsible for funding of HIV testing and other services.

To achieve these objectives USAID will focus on three key interventions. *Improved coordination of TB and HIV services* is essential to ensure early diagnosis, appropriate referral, and prompt, quality care for each disease. To accomplish this, USAID will: support coordination and collaboration between HIV and TB national programs; strengthen and link TB services to VCT and HIV care services; develop training programs on for TB specialists/programs managers on VCT and management of co-infected patients for all levels of providers, as well as TB training modules for VCT providers; and improve coordination among host countries and donor agencies, NGOs, and research institutions. USAID will also explore the use of alternative service delivery approaches, such as community and home-based care, and the involvement of faith-based organizations in such approaches.

USAID will also *support improvements in TB service delivery system links with anti-retroviral (ARV) treatment services*. Facilities that provide HAART (highly active anti-retroviral therapy) for co-infected patients offer a critical opportunity for TB-HIV/AIDS collaboration. Given the need to modify or delay the TB treatment for individual patients who are receiving HAART, care of these patients must be coordinated. Furthermore, the HIV/AIDS community is eager to take advantage of the lessons learned from DOTS program experience, including the application of DOTS principles to treatment programs. USAID will support pilot service delivery models for reaching co-infected patients, monitor and analyze the effectiveness of such models, and document these experiences.⁷

Finally, USAID will *strengthen and expand TB and HIV surveillance* to improve the detection of TB/HIV co-infection and the quality of data on co-infection and epidemiological trends.

MDR TB: Proper treatment of susceptible strains of TB requires multiple drugs over six to eight month period. If therapy is irregular or the drugs are of poor quality, resistant TB strains become dominant. In the 22 HBCs that have completed national or sub-national TB drug resistance studies, rates of MDR TB range from 0 - 10%⁸ in infectious cases that have not been previously treated; levels are generally higher in previously treated cases. Even in non-high burden countries, high MDR rates pose serious threats to the local population. This situation is a concern because drug-resistant TB is more difficult to cure, which translates into greater disease transmission and higher death rates. Second line drugs used to treat MDR TB are often toxic and disabling to patients. The cost of treating MDR TB ranges from 10 to 100 times greater than it is for drug-susceptible TB, which has implications for both health budgets and patient access to care.

USAID will support a two-fold approach to address MDR TB. *USAID will support the strengthening of DOTS programs to improve adherence to recommended treatment regimens and to prevent the emergence of MDR TB*. USAID Assistance will be provided to improve procurement and management of high-quality drugs, and strengthen routine monitoring of drug quality. In addition, *USAID will support interventions to improve the*

⁷ USAID will support these activities through combined funding from the HIV/AIDS and TB programs.

⁸ "Anti-Tuberculosis Drug Resistance in the World." Report No. 2 Prevalence and Trends, The WHO/IUATLD Global Project on Anti-Tuberculosis Drug Resistance Surveillance, Communicable Diseases, WHO, 2000.

treatment of MDR TB. Attention will be given to better monitoring and recording of treatment failures, implementing studies to measure TB drug resistance, expanding laboratory capacity to monitor drug-resistance, introducing new drugs and/or treatment regimens, and support for operations research (such as DOTS Plus for MDR TB pilot projects) to reduce poor outcomes. Expanding the involvement of the private sector in DOTS will be addressed as well, since TB treatment by private health providers is often inconsistent with the recommended drug regimens (e.g. type of drug, dose, and duration) and drug quality standards.

USAID will also support training of private sector providers to raise their awareness of DOTS, as well as programs that link private sector providers with the national TB program. Finally, USAID will support development of a tracking tool to assist the Green Light Committee (GLC)⁹ in scheduling shipments, monitoring drug inventory, and identifying technical support required for the GLC to carry out its expanded role as the procurement and distribution mechanism for GFATM grants awards involving second line TB drugs.

Section IV. Where We Will Do It

USAID's TB efforts will be primarily concentrated in a limited number of priority countries (see table below) to maximize impact and focus financial resources, technical assistance from USAID/Washington and its partners, and staffing. Countries in Tier one will have higher priority for funding and technical assistance from USAID/Washington, than countries in Tier two. These priority countries (or sub-regions of these countries) were selected based on one or more of the following criteria:

- High incidence of TB (estimated incidence rates of over 100/100,000) and/or high number of total TB cases¹⁰;
- HIV/AIDS burden;
- Risk of an escalating epidemic of multi-drug resistant TB.

In addition to the criteria above, other factors such as country commitment and technical and managerial capacity, the capacity and interest of the USAID mission and other key TB partners, and foreign policy interests were considered in selecting countries where USAID provides assistance.

⁹ The GLC is a technical review committee that functions under the auspices of the STOP TB Partnership) that reviews and guides DOTS Plus for MDR TB pilot projects. Pilot projects that receive GLC approval are eligible to purchase second-line anti-TB drugs through a GLC pooled procurement mechanism.

¹⁰ According to the 2002 WHO Global TB Control report, 22 countries account for about 80% of the global TB burden. In order of TB burden, they are: India, China, Indonesia, Nigeria, Bangladesh, Ethiopia, Philippines, Pakistan, South Africa, Russia, Congo (DR), Kenya, Vietnam, Tanzania, Brazil, Thailand, Uganda, Burma, Mozambique, Cambodia, Zimbabwe, and Afghanistan.

Category	Countries ¹¹
Tier 1 (22)	Afghanistan, Bangladesh, Brazil, Cambodia, Democratic Republic of Congo, Dominican Republic, Ethiopia, Haiti, India, Indonesia, Kenya, Mexico, Mozambique, Namibia, Nigeria, Pakistan, The Philippines, Russia, South Africa, Tanzania, Uganda, Zambia
Tier 2 (18)	Angola, Bolivia, El Salvador, Egypt, Georgia, Ghana, Honduras, Kazakhstan, Kyrgyzstan, Malawi, Moldova, Peru, Senegal, Southern Sudan, Tajikistan, Turkmenistan, Ukraine, Uzbekistan, ANE Regional ¹² , E+E Regional ¹³

Section V. How We Will Do It

A. Focus on the country level

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. USAID will focus technical and financial resources on country level programs, with priority to the Tier One countries listed above. The Agency expects to continue allocating 75% or more of the annual TB budget to country level programs, 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 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 program design and activities, integration of new tools and approaches, development of monitoring and evaluation plans, and monitoring and evaluation visits.

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.

¹¹ A number of the top 22 high-burden countries (i.e., Burma, China, Thailand, and Zimbabwe) 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.

¹² Some support provided to China, Mongolia, Papua New Guinea, Laos and Vietnam.

¹³ Some support provided to Armenia, Estonia, Kosovo, Latvia, Lithuania, and Romania.

Global partnerships are an integral part of USAID's program and consist of USAID participation and support for several activities and initiatives. Participation in the Stop TB Partnership is a critical element of USAID's strategy. USAID helped initiate the Stop TB Partnership, 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. Through the USAID cooperative agreement with the TB Coalition for Technical Assistance (TBCTA)¹⁴, the Agency provides technical support and assistance to USAID priority country programs. The TBCTA is considered by the Stop TB Partnership to be a critical player in DOTS expansion. In addition to the US government contribution to the GFATM and GDF, the Agency and our technical partners assist countries by providing technical assistance in the development and implementation of country level proposals submitted to, or funded by, the GFATM and/or the GDF. USAID's support also helps ensure that best practices in various aspects of DOTS are identified, disseminated, and promoted to GFATM Country Coordinating Mechanisms (CCMs) at the country level. Specific examples include USAID's investments in TB education and communication approaches, drug management, operations research, and monitoring and evaluation related to DOTS. USAID will continue to expand coordination with multilateral and bilateral donors and foundations and PVOs, and to initiate new partnerships with PVOs through the provision of support for TB activities within the USAID Child Survival and Health Grants Program. Finally, USAID collaborates and coordinates with the Department of State (DOS), and other U.S. Government agencies, including the Department of Health and Human Services, particularly the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). CDC participates in the TBCTA, and collaborates with USAID in key areas such as technical assistance to USAID missions and operations research and tools development. NIH is an important partner in research and research capacity building, and DOS is a partner in USAID TB programs, particularly in the Europe and Eurasia region.

Regional partnerships are also an important component of USAID programs and enable the Agency to support activities tailored to unique regional and cultural characteristics of specific geographic areas. Through Stop TB Regional Partnerships, grants to regional institutions, and regional initiatives, USAID provides support for regional technical advisors, regional training and networking activities, operations research, and pilot activities such as community-based DOTS.

At the *country level*, USAID missions take the lead in establishing partnerships and coordinating their activities with the National TB Program (NTP) and other donors. Illustrative activities include coordinated planning and strategy development, synchronized monitoring and evaluation activities, participation in CCMs, and support for proposal development to the GDF and GFATM. Once funds are awarded, USAID

¹⁴ The TBCTA is a unique consortium of six of the leading international TB organizations: the Royal Netherlands TB Association (KNCV), The International Union Against TB and Lung Disease (IUATLD), the American Lung Association, the American Thoracic Society, the World Health Organization, and the Centers for Disease Control and Prevention (CDC).

missions and cooperating agencies can assist countries in preparing plans for implementation of GFATM-funded TB programs, monitoring and evaluation, and provide technical assistance to CCMs and local partners. Partnerships with medical, nursing, public health and allied health professional schools, the private sector, professional associations, NGOs, and community- and faith-based groups will be established as appropriate.

C. Build capacity of our partners

To address the need to provide technical assistance at the country level, *USAID will increase and improve the capacity of existing partners*. The Agency will support the training of regional and international consultants through partnerships with organizations such as WHO and the TBCTA. Consultant training and mentoring programs will be established and implemented on topics such as TB control and DOTS, epidemiology, operations research, DOTS program design, management and evaluation, TB drug management and quality assurance, and consultancy skills. The outcome of this effort will be an expanded pool of TB consultants available to provide technical assistance in all regions.

Through targeted grants to PVOs, USAID will also encourage capacity building for US based PVOs and other partners to enhance their ability to support effective DOTS programs and expand DOTS programs in priority countries. In addition, USAID will facilitate the development of effective relationships between the international TB community and the PVO community in the US and in other countries. Finally, the absorptive capacity of existing mechanisms will be monitored and new mechanisms will be initiated to respond to the needs of mission and core programs.

D. Build capacity at USAID

USAID will also increase the knowledge of USAID mission health program personnel. Through periodic State-of-the-Art training activities, participation in regional training conferences and workshops, and other events, mission staff will acquire increased knowledge related to TB epidemiology, DOTS programs, and areas of increased attention such as TB/HIV and MDR TB. USAID mission health program capacity will also be enhanced by periodic technical assistance visits by USAID TB advisors. Tuberculosis will be incorporated in training of new staff through the New Entry Professionals and International Development Interns programs.

E. Communication and advocacy

Through financial support to the Stop TB Partnership and its related working groups, USAID invests in a range of activities to *raise awareness of the Global TB problem*, and the need for increased resources from all sources to develop national TB control programs that offer high quality and sustainable services. Stop TB's role is to establish a gateway to a comprehensive and up-to-date source of information and resources concerning TB. In addition, it promotes awareness of the links between TB and human rights in terms of access to treatment and vulnerability to disease. USAID country level

missions engage in policy dialogue to advocate for maintained or increased host government support for DOTS programs.

The Agency will expand efforts to *educate relevant audiences about USAID's programs*. USAID will develop consistent and quality information regarding the Agency's global, regional and priority country programs. USAID staff and partners will review and update existing materials and presentations, prepare and consolidate messages that describe USAID's programs, identify gaps and create new materials. Information obtained through the monitoring and evaluation system will provide useful inputs for these materials.

To expedite the successful development and expansion of TB control programs and DOTS, USAID will undertake a variety of activities to ensure *synthesis and dissemination of program experiences and lessons learned*. USAID will work through existing international, regional, and country level mechanisms, as well as across Agency offices and missions, to establish more consistent information dissemination activities, and to support and facilitate opportunities for sharing information and lessons learned. Information exchange will target those organizations involved in advocacy, policy, design, development, implementation, monitoring, and evaluation of TB programs. A new emphasis will be placed on the inclusion of PVOs and organizations providing HIV services in this exchange of information, and implementing partners will be encouraged to share their experiences. Mechanisms will include printed material and other media, regional workshops, study tours, and sponsorship of workshops and symposiums.

Finally, USAID will support information, communication and education activities at the community level to improve recognition of symptoms of TB, care seeking and referral, and compliance with treatment.

Section VI. What Resources Are Needed

To accomplish the objectives and results described in this strategy, USAID will require a total budget of \$75 million per year to be allocated to mission and regional programs and to core activities managed by BGH. This budget level assumes that staffing for TB will be maintained, or increase. In Washington, a minimum of three full-time staff members are required, with additional inputs to be provided technical advisors who dedicate a portion of their time to TB.

Section VII. How We Will Measure Our Achievements

USAID will expand and strengthen the monitoring and evaluation system (M & E) for USAID-supported TB programs to measure progress toward goals at the global, national and project level. The M & E strategy will benefit USAID's funded programs, as well as the TB activities of national programs and other donor organizations. USAID will ensure that tools developed for monitoring of USAID programs are consistent with WHO recommendations regarding TB program monitoring and evaluation, and provide a "value-added" to existing monitoring and evaluation activities. Mission programs will collect and examine these data to demonstrate areas of success, and to identify areas requiring more work to reach targets.

A. Programmatic reporting

Key indicators will include:

TB burden: The burden of TB is measured by monitoring the number of 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

Increased case detection: Monitoring of case detection measures the capacity of the health system to identify new sputum smear positive (SS+) cases. While routine monitoring and evaluation systems also collect and report on case detection at the facility, local or district, and regional level, 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

Improved treatment outcomes: Successful treatment of SS+ pulmonary TB cases is the most important outcome indicator of TB programs. National level routine monitoring and evaluation systems collect and report treatment cohort analyses annually, with most countries reporting this information to WHO. In USAID-assisted programs, cohort analysis will be monitored at the national, sub-national or local (district level) as appropriate, depending on the target geographic coverage of the program.

Standard Indicator: Treatment success rate in sputum smear positive cases

Other standard indicators:

- Cure rate
- Treatment default rate
- Treatment failure rate

USAID will report annually 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) and Assistance for Eastern Europe and the Baltics (AEEB) reports.

B. Financial reporting

On the global level, USAID will report the following financial data annually:

- The amount of TB funds allocated to each country, Regional Bureau, and Global Bureau project;
- For the Global Bureau projects, the amounts allocated to core activities;
- Yearly obligations by country (including both direct Mission obligations and field support designations).