TUBERCULOSIS CARE
(TB CARE)

Request for Information (RFI)

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Issuance Date: December 18, 2009
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Subject: Request for Information (RFI) No. USAID/M/OAA/GH/HSR-10-115

FY – 2010 Tuberculosis Care (TB CARE)

The United States Agency for International Development (USAID) Bureau for Global Health, Office of Health, Infectious Disease and Nutrition (GH/HIDN) anticipates awarding one (1) Cooperative Agreement, TB CARE. The goal of issuing this Request for Information regarding this potential RFA for a cooperative agreement is to build and expand upon previous USAID tuberculosis (TB) prevention and treatment efforts over the last eleven years, particularly the success of the Tuberculosis Control Assistance Program (TBCAP) activity. TB CARE will be one of the main global mechanisms for implementing USAID's TB strategy as well as contribute to the TB/HIV section in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The new activity funded under this RFA will complement existing and planned projects in the Bureau for Global Health to provide global leadership and support to National TB Programs (NTPs).

At this time the Agency is requesting information/comments regarding the attached draft program description from potential bidders. Please note that the Request for Information (RFI) for Respond is posted independently. USAID will review all comments prior to posting the Request for Applications (RFA).

Request for Information Guidelines

Respondents are encouraged to comment on the general concept, potential benefits or obstacles, the overall merits and relative priority of the ideas described in this scope of work. USAID will evaluate the responses and modify, as appropriate, the final scope to be included in the RFA.

For the purposes of this RFI, the term “Grant” is synonymous with “Cooperative Agreement”; "Grantee" is synonymous with "Recipient"; and "Grant Officer" is synonymous with "Agreement Officer".

The authority for the RFI is found in the Foreign Assistance Act of 1961, as amended.

Disclaimers:
This RFI is issued solely for information and planning purposes and does not constitute an RFA. Responses to this notice are not offers and cannot be accepted by the Government to form a binding agreement. Respondents are solely responsible for all expenses associated with responding to this RFI. Responses to this RFI will not be returned. Respondents will **not** be notified of the result of any review.

The preferred method of distribution of USAID RFI information is via the Internet. This RFI and any future amendments can be downloaded from http://www.grants.gov.

Responses to this RFI should be no longer than 10 pages in length. Responses shall be submitted electronically no later than **10 AM EST** on **January 12, 2010**, to **kbryant@usaid.gov.**

Thank you for your interest in USAID programs.

Sincerely,

/s/

Bruce Baltas
Agreement Officer
USAID

SECTION A - Introduction and Background

A.1. Introduction

The United States Agency for International Development (USAID) Bureau for Global Health (GH) is issuing this Request for Applications (RFA) for a cooperative agreement to build and expand upon previous USAID tuberculosis (TB) prevention and treatment efforts over the last eleven years, particularly the success of the Tuberculosis Control Assistance Program (TBCAP) activity. TB CARE will be one of the main global mechanisms for implementing USAID's TB strategy as well as contribute to the TB/HIV section in the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The new activity funded under this RFA will complement existing and planned projects in the Bureau for Global Health to provide global leadership and support to National TB Programs (NTPs).

A.2. Problem Statement

Tuberculosis kills approximately two million people per year. Of the estimated two billion people infected with tuberculosis, over eight million develop the disease annually. TB is a the third leading cause of death among women of reproductive age and is a leading cause of death in HIV-positive people, accounting for up to one third of AIDS deaths worldwide. There are 22 high burden countries (HBCs) that account for 80% of the global TB burden, of which over half are located in 11 Asian countries. However, Africa has over 20 countries with an estimated TB case notification rate greater than 100/100,000.

Compounding the slow progress in improving case detection is the rise of drug-resistant TB. Drug-resistant TB is a serious and growing problem that threatens to undermine years of progress in TB control. In 2007, there were an estimated 500,000 cases of multi-drug resistant (MDR) TB and by the end of 2008, 55 countries had detected at least one case of extensively-drug resistant (XDR) TB. The MDR TB cases in India, China, Russia, South Africa, Bangladesh, Pakistan and Indonesia account for approximately 70% of the estimated global burden, while the overall number of MDR TB cases continues to rise in most parts of the world. Access to good quality services to diagnose and treat drug-resistant TB continues to be insufficient. In 2007, 3,681 of the 30,000 (12%) notified cases of MDR TB received treatment though Green Light Committee (GLC) -approved programs, a proportion significantly lower than the Stop TB Partnership's Global Plan to Stop TB targets. 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.

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 1.7 million annual TB deaths, approximately 456,000 are among persons who were HIV-positive. In 2007, analyses of improved data resulting in World Health Organization (WHO) revising the estimated burden of TB/HIV; the 1.37 million co-infected persons is nearly double the number previously estimated. HIV infection is the most significant risk factor for a latent TB infection to convert to active TB and HIV-positive persons are 20 times more likely to develop TB than an HIV-negative person.

The global resurgence of TB has been fueled by increasing HIV/AIDS prevalence, emerging TB drug resistance, inadequate investments in public health systems, and economic instability. The disease threatens the poorest and most marginalized groups, disrupts the social fabric of society, and undermines gains in economic development. Ninety-five percent of all TB cases and 98% of all TB deaths occur in developing countries. These countries have requested assistance in ensuring that their TB programs meet the needs of their citizens to access quality medications, obtain adequate diagnosis, receive standardized and observed treatment with surveillance, and benefit from a quality reporting system.

A.3 Stop TB Strategy

The recent gains in global TB care and prevention have been achieved through comprehensive and systematic implementation of the WHO Stop TB Strategy. The strategy has six components including the well-established DOTS strategy, one of the most cost effective and affordable global health initiatives. Worldwide, the Stop TB strategy recommended by the WHO and the International Union Against Tuberculosis and Lung Disease (The Union), has been adopted by 180 countries, including all 22 high burden countries (HBC). If adapted to local settings and implemented appropriately, the strategy, which is implemented through national health programs, can achieve universal access to diagnosis and treatment for TB, limit the emergence and spread of drug-resistant TB, strengthen health systems, improve gender equality in access to services, and coordinate TB/HIV service delivery. The six components of the Stop TB strategy can be found in the table below.

Table 2. 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 systems 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**

Success in the fight against TB will not be achieved without active detection and effective treatment of individuals with TB disease. It is critical to involve the full spectrum of health care providers, including public, private, non-governmental/non-profit/academic organizations, communities, and volunteers.

Implementation of the Stop TB strategy strengthens the primary health care system as it ensures sustained access for patients with TB to diagnosis, treatment, and follow-up services. Important elements of a successful system include appropriate human resources, networks of capable laboratories, recording and reporting systems, and drug management systems that prevent drug supply interruptions or use of inferior quality medicines. However, without political commitment and effective leadership to fund and implement national TB control programs, the strategy can not achieve and sustain global TB control. Proper implementation will improve access to affordable, equitable, committed, and well organized primary care services.

Over the past several years, increased investment in scale-up of the Stop TB Strategy has resulted in progress towards global targets. However, these investments have not been enough to completely reverse the years of neglect, and an accelerated approach focusing on several key areas including information, education, and communication (IEC), social mobilization, involvement of private and voluntary health care providers, economic analysis and financial planning, and operational research has been instituted to widen the reach and impact of the program. An essential part of this acceleration is the intensified effort to increase collaboration with HIV/AIDS programs and coordinate with public and private organizations, as well as greater attention to ensure effective treatment and prevention of drug resistant TB.

A.4 USAID's Commitment to Tuberculosis Control

The United States Government (USG) through USAID is the largest bilateral donor, supporting global TB prevention and care in 40 countries. Over the past 8 years, USAID's TB prevention and care programs has allocated approximately $730 million to save lives and prevent the spread of TB and MDR TB. Countries with USAID-supported TB control efforts, the average country case detection rate in 2007 reached 80%. USAID is implementing TB programs by accelerated detection and treatment of TB for all patients, scaled-up TB/HIV integration, expanded prevention and treatment of MDR TB, and overall strengthening of the health care system.

In 2008, the United States Congress demonstrated its continued commitment to TB control with the passage 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). This Act authorized a considerable increase in funding for TB prevention and care by the USG. In May 2009, President Obama announced the Global Health Initiative (GHI) to further increase the USG's commitment to health. The GHI focuses attention on tackling broader global health challenges, continuing the support for HIV/AIDS and malaria, and increasing support for TB, child and maternal health, family planning, and neglected tropical diseases. The GHI adopts an integrated, women-centered

approach to fighting diseases, improving health, and strengthening health systems while contributing to the achievement of the goals and targets laid out in the Lantos-Hyde Reauthorization Act.

USAID's goal is to halve TB prevalence and death rates in USAID assisted countries by 2015 (relative to the 1990 baseline), consistent with the Global Plan to STOP TB. Three key targets have been identified for achieving this goal:

1. 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 those cases in countries with established USAID TB programs;
2. Treat successfully 4.5 million new sputum-positive TB cases;
3. Diagnose and treat 90,000 new cases of multi-drug resistant (MDR) TB.

In order to achieve these goals and targets, USAID will accelerate implementation of proven, cost-effective interventions designed to prevent the further spread of TB and drug resistant TB, and to prevent deaths. USAID is committed to the following:

- Accelerate implementation of improved basic TB services and MDR TB services to increase the number of patients receiving early and effective treatment; and
- Contribute to improvements in the health system as an integral part of achieving gains in TB control.

TB CARE will be one of the main USAID mechanisms to contribute to this goal and objectives in select countries by 2015.

USAID is a global technical leader in policy and tool development, and strategic guidance. USAID is active in the Stop TB Partnership Board and working groups, and works closely with the Global Fund Against AIDS, Tuberculosis and Malaria (Global Fund) grants and other global TB partnerships to ensure an efficient and effective approach to achieving success. In addition, our efforts are contributing to research in new and expanded tools and technologies for improved diagnosis, treatment, policy and implementation. At a country level, USAID TB activities are aligned closely with NTP to support their strategic plans and ensure close coordination with Global Fund and other country partners. The programs are embedded within the Ministry of Health's (MOH) NTP to ensure country ownership, maximize efforts and avoid duplication.

USAID's TB effort is concentrated in a number of countries (Table 2) to focus financial and human resources of USAID and its partners. The country selection is based on one or more of the following criteria:

- 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 include political commitment, technical and financial need, and managerial feasibility.

Table 2. USAID TB Priority Countries[1]
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

Please refer to the following web page for further details on USAID's TB Control Strategy. There will be an updated version in the near future in accordance with Lantos-Hyde Reauthorization Act and the GHI and consistent with the information in this program description.
http://www.usaid.gov/our_work/global_health/id/tuberculosis/tbexpanded09.pdf

A.5 USAID/GH – Funded TB Partners

USAID works with a wide array of partners to achieve our TB care and prevention objectives including: health ministries, NTP, other government entities, and local institutions at the country level; multilateral and bilateral donors; international organizations such as the WHO Stop TB Department; private providers, private corporations, foundations, faith-based groups, and other non-governmental organizations; and other USG agencies, including close collaboration with other USG agencies such as the Centers for Disease Control and Prevention (CDC) and National Institutes for Health (NIH). The USG is also a major funder of the Global Fund.

USAID field Missions either program funds through bilateral or global programs. USAID programs have the mandate to work with the MOH, NTP, and other local organizations at the country level. The USAID Global Health Bureau (GH) in Washington manages a number of TB programs, of which TB CARE will be one. The list below briefly describes the major USAID Global Health TB partners, including activities supported under each organization or project. The country specific TB program information can often be found on the USAID GH and Mission website.

[1] Some of the top 22 high-burden countries do not appear in the table of priority countries for the USG. For example, operational obstacles prevent country level support in Burma, and for China and Thailand, country resources are available. These countries may require technical assistance or limited country-level support, respectively. Vietnam may be added to the list of countries where USG assistance is provided if adequate resources become available.

TB CAP: One of the key mechanisms for supporting USAID's TB care and prevention strategy has been the TB CAP project. This unique partnership of seven organizations has partnered with USAID to control TB globally since 2000, but most of the individual organizations have actively worked in this area for almost a century. The TB CAP partnership consists of the KNCV Tuberculosis Foundation, the Union, WHO, Management Sciences for Health (MSH), Family Health International (FHI), Japan Anti-Tuberculosis Association (JATA), the American Thoracic Society (ATS), and technical collaboration from the CDC. These partner organizations collectively refer to themselves as the Tuberculosis Coalition for Technical Assistance (TBCTA).

The purpose of TB CAP assistance is two-fold. First, it attempts to improve and expand the capacity of USAID to respond to the global TB epidemic by providing well-coordinated state-of-the-art, context appropriate, technically sound and cost-effective consultation and technical assistance to high-prevalence countries and Missions. A further goal is to build additional global capacity for the provision of technical assistance.

Second, TB CAP is intended to complement and expand existing global TB control efforts by working in collaboration with other global TB partners and maximize on-going efforts to accelerate the pace of DOTS expansion to meet global targets. By the end of 2010, the aim of TB CAP is to reach the following specific goals in countries with significant investment:

- 90% of public clinics implementing DOTS
- At least 70% case detection rate
- At least 85% treatment success rate and/or cure rate
- 75% of countries meeting MDR TB quality standards defined by TB CAP
- 100% of countries have nationwide TB and HIV programs effectively coordinated

Many of the lessons learned from this activity, as well as other USAID TB control efforts, have contributed to the development of this RFA, including the mid-term evaluation of TB CAP. The evaluation report can be found on the USAID website at: http://www.usaid.gov/our_work/global_health/id/tuberculosis/publications/index.html. In addition, all USAID-funded TB CAP publication and annual reports can be found at www.tbcta.org.

CDC: USAID collaborates closely with CDC on a wide variety of TB control activities. Under this partnership, CDC conducts operational research and training as well as provides technical assistance in TB/HIV, infection control, information systems, MDR-TB, and other related activities to support USAID country and regional programs.

CSHGP: Under the Child Survival and Health Grants Program (CSHGP), USAID provides grants to U.S. Private Voluntary Organizations (PVOs) to address gaps in national or sub-national TB control programs. The grants are for a wide range of interventions including DOTS expansion and strengthening, increasing and strengthening human resource capacity, and adapting the Stop TB Strategy to address special

challenges such as TB/HIV and MDR-TB. A special area of focus for most PVOs is at the community level, particularly focused on access to services, communication and social mobilization aspects of the Stop TB Strategy. The evaluation of the CSHGP TB grants can be found at http://pdf.usaid.gov/pdf_docs/PDACM042.pdf

Global TB Drug Facility: USAID provides support to the Global TB Drug Facility (GDF) for country grants for the purchase of TB drugs. In addition, USAID provides technical assistance to the GDF to ensure pharmaceutical management issues are properly addressed as well as provides support to countries for monitoring GDF grants.

Strengthening Pharmaceutical Services (SPS): The SPS project is a USAID cooperative agreement with MSH that provides technical assistance on drug selection, forecasting, availability, and proper use by both providers and consumers. The project provides support to NTPs in drug management as well as external technical assistance.

Stop TB Partnership: USAID is a financial supporter of the Stop TB Secretariat, a member of the Stop TB Coordinating Board, and is represented on all of the Stop TB working groups (DOTS expansion, new TB drug development, MDR TB, TB/HIV, and TB diagnostics). USAID support was instrumental in the development of the Global Plan, and to the establishment of national Stop TB partnerships and preparation of plans for DOTS expansion in most HBCs. USAID supports the Stop TB Secretariat to develop new tools and provide technical assistance for social mobilization and communication.

TB IQC: The TB IQC Contract is a set of Indefinite Quality Contracts (IQCs). The mechanism allows USAID missions and bureaus to access short and long-term technical assistance and programmatic support on all aspects of adapting the Stop TB Strategy in different settings. The five awardees of the IQC are Program for Appropriate Technology in Health (PATH), Abt Associates, Chemonics International, Medical Service Corps International (MSCI), and University Research Corporation (URC). Recently, the Global Health Bureau awarded a Task Order (TO) to PATH. The TO will provide technical and management support to on-going USAID funded tuberculosis program activities at global, regional and country levels, carry out reviews and analyses of TB program activities, and provide USAID offices and missions a mechanism through which expert short and long term technical assistance can be accessed.

TREAT TB: Technology, Research, Education and Technical Assistance for Tuberculosis (TREAT TB) is a 5-year cooperative agreement with The Union. TREAT TB focuses on field evaluations of diagnostic techniques for TB, clinical trials and operations research to improve patient management, treatment efficacy, disease prevention, and infection control measures for TB and MDR TB.

WHO Stop TB Department: USAID provides support to the Stop TB Department at WHO in an array of TB control activities at the global and country level. Although the support covers the four main areas of USAID's TB strategy, USAID particularly supports MDR TB surveillance, operational research and technical assistance, national and global TB monitoring and surveillance, tools development and technical assistance for public

private mix (PPM), and tools development and technical assistance for human capacity development.

Section B – Program Description

B.1. Technical Approach

TB CARE will contribute to the overall USAID objectives described in Section A.4. It is anticipated 15% of this activity will be Core funded for global leadership and policy development, and the other 85% will be more directly supporting NTPs in implementing their national strategic plans through Field support. The approach to providing global leadership and field implementation should be comprehensive and aligned with the four main technical areas below. The expected outcome for TB CARE is described at the top of each technical area. The technical areas should be a combined comprehensive strategic approach. In addition, TB CARE has four main overarching elements, including collaboration and coordination, access to services for all patients, responsible and responsive management practices, and evidence-based project monitoring and evaluation. They are an integral part of strategic approach and should be also addressed as much as possible within each the technical areas to ensure cohesiveness and avoid fragmentation (see section B.3 for more information).

TB CARE will not support Core funded global leadership activities for drug management or operational research. USAID has other mechanisms for implementing the global leadership components of these activities.

Technical Area 1: TB care and treatment (DOTS expansion and strengthening)

TB CARE will assist national programs using field support to provide universal and early case detection to surpass the 70% target and successfully treat over 85% of those cases in at least 12 countries.

This technical area is the heart of the four main technical areas under TB CARE. Quality national TB programs are essential for meeting the overall USAID and project objectives. Although much has been accomplished in this area, there is still considerable work to be done in improving the quality and access to these services. The accelerated and early detection and treatment of TB is a key component. Early detection of TB and effective treatment reduces transmission of the disease and slows the emergence of drug resistance. TB CARE should reduce transmission and alleviate suffering by systematic implementation of DOTS nationwide. Particular attention should be given to targeting the most vulnerable groups.

TA 1.1 Strong TB Leadership and Management

Country ownership requires a NTP with strong leadership and management skills to successfully develop and implement an effective strategic plan. Leaders in TB prevention and care are required at all levels, although their roles and responsibilities will vary depending on the structure of the health care system.

The leaders need to be able to develop systems for effectively managing, retaining and increasing the human and financial resources. These are critical skills not necessarily taught through the formal education system in many of the focus countries, requiring the development of these skills at all levels. TB CARE must have a strategic and comprehensive approach to building NTP leadership and management capacity that extends beyond tool development.

TA 1.2 Quality Supra National and National TB Laboratory Networks:
A functional internal and external laboratory network is key for a successful TB program. The network must be able to address the management, organizational, bio-safety, and work quality aspects of the laboratory at all levels. This technical area will focus on the management, supervisory and quality assurance systems for smear microscopy, culture, drug susceptibility testing (DST), and any other new technologies (see links to TA 2.1). TB CARE must to have a comprehensive strategic approach to building the capacity to manage, organize and address gaps in the internal and external laboratory network globally, regionally and at the country level.

TA 1.3 Universal and Early Access to Quality Diagnosis and Treatment:
Every individual has the right to access quality treatment. Although TB treatment is provided at the lowest level of the health care system, quality care is still not accessible to many groups of people. Innovative ways to extend the reach of quality TB diagnosis and treatment earlier to those without access is critical. A pro-active approach to identifying cases early, and extending beyond those who have accessed formal health care services should be developed. The approach should be comprehensive to include the scale-up of Practical Approach to Lung Health (PAL) and TB/HIV coordination strategies. In particular, access to treatment needs to be expanded to ensure women are appropriately reached and gender considerations are integrated into all TB programs (refer below to B3. Overarching Element Woman Centered Approach/Gender Considerations). TB CARE should focus particularly on addressing the cultural, social, economic and/or political barriers to access to services for individuals and/or groups at high risk for TB.

TA 1.4 TB Infection Control:
The prevention of TB transmission in all settings is another priority area for TB CARE. A systematic and comprehensive approach to developing and implementing infection control measures in facilities and other congregate settings with TB, MDR TB and HIV patients should be an integral part of the expansion of DOTS and scale-up of Programmatic Management of MDR TB (PMDT). The policy, strategy, and implementation to addressing community TB infection control should also be considered in this approach. TB CARE will support the development and implementation of national policies and guidelines, strategic plans, training and capacity building, renovation, and procurement of supplies as needed.

TA 1.5 National Access to Quality TB Commodities

A TB program cannot function without quality-assured drugs in the right place and in adequate quantities. There needs to be a nationwide system to successfully select, forecast, procure, distribute and monitor the anti-TB drugs as well as all other drugs. Although TB drugs are financially supported by donors in most high burden countries, there are still drug stock outs and problems with the management of them. TB CARE must ensure a nationwide system for a sustainable supply of anti-TB drug is in place. The development, implementation and removal of barriers to this system will be the focus of this project. The integration of the anti-TB drugs into the overall commodity management systems should be a focus. This project will only work at the regional and country levels in this technical sub area.

TA 1.6 Effective TB monitoring, evaluation and surveillance

A strong evidence base for monitoring and evaluating the program performance is an important part of this technical area. Quality data needs to be available for analysis and use at all levels, particularly at the facility level where it is collected. The health care workers at the facility need to understand the concepts of the data collected, and have the ability to analyze and use it to improve their own program performance. In addition, the district and higher level staff must have the ability to provide constructive feedback to the facility level to improve the quality of services. Lastly, data should to be used to create evidence for new and improved approaches and inform policy.

Technical Area 2: Programmatic Management for Drug Resistant TB (PMDT)

TB CARE will assist national programs using field support to provide universal access to DST for suspected cases and treatment to all those with MDR TB cases in at least 12 countries.

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 sero-prevalent region of sub-Saharan Africa is particularly concerning because of the rapid progression from TB infection to disease among people with HIV/AIDS. Weak or non-existent infection control measures, combined with congested health facilities and prisons, can create a volatile situation for disease transmission (see technical area 1.4). The effort required to develop and implement strong Programmatic Management for Drug Resistant TB (PMDT) programs often requires a considerable amount of financial and human resources to develop the systems for program success. Most countries are only beginning to pilot PMDT and develop surveillance systems for monitoring drug resistance. However, this is a rapidly changing field as research evidence emerges, e.g., new diagnostics, new regimens, and evolution of the GLC. TB CARE should be in the forefront to ensure countries can appropriately absorb all new information and approaches to scale-up. This project will play a pivotal role in ensuring development, piloting and scale-up of PMDT in countries with drug resistance TB.

TA 2.1 MDR TB Diagnosis:

The capacity of laboratories to detect drug resistant TB strains in the USAID focus countries is often limited. The development, introduction, and expansion of laboratories to conduct quality culture and DST, and introduce new and more effective diagnostic tools for MDR TB detection is an urgent and critical issue to be addressed by TB CARE. The project needs to have a comprehensive and rapid approach to building this capacity at the national and supranational level.

TA2.2 MDR TB Treatment:

The availability of treatment for MDR TB is limited in many of the USAID focus countries. The access to universal quality treatment for MDR TB is a priority for USAID and this project. Services to rapidly diagnose and treat drug resistant TB in accordance with WHO guidelines for PMDT must be rapidly scaled up. TB CARE will assist countries with the development and implementation of comprehensive systems for all aspects of care and treatment in a variety of settings. This assistance will also include coordination with other donors, and international and local partners involved in MDR TB scale up. In addition, the drug procurement, forecasting, quantification, and management will also be supported to ensure adequate supply and use.

TA 2.3 Routine surveillance for MDR TB:

Accurate and available MDR TB surveillance data are essential for targeting interventions and resources more effectively as well as improving program performance. TB CARE will support country-level drug resistance surveillance and surveys to ensure all focus countries have this information available. In addition, TB CARE will improve the capacity of the national level staff to set up systems to collect quality data, analyze the information and use it for program improvements.

Technical Area 3: TB/HIV care and treatment

TB CARE will assist national programs using field support to provide universal and early access to diagnosis for TB and HIV as well as access to treatment for those people eligible in at least 12 countries.

TB and HIV/AIDS are each responsible for significant global mortality and morbidity, but together create a deadly combination which presents many technical and programmatic challenges to successful prevention, diagnosis, and care for those affected. A proactive and synergistic approach by the national TB and HIV/AIDS programs is required to expand services to achieve universal access to accurate and appropriate diagnosis and treatment. It requires concerted and united leadership to develop global policies and guidelines for country adaptation, monitor progress, and present global best practices to continue to improve programs. These tools and best practices require expansive implementation from the national to the community level to ensure access to quality services for TB and HIV. This is an important area of TB CARE and the approach should strategically address how this will be achieved in countries with high

TB/HIV co-infection (see technical area 1.4 for infection control). TB CARE must work closely with PEPFAR and other partners to ensure maximum impact.

Technical Area 4: Health Systems Strengthening

TB CARE will assist national programs using field support to fully contribute to health system strengthening as it relates to TB, particularly for improving political commitment, strengthening human resources, enhancing health information and surveillance systems, engaging all providers, and mobilizing the community in at least 12 countries.

A strong health care system is necessary for the TB program to operate efficiently and effectively. Although the project will be expected to meet TB-specific outcomes, it is important to strengthen the overall health care system as an integral part of achieving gains in TB control. Since the DOTS program is a health systems approach to the prevention and care of TB, effective implementation of it is the first step in contributing to a stronger system. There are cross cutting TB technical areas that should be better integrated with other health interventions and services to ensure more efficient systems. Some of these areas have already been piloted and tested and others require new thinking and approaches for introduction and implementation at the country level. TB CARE must develop a comprehensive approach to achieve better efficiencies in the overall system, while ensuring quality TB services and TB-specific outcomes.

TA 4.1 Political Commitment:

Country ownership for TB prevention and care by the national governments can be expressed in many different ways, including leadership and management as well as commitments to providing adequate financial and human resources. This technical area is focused on the government's financial commitment to TB and health care. Although there is an influx of funds for health programs, it is critical the government maintain its resources for TB. Donor support is often provided on the condition it is addressing program gaps and not replacing the government's financial support. It is important these conditions are monitored and discussed with the government on a regular basis at the time of developing strategic plans and annual work plans. However, it is not enough to monitor the government's contribution by the proposed budget in the annual plans. It is important to ensure the funds are actually allocated to the TB program in a timely fashion. In addition, there should be increased political commitment at the organizational level of financial decision making. TB CARE is expected to develop approaches in each country to engage policy-makers and monitor progress on the government's financial and other high level commitments in coordination with all donors supporting TB and other health care efforts.

TA 4.2 Human Resources Development (HRD):

This is the most critical component of the health care system and TB program. A concerted effort must be made to improve the development, quality and retention of the human resources dedicated for health. Since most community and facility level staff are not TB specific, there needs to be a targeted approach to enhance the

capacity of community and facility level staff to improve the quality of services provided, expand TB case finding across all health areas, and integrate the support into all other related health interventions. Innovative approaches should be developed to coordinate and integrate these efforts to strategically develop the human resources. TB CARE should work with the MOH, NTP and other partners to ensure a consistent and integrated approach to HRD including the required skill sets, motivational support, location, job description, and evaluations. In high HIV prevalent countries, TB HRD efforts should be linked and coordinated with HIV HRD efforts.

TA 4.3 Health and TB Information and Surveillance Systems:

The TB recording and reporting system usually exists at all levels and is being reported on a regular basis. However, the treatment, lab management and drug management TB information systems are not linked to provide a comprehensive system. TB CARE should develop approaches to link the systems through one consolidated electronic system. In addition, there are still problems with the completeness, quality, and use of the TB data collected, which should be strengthened by TB CARE (see also TA 1.5). New innovations should be explored to improve the linkages and comprehensive of the systems. TB CARE will also make a concerted effort to harmonize the TB surveillance system with other diseases and the overall health information system without losing critical TB data collection, particularly HIV surveillance systems in high prevalent settings.

TA 4.4 Engaging all Providers:

In many countries the private, quasi-governmental, and non-MOH public sectors play an important role in providing health and TB services. The quality and monitoring of services of all care providers and links to the MOH services must be improved to meet the targets for case detection and successfully treatment. Many countries have engaged TB providers through pilot public private partnerships (PPP) projects but very few of them are scaled-up nationwide and include all types of providers. TB CARE will scale-up the current best practices nationwide and to include the broad range of providers (e.g. private physicians, pharmacists, hospital staff, work place health staff, prison health practitioners, military health practitioners, etc). In addition, these activities should be conducted in collaboration and complement other health PPPs.

TA 4.5 Community Mobilization:

The formal and non-formal community has a critical role to play in many aspects of TB prevention and care, including raising awareness, reducing stigma, advocating for more resources, intensifying case finding, improving diagnosis, and improving treatment adherence. If properly motivated, their efforts can increase political and community commitment, increase case detection, and produce better treatment outcomes. A systematic approach needs to be developed and scaled-up to promote and sustain their involvement. However, the community can not be expected to have the capacity engage with each health issue separately. They are the lowest level of the system and needs to be strengthened in a systematic way that benefits all health

interventions but at the same time does not overburden them. TB CARE should develop a practical approach to maximize the contribution of the community in TB prevention and care as well as harmonize it with other disease specific community approaches.

B.2. Overarching Elements

The overarching elements are key issues that cut across the TB technical areas. They need to be concisely incorporated into the overall approach to addressing the technical areas. TB CARE must have a clear and detailed description of systems and interventions to ensure these areas are adequately and comprehensively addressed over the life of the project.

C ollaboration and Coordination

1. Maximize, Leverage and Coordinate all available country and international TB resources

There are limited human and technical resources available to address the TB issue at the global level and in developing countries. TB CARE will be one of the main mechanisms to implement USAID's TB strategy. It will also contribute to the TB/HIV section of the PEPFAR strategy. TB CARE will be expected to draw from and communicate with the Stop TB Coordinating Board and other international groups working on TB. It will also need to play a critical role in coordinating and collaborating with partners, including other USG, PEPFAR, and USAID partners, local governments, Global Fund, WHO, World Bank, United Kingdome Department for International Development (DfID) and others. Although collaboration and coordination has always been a focus, there needs to be a concerted effort to ensure a more integrated and non-duplicative approach. The development of national TB strategies with robust budgets showing the partner contributions and remaining gaps is an important start for an integrated approach at the country level. This project will be expected to assist the government to monitor and resolve issues related to the implementation of the different inputs to the strategy. Most importantly, this project should focus on providing the required assistance to Global Fund Principal Recipients to maximize the outcome of the Global Fund TB grants. The functioning of the combined contributions to the National TB Strategy will be a key indicator of TB CARE's success.

3. Strong internal partner coordination structure

A complex and multi-faceted project needs to have strong streamlined systems in place. The roles and responsibilities of each of the project partners need to be clear and avoid duplication. There also must be a strong monitoring and controlling body that has the knowledge of the project operations and is equipped with the authority to resolve problems, set standards, and improve operations. The system needs to be consistent yet, flexible enough to adapt to the changing environment at all levels. In addition, communication is a very important part of ensuring each moving part of the project is successful. A

transparent and communicative approach must be developed and implemented at all levels of the project. TB CARE should develop a productive environment for staff input and participation at all levels of the project to maintain a healthy balance of operations and investment in the project.

A ccess to TB services for all patients ---

1. Woman Centered Approach/Gender Considerations

According to the recently released WHO Women and Health Report, TB is the 4th leading cause of death of female adolescents (10-19 years old) globally and in low income countries and 3rd leading cause of death of women of reproductive health age (20-44 years old) globally and in low income countries. Considerable effort is still required to remove barriers to accessing TB services by girls and women. TB CARE should rapidly develop a strategic framework for developing interventions to identify and remove these barriers. Any other gender or age discriminations present in countries or regions should also be addressed to ensure equal access to TB case finding, prevention, and treatment. The interventions need to be integrated into the technical areas to ensure country appropriate activities are implemented in a consistent and timely manner. TB CARE should provide a stepwise and practical approach of how this will be accomplished from the global to the primary health care level.

2. Vulnerable Populations

TB is a disease of poverty affecting the most marginalized and hard to reach populations. There have been limited efforts to systematically identify and address these groups in USAID focus countries. The strategies developed for the general population are not necessarily effective for all of these groups. It requires a more concentrated and usually concerted effort that meets directly the needs of these populations. TB CARE should provide an approach for identifying the vulnerable populations and developing strategies to scale-up interventions to provide access to the necessary TB services.

R esponsible and Responsive Management Practices

1. Cost-effective and Efficient

USAID has limited resources available for TB prevention and care. It is pertinent to ensure these are used as cost-effective and efficient as possible. TB CARE must have strategies in place to ensure policies and procedures are developed to be efficient and effective systemically across all partners and at all levels. There needs to be controls to monitor the implementation of the policies and procedures as well as improve them as new information deems necessary. These systems should include policies on staff salary increases, maximum daily rates, overhead, procurement of goods and services, sub-agreements, travel, communication, waivers, offices, etc.

2. Financial Vigilance

USAID is held up to the highest standards of financial responsibility by the US government. It expects the same level of financial vigilance from its partners. TB CARE needs to have nimble financial systems in place to provide rapid and regular quality data at all levels. Accruals need to be collected to provide USAID with financial information upon request. TB CARE will have adequate, consistent and comprehensive controls in place to ensure the system's quality. Up-to-date and complete country level financial information needs to be available to Missions on a regular basis.

3. Country-based Implementation

The approach to quality and quantity country level support is the main thrust of this project. TB CARE will develop effective and efficient management practices to assist the countries in obtaining adequate and quality technical assistance, relying heavily on staff in-country. Project staff will work closely with the Ministry of Health (MOH)/NTP to build their capacity to solve problems and achieve national TB program objectives. TB CARE will play a leadership role in coordination of TB activities and provide expert advice on variety of TB technical issues. The project needs to balance the urgent need to ensure critical TB detection, prevention and treatment are widely available and implementing interventions through a sustainable health systems approach, building capacity of host stakeholders and systems. TB CARE will actively integrate efforts with other technical assistance provided by partners to reduce burden on country staff and enhance absorptive capacity for program success. In addition, the ability for the project to operate with limited in-country capacity and absorption but address the urgent issues at hand will be critical to its success.

E vidence – based project monitoring and evaluation (M&E)

1. Strong project monitoring and evaluation system

   USAID is a results oriented organization and expects projects to continuously present achieved results for its investments. TB CARE must have a rigorous and rapid system for measuring, collecting, analyzing, using and reporting the project data at all levels and across levels. The internal project monitoring and evaluation system should include tangible process, outcome and impact measurements that directly relate to the interventions at the global, regional and country levels. The system should be able to provide sub-national, national and global results on these measurements that will be used for guiding year-to-year programming, improving performance, conducting advocacy at various levels, and determining future funding levels.

2. Evidence-based project interventions and policy development

Evidence-based programming is a focus for TB CARE. The project needs to develop a mechanism for continuously evaluating TB CARE's innovative interventions to determine the appropriateness for informing policy and scale-up. There needs to be a baseline developed as well as a strong and specific evaluation system in place to accurately measure the inputs to determine their relevance for expansion or policy development. As appropriate, TB CARE will work closely

with other projects to ensure maximizing efforts and avoiding duplication, particularly with USAID's global project TREAT TB.