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REQUEST FOR INFORMATION (RFI)

Activity Title:	**Eliminate Tuberculosis in Ethiopia (ETBE)**
RFI Number:	**RFI-663-19-00002**
Issuance Date:	**March 8, 2019**
Response Due:	**April 8, 2019, GMT/Ethiopia Time**

I. Request for Information

This is a Request for Information (RFI) issued solely for information and planning purposes. This is not a Request for Application (RFA) or a Request for Proposal (RFP) and is not to be constructed as a commitment by the U.S. Government to issue a notice of Funding Opportunity (Request for Application - RFA), or ultimately award a contract or assistance agreement on the basis of this RFI, or to pay for any information voluntarily submitted as a result of this request. Responses to this RFI shall not be portrayed as applications or proposals and will not be accepted by the U.S Government (USG) to form a binding agreement. Responders are solely responsible for all expenses associated with the response to this RFI.

USAID-Ethiopia will not provide answers to any question submitted in response to this request. USAID posts its competitive business opportunities on www.grants.gov or www.fbo.gov. It is the potential applicant's responsibility to monitor these sites for announcements of new business opportunities. Responses may be used by USAID without restriction or limitation.

This request for information (RFI) is a preliminary call for expressions of interest for a potential activity to address critical gaps of the comprehensive Tuberculosis (TB) program in Ethiopia. The potential activity will build on the previous USAID TB activities; HEAL TB, Challenge TB and PHSP which were awarded to Management Sciences for Health in 2011, KNCV in 2014 and Abt associates in 2015 respectively. Eliminate TB in Ethiopia (ETBE) will closely work with the health system at the national (MOH, EPHI, EPSA, EFDA) and Sub national health structures (Regional health bureaus, Zonal health departments, Woreda health offices), referral health care facilities, academic institutions, research institutions, local organizations and professional associations with the overall goal of reducing TB incidence and TB mortality while building government health platforms for TB services. This program will focus in implementing high impact/high yield interventions for improved TB,MDR-TB case finding, expanding TB laboratory services including access to Drug sensitivity Testing (DST) , strengthening health system platforms for TB services and generating local evidence for program improvement and learning. This RFI will provide stakeholders an opportunity to review, comment, and enhance USAID-Ethiopia's perspectives on TB programming in Ethiopia.

II. RESPONSE REQUIRMENTS

USAID seeks input from organizations, or consortia of organizations, consultants, or academia that possess or can source the following skill sets and experience.

- Experience of working in developing and high TB,MDR-TB,TB/HIV burden countries like Ethiopia
- Demonstrated Organizational Capacity in Tuberculosis technical area in settings similar to Ethiopia
- Demonstrated successful past performance in quality of products or services, cost control, timeliness, key personnel and customer satisfaction in previous and/or existing projects, particularly TB projects in a similar setting
- Change management and institutionalization of systems and practices in the public health sector
- Demonstrated capacity in building partnership with health ministries , their internal structures, state level health technical agencies/ institutions and subnational health systems
- Demonstrated experience of implementing comprehensive TB, MDR TB and TB/HIV programs in developing countries like Ethiopia

Interested parties should provide a short submission, not exceeding 25 pager documents addressing the questions listed in addition to any comment to the Attachment of this RFI. We value concise, issue-specific responses with references to page and section numbers of the draft program description.

Questions

1. What are the major gaps in Ethiopia's comprehensive TB program?
2. With Ethiopia's progressive and growing National TB program (NTP) and general health system, what are the major barriers in finding all estimated TB and drug resistance TB cases?
3. What are the major gaps and barriers in improving community TB care services, quality of TB care services, addressing the needs of key affected and vulnerable populations, improving TB program management and monitoring & evaluation of TB program?
4. What can be done differently in Ethiopia's TB control and prevention program to narrow the current gaps and enable Ethiopia to be one of the low TB, DR-TB and TB/HIV burden countries?
5. The Ethiopian Health system is geared to educate and build the capacity of the public to produce its own health. Prevention of TB infection and disease progression is one of the strategies of Ethiopia's National TB program. What are the barriers to implement TB infection control measures, to reach all eligible with TB prevention measures including latent TB treatment? What can be done differently to implement TB infection measures and reach all eligible with TB prevention measures?
6. Access to Quality assured laboratories including Drug sensitivity testing (DST) is one of the pillars of the National TB program and there have been concerted efforts and investments to ensure access despite which more 24 percent of public health facilities don't have a single laboratory personnel . What are the gaps /barriers in terms of creating access for TB laboratories, rapid diagnostics and culture and DST? What can be best done to address TB laboratory gaps/ barriers including Culture and DST gaps?
7. What are the major TB program support needs (top priority needs) at different levels of the health system (National, sub national, health facility and community level needs)?

8. Ethiopia has been one of the recipients of global assistance (financial and technical assistance) in its effort to control and prevent TB and DR-TB. What are the challenges/ barriers to sustain the gains and takeover the roles of the external support?
9. Health system platforms for TB services; human resource capacity building, drug supply management , bio-medical engineering, monitoring and evaluation, program learning and evidence generation for program improvement had been considered one of the strategies of TB control and prevention program. With greater thinking of sustainability and self-reliance and the country's progress towards a lower middle income country, which health system platforms needs to be prioritized for further support?
10. From a recent National Health Account report (NHA), TB patients are shouldering approximately 36% out of pocket expenditure which is a huge financial burden to the patients and their household. What can be done to achieve the global goal of zero catastrophic cost for TB patients?
11. Knowing the major gaps in TB program funding and high donor dependence, what strategies are needed to enable domestic resource mobilization to cover for the growing cost of TB diagnostic and treatment commodities?
12. What are the technical capacity gaps in the national TB program that would require additional technical assistance and what would be the best modality to provide the support?
13. Building local capacity is a critical approach to ensuring Ethiopia's journey to self-reliance and what opportunities exist to work with local institutions and what are the investments and strategies needed to strengthen the local capacity.

III. Instructions for Submitting Responses/ comments

All comments must be submitted electronically to caddis@usaid.gov with a copy to Mr. Belay Teame at bteame@usaid.gov and Tsegereda G/Medhin at tgebremedhin@usaid.gov. Responses to this RFI will be accepted through the date listed on the cover page of this RFI. You will receive only an electronic confirmation acknowledging receipt of your response, but will not receive individualized feedback or suggestions. No Basis for claims against the U.S Government shall arise as a result of a response to this request for information or from the U.S Government's use of such information. Specific questions about this RFI should be directed only to the email addresses identified above. This office will not respond to any telephone or other inquiries regarding this notice.

Sincerely,

Martin Fischer
Contracting /Agreement Officer
USAID/Ethiopia

Attachment: Draft Program Description

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Attachment A - Draft Program Description

1. Title

The title of this program is Eliminate TB in Ethiopia (ETBE).

2. Objective

The purpose of the USAID Eliminate Tuberculosis in Ethiopia (ETBE) Activity (hereafter referred to as "USAID/ETBE" or the "Activity") is to contribute to national goals to reduce tuberculosis (TB) incidence and mortality by increasing the quality, access and sustainability of TB services.

3. Background

Relevant background is provided below relating to alignment of the ETBE TB follow-on program with USAID/Ethiopia's recently developed strategic priorities for its next Country Development Cooperation Strategy and the Global Accelerator to End Tuberculosis.

A. Global Framework and USAID priorities for TB Control and Elimination

WHO's global End TB strategy, endorsed by member states, advocates for the overall global goal of ending TB by 2050 (with a pre-elimination target by 2035) through "integrated patient centered TB care and prevention"; "Bold policies and supportive systems" and "Accelerated research and innovation." As part of this global strategy, USAID has committed to expanding TB program support to high priority countries focusing on the specific technical areas. USAID's comprehensive approach includes support to reach every person with TB, cure those in need of treatment, prevent the spread of disease and new infections, and promote self-reliance.

With the recent (2018) UN High Level Meeting (UNHLM) on TB, more commitments have been made by member states to reach all people by closing the gaps on TB diagnosis, treatment and prevention. These include commitments to successfully treat 40 million people with tuberculosis from 2018 to 2022, including 3.5 million children, and 1.5 million people with drug-resistant tuberculosis including 115,000 children. In order to achieve these targets, there is a need to: transform the TB response to be equitable, rights-based and people centered; develop essential new tools to end TB; invest the funds necessary to end TB; and commit to decisive and accountable leadership at national and global levels.

The USAID/Ethiopia mission's investments to End Tuberculosis will also strengthen Ethiopia's journey to self-reliance; this effort therefore requires implementing sustainable TB program activities. The USAID new TB business model, the "Global Accelerator to End Tuberculosis," would be a guiding platform for our investments, with programming to advance both the commitment and capacity themes of the Accelerator. As part of the broader TB portfolio, field support activities under the TB Accelerator would complement our bilateral flagship TB activity

(ETBE) to achieve our goal of ending the TB epidemic while building sustainability and self-reliance in Ethiopia.

B. Health System Context in Ethiopia

Ethiopia, with an estimated population of 105 million in 2018, is administratively divided into nine Regional States and two City Administrations. The Regional States and City Administrations are further sub-divided into 117 zones, 1018 woredas , and approximately greater than 16,000 kebeles (each with a population of 5,000 on average). There is extensive decentralization of service delivery, with relatively autonomous regions. The health system of Ethiopia is organized in a three-tier system, composed of primary health care units, Zonal Hospitals and Referral/Regional Hospitals. The woreda is the basic administrative unit and it is further divided into kebeles with at least one health post in each kebele. In each of the administrative levels, there are Regional Bureaus, Zonal Departments and woreda offices to administer health services. The Health Extension Program, which is focused at Kebele level, is implemented by health post based health extension workers who also conduct the community outreach activities. Ethiopia has made significant improvements in the health of its population with most of the Millennium development goals of the health sector met including the Tuberculosis (TB) targets to halve prevalence, and reduce incidence and mortality.

USAID's contribution to the GoE's investments in expanding universal health coverage and combating major infectious diseases has been remarkable. Health coverage and key health indicators as well as major infectious disease burden have been showing significant improvement in the past decade in Ethiopia. Child health, maternal health, malaria, HIV and TB are areas that have improved significantly resulting in reduced mortality and increased life expectancy from 47.1 during 1990 to 65.7 during 2016. According to the Ethiopian Demographic and Health Survey (EDHS) 2016, infant mortality has decreased from 77 deaths to 48 deaths per 1000 births (38%) and under-five mortality has decreased from 123 deaths to 67 deaths per 1000 births (46%). Furthermore, the total fertility rate decreased from 5.5 children per woman in 2000 to 4.6 children per woman in 2016 and maternal mortality declined from 676 maternal deaths per 100,000 live births in 2011 to 412 per 100,000 in 2016. These improvements are due, in part, to improvements in health policy and expanded health coverage.

C. Tuberculosis context in Ethiopia

Ethiopia continues to be among the 30 High TB, MDR TB and TB/HIV burden countries. According to the 2018 WHO Global TB Report, the incidence and mortality of DS-TB are estimated to be 164 and 24 per 100,000 populations respectively and DS-TB treatment coverage (notified/ estimated incidence) was 68 percent. The incidence of MDR/ RR-TB is estimated to be 5.2 per 100,000 populations and treatment coverage is 21%. Within the same report, 2.7% of New TB cases and 14% of previously treated TB cases are estimated to have MDR/RR-TB with 42% and 100% access to rifampicin resistance testing respectively. Among the total 117,705

notified DS-TB Cases in 2017, 69% are pulmonary TB cases and only 58% of the total cases notified are bacteriologically confirmed. 90% of new DS-TB cases enrolled in 2016 and 70% of MDR/RR-TB cases enrolled in 2014/15 have successfully completed their treatment which is above the global average and one of the good outcomes from the high burden countries (National TB Program Report and 2018 WHO TB report).

The latest TB prevalence survey in Ethiopia was conducted in 2010-11. Re-estimating the TB prevalence in Ethiopia would be another key priority to determine the actual magnitude and trend of the disease burden. The planned prevalence survey to be conducted during 2016/17 did not materialize due to change in leadership of the key institutions. The conduct of prevalence survey/TB burden estimation remains important.

Problem statement: Remaining gaps and needs

TB technical gaps and needs

Despite the significant progress that Ethiopia has achieved in TB control program in reducing incidence and mortality as well as increasing program management capacity, the low case notification rate of TB and DR-TB cases is the primary challenge. Nearly 30% and 70% of TB and DR-TB cases are missed. The critical challenges in program implementation that contribute to low case finding are the slow expansion of new molecular diagnostics (GeneXpert) and culture laboratories for both genotypic and phenotypic culture and DST testing, lack of efficient sample transport capacity from the remote part of the country to diagnostic centers, the limited implementation of effective high impact interventions/strategies for case finding, inability to fully capitalize on existing investments (e.g., improved culture labs not fully used due to supply, maintenance and staffing issues; PMDT treatment initiation centers not fully used due to incomplete roll-out of new drugs and regimens), and a lack of innovative solutions to address identified gaps. Other issues include gaps in human capacity, high staff turnover, weak logistical and commodities management resulting in shortage of supplies and commodities for high priority interventions.

The development of new drugs (bedaquiline and delamanid) and the implementation of GeneXpert as a game changer in diagnostic standards are some of the developments that highlight the improvements in TB diagnosis and management in the past decade. However, more work is needed to scale up uptake of new drugs, implement point-of-care diagnostics, apply newly developed more effective vaccines, enhance capacity for universal access to DST, enhance case finding strategies in difficult to reach and key affected populations, extend quality TB services to private providers, and a sustainability strategy using domestic TB program financing and reducing catastrophic cost to patients/households. The goal of TB elimination will not be achieved unless stronger TB prevention strategies through TB infection control (TBIC) measures and a broader strategy for the treatment of latent TB infection. As part of End TB strategy, WHO and global partners including USAID have developed different strategies and innovations to meet the goal of ending TB epidemic by 2050.

Though Ethiopia has achieved all the MDG (millennium development goal) TB program targets from the very low baseline and adopted the End TB strategy with the ambition of ending TB, TB remains one of the major public health problems in the country, ranking 6th among the top ten killers and being the leading infectious killer in 2016 (4). DR-TB is poorly controlled, with >79% of estimated DR-TB cases missed by the system. There is also a low case notification rate (treatment coverage) for drug sensitive TB (DS-TB), limited expansion of comprehensive TB to the non-state actors, lack of prioritization for key affected populations; limited access to latent TB treatment and implementation of TBIC measures; lack of innovations introduced and widely used by the NTP, such as modern digital tools for health for TB detection and adherence and still significant mortality rate. These are the critical gaps that need due consideration in the effort to end TB.

Poor treatment adherence, co-morbidities, patient delay (late diagnosis and treatment, misdiagnosis, undiagnosed drug resistance, preference to other options including holy water and traditional medicine), stigma, socio-economic barriers hindering access to services and lack of psychosocial and economic support could be some of the root causes for the high mortality and morbidity due to TB. Though it requires a structured investigation, the TB related mortality could be due to a complex of patient related, health system related and socio-economic reasons which are not visible in routine program quality checks and program monitoring activities.

Despite the concerted effort and implementation of different case finding strategies, TB case notification rate (treatment coverage) for DS-TB has been consistently below 70% in the past 10 years which could be associated with different factors. Based on the mid-term evaluation of the National Strategic Plan (NSP) in early 2017 and routine program monitoring reports, the below gaps were identified as the key barriers to improve the case notification/ treatment coverage:

- Limited expansion of services to private sector and public health facilities out of the formal health sector, which limits the engagement of all care providers.
- Sub-optimal implementation of community based TB care and lack of effective community TB strategies.
- Lack of prioritizing and focusing on high burden key populations (pastoralist, prisoners, migrant workers, urban poor)
- Implementation of similar strategies in both PHCU and high load hospitals resulting in low quality TB screening practice/triaging
- Limited access to highly sensitive diagnostics services especially GeneXpert.

A joint consultation in July 2018 organized by Global Fund came up with a similar list of recommendations, with additional points on expanding sputum transport, overcoming financial barriers for patients (as identified by the patient cost survey), improving the quality of data for decision making, the scale-up of new drugs and the shorter regimen, domestic resource mobilization, and human resource issues especially on laboratory staffing.

The emergence of DR TB and its very low case notification is one of the major challenges that many national TB programs face globally and Ethiopia is not an exception. Though Ethiopia has made significant progress in expansion of treatment initiating centers to the regions and in embarking on new developments in DR-TB programming (initiation of new anti-TB drugs and expansion of diagnostic health facilities), the case notification for DR-TB is alarmingly very low detecting only 21% of the estimated burden. The very limited access to first- and second-line DST due to a limited number of diagnostic facilities and lack of reliable sample transport system, limited expansion of TB services to health posts, limited capacity of health care providers and the lack of a reliable monitoring and reporting mechanism are a few of the critical gaps that are contributing to the very low DR-TB case notification[6].

TB/HIV collaborative activities have been well implemented in Ethiopia with 89% of TB patients accessing HIV testing and ~ 95% of HIV patients accessing TB screening with GeneXpert as a primary test for presumptive TB cases. Access to TB prophylactic therapy with INH has improved with 52% of eligible PWHA and 40% of eligible children receiving INH but still more than 50% of eligible clients are not reached. If the country has to achieve the ambitious End TB targets, initiation of latent TB treatment, and optimal implementation of TB infection control measures with particular emphasis to administrative measures and strengthening TB program management at national and sub-national level need due emphasis. The DRS to estimate the burden of DR-TB is in its final stage of data analysis and preliminary results are expected to be shared soon.

TB programmatic management gaps and needs

The NTP has approximately a 40% funding gap every year. The funding level from the Global Fund has decreased by 38%, and only 11% of needed TB resources (which is ~20% of actual TB resources) come from domestic funding. With the consistently lower domestic financial commitment, a decreasing funding level from the traditional donors and with the existing funding gap, it will be difficult for the NTP and sub-national programs to achieve the End TB milestones and objectives set for 2020 and 2025 respectively.

Overall, there are always areas for improvement in performance with the existing resources, but the TB program in Ethiopia may have reached fundamental limits in some areas due to financial constraints. Examples include the cost of the roll-out of GeneXpert testing for all new TB patients (or all symptomatic), the treatment costs for the expected larger cohort of MDR-TB patients, and the regional lab capacity to support these activities. To cover such major improvements, more resources are needed. USAID TB resource/funding are a significant percentage of TB support in Ethiopia, almost equaling the amount of funds from Global Fund. Thus, a proportion of the USAID funding may have to go towards implementation. But, with no major expansion of Global Fund or USAID resources expected, this will not be enough for future service expansion. Without a focus of some of USAID Ethiopia's TB support on domestic resource mobilization, the necessary expansion in funding is unlikely to occur – this explains the

inclusion of domestic resource mobilization in the objectives below. More than 80% of the current Global Fund grant (managed by a government Principal Recipient) is focused on commodities, so the NTP has more experience in managing commodity procurements and distribution, and less experience on managing additional activities aimed at strengthening the programmatic and technical approach throughout the health system. Indeed, the past Global Fund grant was under-spent on its activity budget, reflecting the difficulties of moving and productively utilizing activity resources under existing GoE systems. The lack of other institutions including CSOs as sub-recipients could have undermined the ability of the system to absorb the funds and also enhance performance.

The quality of TB program data has significantly improved in the past 3 years with continuous capacity building support to the national health information system (HMIS), including providing hands-on training to health information technicians. The federal ministry of health is changing its public health reporting system from HMIS to DHIS2 and the TB program needs to work with the responsible authorities and protect the gains in data quality. Despite the encouraging data quality improvements in DS-TB, the very poor reporting system for community TB care activities, incomplete data on latent TB treatment/ TB infection control and insufficient quality of DR-TB data are few of the gaps that need to be addressed by the NTP and other actors.

National TB response

Ethiopia has adopted the End TB strategy (as a follow on to the Stop TB strategy) and started its implementation as of 2016. The Ethiopian National TB program is currently implementing comprehensive TB, DR-TB and TB/HIV interventions with an emphasis on expanding high quality services at primary health care levels including community TB care; Improving access to quality TB services through expanded and decentralized DOTS services, strengthening and expanding DR-TB services (MDR/XDR), expanding access to TB laboratory service including implementation of rapid molecular technologies (GeneXpert and LPA) for first line and second line drugs, strengthening TB/HIV collaborative services, strengthening health system platforms for the TB program, enhancing local evidence generation for program improvement, and monitoring & evaluation of TB program implementation.

Despite the concerted efforts and the prevailing magnitude of TB in Ethiopia, the domestic funding covers only 11% of the National Strategic Plan (NSP), with 33% coming from international donors, and an ~56% funding gap (WHO 2018 report) to implement its strategic plan. On top of the very limited domestic funding, there is a significant decrease in financing of the Ethiopian TB program from its traditional donors; with close to 37% funding decrease from Global Fund alone in the 2018-2021 funding period.

D. **USAID/Ethiopia's support to the Ethiopian National TB Program**

USAID has been playing a pivotal role in Ethiopia's effort to control TB especially in the past decade. USAID's support is based on the U.S. Government Global TB Strategy, WHO's End TB Strategy, the US National Action Plan for Combating MDR-TB, and the GoE's Health Sector

Transformation Plan, and is implemented in collaboration with the MOH and other donors and partners to meet the Global End TB milestones set for 2025.

This USAID/Ethiopia support has been undertaken through its global and bilateral TB activities: TBCTA, TBCAP, TB Care I, HEAL-TB, PHSP, and Challenge TB. Other TB funded activities focused on health systems strengthening as wrap-around activities in addition to the TB-specific projects have been supporting the TB program. USAID's activities and technical support have been fundamental in the establishment and capacity building of national and sub-national TB programs and in the adaptation of new diagnostic and treatment modalities for TB including introduction of the short treatment regimen (STR) and new drugs for DR-TB, new TB diagnostic services and evidence generation platforms.

Ethiopia is at the forefront in generating and disseminating local evidence for TB program improvement under the leadership and coordination of the Tuberculosis Research Advisory Committee (TRAC). USAID's support to operational research capacity development using TRAC as the platform has been very fruitful. The efforts to generate local evidence, mainly focusing on implementation, operational and epidemiological research, have been commendable and well recognized internationally. Research priorities for 2017-2022 have been identified and Ethiopia has revised its TB research roadmap that will guide the research agenda of TB program activities.

In addition to USAID, partners like the Global Fund, WHO, GLRA, CDC, CHAI, and other international and national organizations are providing both technical and financial support to the NTP in its effort to end TB in Ethiopia.

USAID Ethiopia's existing flagship TB program activities

Challenge TB

The ongoing USAID/Challenge TB (CTB) Project is a 5 year field support activity(October 2014 to September 30, 2019) and is implemented in Ethiopia by KNCV TB Foundation, Management Sciences for Health (MSH) and World Health Organization (WHO). USAID/CTB has been building the TB control program's capacity by capitalizing on the investments that have been made by previous USAID TB program activities, namely TBCTA, TB CARE, HEAL-TB, and PHSP.

Challenge TB collaborates with the National TB Program (NTP), major national institutions (EPHI, AHRI, PFSA and FDA), Ethiopian universities and other local institutions, and helps the Regional Health Bureaus (RHBs), Zonal Health Departments (ZHDs), woreda (district) health offices and primary health care units take ownership of TB program management and activities. Challenge TB covers more than 85% of the total population of Ethiopia. It implements activities at the national level and in seven regions and two city administrations (Tigray, Amhara, Oromia, SNNPR, Hareri, Gambella, Benishangul Gumuz, Addis Ababa and Dire Dawa).

Challenge TB supports a comprehensive package of TB, TB/HIV, and multidrug-resistant TB (MDR-TB) interventions. Through this assistance, the Regional Health Bureaus (RHB), Zonal Health Departments (ZHD), woreda (district) health offices and primary health care units have been fully engaged to ensure improved and sustainable program management capacity. Challenge TB focuses on increasing case notification and decentralization of TB services to all public health facilities with the engagement of communities through Health Extension Workers (HEW). The project is also helping to strengthen Ethiopia's health system by supporting the national laboratory network, program management teams of regional, zonal and woreda health offices and health facility staff capacity, woreda planning and improved drug supply management and TB infection prevention standards.

The primary TB investments by USAID/Ethiopia (TB CARE, HEAL TB, Challenge TB and PHSP) contributed to:

1) Introducing innovations: Introduction and expansion of GeneXpert for rapid diagnosis, new pediatric formulations, two new TB drugs for (pre)-XDR-TB, and STR for MDR-TB
2) System strengthening: TB dashboards at zonal, woreda and facility level, which restored the quality , focus and strength of core TB functions
3) DS-TB Case finding: E.g., expansion of OPD screening, community case finding by HEW (25% contribution); contact investigation, expanding use of GeneXpert, and quality improvement. In HEAL TB regions, case finding declined half as fast as the national average; it is harder to assess total gains now as >90% of population is covered by Challenge TB
4) DR-TB case finding: Expanded Xpert coverage (see above) and use in revised algorithms; sputum transport by postal system and vans to both Xpert and culture.
5) Lab capacity: Supported the establishment of 10 regional labs for culture and drug-sensitivity testing; 6 can now do rapid tests for second-line drug resistance
6) DS-TB treatment: Improved treatment success rate from 89% to 94% with the treatment of a total of 1.2 million TB patients since 2010.
7) DR-TB treatment: Supported the establishment of nearly 60 MDR-TB treatment initiation centers including two centers of excellence on PMDT, plus 600 treatment follow-up centers. More than 4,400 DR-TB patients have been enrolled with 70% treatment success rate since 2010.
8) Operational research: A leader internationally in evidence generation for the TB program

For Year 4, Challenge TB Ethiopia's 8 high impact interventions were identified as:

1) Contact investigation and provision of Tuberculosis Preventive Therapy (TPT)
2) Expanding use of GeneXpert as a primary test and universal DST for rifampicin
3) Enhanced community-based TB care (including clarifications of the current barriers to increased case finding through community TB efforts, distinct rural vs urban strategies, and sputum collection strategies)

4) Introduction and expansion of new drugs and the shorter regimen
5) Expanding genotypic and phenotypic first and second line DST (including expansion planning)
6) Sample referral (including analysis of benefits and costs of different options, and long-term vision for final network and sustainability)
7) Key affected population strategy
8) High load health facilities and hospital initiative (including clarified plan for institutionalization)

The project also had cross-cutting work on drug supply and management and operations research.

Private sector TB-related USAID activities

The Private Health Sector Program (PHSP) is a USAID/Ethiopia-supported project that works on both policy and implementation around private provider engagement in the delivery of priority health services. It works across multiple health technical areas, including TB, and has been directly responsible for the existing private provider TB achievements in Ethiopia of ~14% of TB case finding. Part of this success has come from pooling the project activities across multiple health areas, which makes both policy and provider engagement more efficient.

USAID/Ethiopia health system activities related to TB

USAID/Ethiopia TB resources have helped co-finance a number of other mechanisms that address underlying health system issues. This includes work under:

a) The Health Financing and Governance (HFG) project on health financing issues such as domestic resource mobilization and community-based health insurance;
b) The Strengthening Ethiopia's Urban Health Program (SEUHP) project on urban health issues; and
c) The Human Resources for Health (HRH2030) project on human resource issues, including pressing issues for TB such as pre-service training and attrition and turnover.

ETBE will be expected to collaborate with these and other ongoing USAID efforts in order to synergize and achieve the ETBE and Global TB Accelerator objectives.

E. Alignment with USAID/Ethiopia's new Country Development Cooperation Strategy (CDCS)

USAID/Ethiopia is in the process of finalizing its next generation five year Country Development Cooperation Strategy (CDCS). The Mission's overall development hypothesis that has guided strategic thinking is that: if Ethiopians are healthier and better educated they will be empowered to drive Ethiopia's socio-economic development.

Development Hypothesis:

With our overall USAID/Ethiopia's Health Office moto of "Healthy People Drive a Prosperous Ethiopia", the ETBE Development hypothesis is:

"USAID's continued support to the National TB Program in providing high-quality TB, TB/HIV and DR-TB preventive, diagnostic and therapeutic services in a patient-centered approach and through developing sustainable health systems will ensure Ethiopia's journey to self-reliance to achieve its strategic goal ending TB by 2050.

Mission priorities: Consideration as per the CDCS guidance

The TB follow-on program (ETBE) directly contributes to the focus on health and economic outcomes. The program will help expand and advance gender-equitable health and education outcomes with a specific focus on increasing the utilization of quality health and nutrition. Regarding our drive to ensure Journey to Self-Reliance, the activity will help strengthen health and nutrition systems through a sustainable health system and through program management capacity building. Self-reliance, gender, private sector engagement, urbanization, and targeting key and vulnerable populations (eg. migration/ migrant workers) are mission strategic priorities and will be integral parts of the overall TB strategic approach of USAID/Ethiopia

Self-reliance:

Self-reliance will be emphasized as an important outcome, as also noted in USAID's Global TB Accelerator to end TB program. The activity will work with the MOH and other local partners at national and sub-national levels to ensure local ownership, with a strong emphasis on sustainability from the outset to support Ethiopia to achieve self-reliance. The activity will support the GoE Reform Agenda with an emphasis on building model woreda health systems; improving the quality of health care services; and building stronger health systems. As one of the major End TB strategies, reducing catastrophic cost/out of pocket expenditure for patients will be emphasized. However, self-reliance can only be achieved with the engagement of all care providers, including Civil Society Organizations (CSOs), local Non-Governmental Organizations (NGOs) and the private sector. Accordingly, ETBE will engage all actors and collaborate with other mechanisms to ensure self-reliance and sustainability. Moreover, ETBE will provide a focused and deliberate capacity building to health work force at different levels of the health system and ensure access to and sustain quality services. This will allow USAID to build on the existing capacity of relevant MOH technical offices and program components to excel in their capacity to implement quality and more effective program activities.

One major challenge with TB program activities in Ethiopia is the high donor dependence and the growing cost of new diagnostics and drugs, high patient cost and the requirement for more resources to implement high impact interventions. In addition, the existing model procurement using Global Fund is showing signs of inadequacy to cover the growing demands for diagnostics and related commodities. Therefore, while working on alternative sources of sustainable financing, as a transition strategy, the activity will be required to engage in the procurement of

very critical commodities and medical supplies while ensuring self-reliance. In addition, ETBE will collaborate with other mechanisms to improve TB program financing through increased domestic and innovative resource mobilization including finance.

Private sector engagement:

Engaging private providers in TB care and prevention through public-private mix (PPM) continues to be one of the priorities for TB program activities, given that existing investments have shown high efficiency (~$34 of investment per case detected) and greater contribution to the national case finding (14%) with encouraging treatment outcome for patients. This was possible through strong policy framework for private sector and working closely with government system. While private sector engagement is one of the End TB strategies of engaging all care providers, ETBE will continue to collaborate with other mechanism to ensure all actors are engaged and no TB/DR-TB cases are missed in the system.

Urban poor:

Urban poor and migrant workers are important target populations in the high impact interventions that target key affected populations strategy and are included within Technical Area 3 - Implement high impact TB case finding and prevention strategies (Contact investigation, community TB care, key population interventions).

Gender:

Gender inequalities influence many health and development outcomes in Ethiopia. USAID/Ethiopia is committed to addressing these inequalities throughout its programs. A gender assessment will be conducted to provide the Mission with guidance on how to build on its current work in gender programming. Gender disparities in health-seeking behavior contribute to differences in vulnerabilities especially in gender-related delays in TB diagnosis, treatment interruption, and gender-based TB stigma and discrimination. The proportion of registered TB cases in Ethiopia is 56% males versus females 44%. This discrepancy needs to be assessed further if the low detection rate and treatment for TB among women have been seen due to delay in accessing care, poor compliance to treatment, and belief in alternate treatment or rather a higher vulnerability of men. The activity will conduct a gender assessment and integrate gender sensitive interventions as appropriate.

4. General Activity Guidance

The following provides the operational guidance that will be critical for the successful and sustainable implementation of this program. This section includes: overarching guiding principles; the collaborating, learning and adapting approach; geographic scope; gender considerations; overall technical approach; and the management approach.

4.1 Guiding principles and overarching concepts

This activity will be supporting the NTP to implement high impact and prioritized interventions that will enhance the general goal of ending TB as a public health problem in Ethiopia. While focusing and prioritizing interventions in the four technical areas described below, this activity will be following the following guiding principles of USAID:

***Compliance to international standards and guidance*:** This activity will make sure that its strategies, interventions and activities are in compliance with WHO, US Government standards and Ethiopian's HSTP while being cost effective, evidence-based and beneficial to the Ethiopian National TB program and to the Ethiopian community.

Timely introduction, adaptation and rapid scale up of proven interventions and innovations: In collaboration and consultation with the NTP and other stakeholders, this activity will contextually adapt and scale up WHO- and USG-endorsed new technologies, innovations and strategies. In addition, the activity will work with USAID-Ethiopia and other stakeholders to address barriers for scale up of new technologies and evidences in TB programming.

Design and implement contextual strategies: While adapting and complying with the global guidance to eliminate TB, this activity will develop contextual and tailored TB control and prevention strategies to be cost effective and impactful with the USG resources.

***Ensure sustainability, local ownership and inclusive engagement*:** This activity will harmonize, align and coordinate its activities with the FMOH's strategic plan and other stakeholders. To ensure sustainability and ownership of the activity's interventions, the activity will build local capacity and engage local institutions including academia and CSOs as implementers of the activity through sub-awards. In addition, the activity will be targeting key affected and vulnerable populations (prisoners, children, urban poor, migrant workers, PLWHA, miners and others) and design strategies that overcome their limited access to TB services.

Support the successful implementation of Global Fund grants: The activity will support the health system at different level and ensure that Global Fund activities are strategically planned, effectively implemented, appropriately monitored and aligned with our activities.

Utilize clear and comprehensive monitoring and evaluation plans: The activity will have a comprehensive monitoring and evaluation plan that includes a comprehensive set of indicators that will measure the activity's performance and the overall targets of the END TB strategy.

As a flagship TB activity for USAID/Ethiopia, the following overarching concepts for the TB programming will be considered:

1) Complete any "unfinished agendas" from Challenge TB (e.g., innovations not yet optimized or fully adopted)
2) Demonstrate a continued capacity to pilot and introduce new program innovations, including any new diagnostic and drug solutions

3) Continue charting the pathway to universal DST
4) Prepare NTP for how to work differently in a scenario of lower TB burden: e.g., with different technical approaches and possible change in organizational structures and ways of working
5) Include some unaddressed End TB strategy approaches, including the multisectoral agenda for TB, preparation for universal health coverage (UHC), and mitigation of patient catastrophic costs
6) Explicit, technical work on domestic resource mobilization for TB – including advocacy strategies, policy pathways, and measurable results.

ETBE will sustain and build on the successes of existing and previous USAID TB activities (CTB, HEAL TB, TB Care and PHSP), focusing on the identified gaps. Accordingly, the activity will be supporting the National and sub-national TB programs to improve access and utilization of comprehensive and quality-oriented TB, DR-TB and TB/HIV services; to improve treatment coverage (both drug sensitive and drug resistant TB) by reaching key affected populations; strengthening and expanding quality of DR-TB diagnostic and treatment services; improving the implementation of TB Infection control measures including treatment of latent TB; expanding and strengthening high quality TB diagnostics including access to DST, and strengthening health systems so that they are more able to sustain and strengthen the overall TB response.

4.2.Collaborating, Learning and Adapting (CLA)

USAID is integrating CLA best practices into all aspects of its operations and programming to achieve better development results. This involves strategic collaboration, systematic and continuous learning, and adaptive management. CLA asks:

- Do you take the time to think critically about your work?
- Are you strategic in who you collaborate with, what you're learning, and
- Do you use those learnings to change accordingly?

While CLA is not a new idea, these practices often do not occur regularly, are not systematic, and not deliberate. CLA is not a different or extra work stream or done for its own sake. It is a different way of approaching program design and making implementation as effective as possible to maximize development impact. Strong CLA practices vary with organizational culture, program contexts, and their enabling environments. CLA practices need to be tailored where investments at different levels of the health sector and the enabling environment are implemented by different implementing partners.

Partners can achieve this intentionality by identifying knowledge gaps in their program's theory of change or by filling gaps in the evidence that designers used when creating the program. The intentionality may be achieved by creating and taking opportunities for stakeholders to track progress, discuss challenges, opportunities, and changes in context. Another opportunity to be intentional emerges as collaboration opportunities are created or required, especially if USAID/Ethiopia or Washington stakeholders are involved.

ADS 201.3.4.10.B describes potential approaches to CLA that include, but are not limited to:

- Having partners identify knowledge gaps in the theory of change for their program or in their technical knowledge base and supporting them in identifying and implementing ways to fill these gaps;
- Planning for and engaging in regular opportunities for partners to reflect on progress, such as partner meetings, portfolio reviews, and after-action reviews. These opportunities may focus on challenges and successes in implementation to date, changes in the operating environment or context that could affect programming, opportunities to better collaborate or influence other actors, and/or other relevant topics;
- Encouraging or requiring partners under a program to collaborate, where relevant. Collaboration activities may include joint work planning, regular partner meetings that facilitate knowledge sharing, and/or working groups organized along geographic or technical lines. These activities require time and resources, and appropriate resources should be budgeted;
- Involving implementing partners in the USAID learning activities, such as portfolio reviews or stocktaking efforts, as appropriate; and
- Using the knowledge and learning gained from implementation, opportunities to reflect on performance, monitoring data, evaluations, knowledge about the context, and other sources to adjust interventions and approaches as needed.

These practices need to drive decision-making and program adjustments in an intentional way that responds to new information and changes in context.

4.3.Activity's targeted setting (geographic and population target)

ETBE will be national in scope and work at the national, regional, zonal, woreda and health facility levels. However, taking into consideration the previous and ongoing USAID investments in TB control program support at all levels, geographic focus for interventions will be highly prioritized and the activity will maximize efficiency by building on the investments that have already been made.

Through HEAL TB and Challenge TB, the geographic scope of USAID/Ethiopia's TB activities has gradually increased over time, and the implementing approach has become less intensive, moving from facility to woreda to zonal (and now multi-zonal)-level support and above. Under ETBE, the intensity of support at lower levels is expected to continue to decrease, with significant efforts to strengthen Government capacity so that Government staff can take over the tasks that were implemented by project staff under Challenge TB. This strategic approach will allow more resources, capacity and time to be spent on non-routine, high impact interventions with proven effectiveness that would require additional technical expertise and resources. The experiences from ongoing CTB high impact interventions and the lessons that will be generated from the CTB End of Project Evaluation will be used to enhance the activity strategy and performance. A total of 100+ million people are currently targeted with the different levels of

USAID TB support at national, regional, zonal, woreda and health facility levels. After a series of consultation processes and consensus with the Host Government/FMOH, ETBE intends to be focused and prioritize geographic scope and thematic areas of the comprehensive TB, DR-TB and TB/HIV program.

4.4.Technical approach

The potential recipient will design and manage interventions that will improve the National TB program performance by addressing the following thematic areas; TB and DRTB case finding to narrow the lower treatment coverage, access to TB diagnostic services include universal access to DST, strengthening health system platforms for TB services , expanding quality assured and patient centered TB treatment services and prevention of TB infection and disease progression by implementing TB infection control measures and latent TB treatment services. The activity will build on the achievements and successes of USAID TB activities and other health system activities of USAID. The activity will build the capacity of the national and subnational health structures to sustain the program and ensure self-reliance. The interventions of the activity will be informed and guided by strong evidences, best practices and international standards that lead to the overall goal of TB incidence and mortality reduction by efficient and effective use of limited resources. The recipient will be expected to prioritize thematic areas(high impact interventions and cost effective) and geographic areas in Ethiopia with the overall goal of impacting the national TB program performance and demonstrating best approaches/ practices to the program. ETBE will build national and sub national capacity in research and innovation to generate local evidences that will inform NTP to better plan and manage the program. The activity will support the NTP to fast track and adopt new technologies and global developments in TB program. In addition, the activity will provide focused support to the NTP in generating quality data, performance review and dissemination of results to local and international stakeholders, implementers, beneficiaries and to the scientific community. The recipient's proposed interventions should be evidence based, build local capacity, sustainable and locally owned.

5. Program Description

The goal is to reduce TB incidence and mortality to achieve End TB strategy milestones and targets for 2025 and 2035 in Ethiopia. By reducing Ethiopia's TB incidence and mortality, the activity will contribute to the overall global goal and US government goal of ending TB by 2050. To achieve ETBE's and the global TB Accelerator objectives, the potential recipient is expected to have the appropriate mix of managers, technical experts and support staff at the National, regional and zonal levels and ensure the capacity of government counterpart personnel is built with the overall intention to sustain the activities interventions. ETBE will be mainly focusing in ensuring access and utilization of quality TB and DR-TB services while supporting the

government system and collaborating with other stakeholders to narrow knowledge, practice and attitude of the community towards TB and DR-TB.

To contribute to the global and US government goals of ending TB, the activity will be focused and deliberate to implement high impact TB/DR-TB case finding and TB prevention strategies, to improve access and utilization of TB diagnostics including universal access to DST, to improve access to quality assured and patient centered TB /DR-TB management services and in strengthening health systems. The activity's planning and program management will be informed with local evidences and aligned with the national TB program plan and health sector transformation plan. . The activity will contextually adapt WHO's End TB strategy with special emphasis on effectively utilizing USG resources and achieve intended objectives and targets.

5.1. Objectives of Eliminate Tuberculosis in Ethiopia

Objective-1: TB diagnostic and universal DST service expansion and utilization

A well-established laboratory network, capable of providing quality diagnosis from the primary care until the tertiary health care service delivery to ensure basic TB case finding and universal DST are the cornerstone of any TB program.

The priority under this objective is TB diagnostic and universal DST service expansion and utilization, including using GeneXpert as a primary test and full use of First line & Second Line genotypic and phenotypic drug sensitivity tests.

Objective-2: Quality-assured, patient-centered TB and DR-TB management

This objective focuses on the quality of treatment, including expanded quality-ensured patient centered DS-TB and DR-TB (RR, MDR, pre-XDR and XDR-TB) management, and use of the MDR-TB Short Treatment Regimen (STR) and new drugs (NDs) when indicated..

Objective-3: Implement high impact case finding and prevention strategies

This objective focuses on the Implementation of high impact TB case finding and prevention strategies, including contact investigation, community TB care, key population interventions, screening in high load facilities, TB prevention using LTBI treatment, TB Infection control (TB-IC)C and TB/HIV activities.

Objective-4: Strengthen health system support

This objective is directed towards strengthening the health system elements that are essential for a strong TB program, with focuses on M&E/OR, commodities, domestic resource mobilization, biomedical engineering, improved program management and staff capacity

building, capacity of the system to optimally absorb the ETBE support and take more ownership.

5.2.Expected results (To be disaggregated by sub-objectives)

While contributing to the long-term ambition of ending TB by 2050 and reducing TB incidence by 50% and TB mortality by 75% from the 2015 base line, this follow up TB activity will support the national TB program achieve the following targeted results by October 2024 in Activity-supported areas:

- ≥ 90 percent Treatment coverage for all forms of DS-TB cases
- ≥ 80 percent treatment coverage of estimated DR-TB cases
- ≥ 95 % Treatment success rate and ≥ 90% cure rate for DS-TB
- ≥ 85% treatment success rate for DR-TB cases
- 100 % HIV testing for TB (DS-TB and DR-TB) patients
- 100% Antiretroviral therapy for TB/HIV co-infected patients
- 80% of all bacteriologically confirmed cases nationally diagnosed through GeneXpert, through expanded use of GeneXpert as a primary test and the use of sample referral
- 100% access to first line DST for all TB patients
- 100% access to second line DST for all DR-TB patients
- > 90% uptake of new diagnostics and new drugs
- > 90% preventive treatment initiation for PLHIV and child contacts
- Additional indicators on expanded LTBI screening coverage and TPT (define after national consultation)
- 50% domestic financing for TB
- 0% of TB households suffering from catastrophic costs due to TB
- 0% of facilities with TB drug stock out
- 100% implementation of standard TB infection control measures

5.3.Indicators

The following indicators should be reported quarterly, unless otherwise specified:

- Incidence of DS-TB and DR-TB and TB related mortality rate (reported annually)
- #/% DS TB cases notified as a proportion of estimated DS-TB incidence
- #/% DR TB cases notified as a proportion of estimated DR-TB incidence
- % Treatment success rate and cure rate for DS-TB
- % treatment success rate and cure rate for DR-TB cases
- % HIV testing for TB (DS-TB and DR-TB) patients
- % Antiretroviral therapy for TB/HIV co-infected patients
- % of all bacteriologically confirmed cases nationally diagnosed through GeneXpert

- #/% GeneXpert tests (for presumptive DS-TB, presumptive RR-TB and new pulmonary TB cases)
- #/% SL LPA tests for RR patients
- #/% DR-TB (RR, XDR-TB) patients treated using Short Treatment Regimen (STR)
- #/% DR-TB (RR, XDR-TB) patients treated using New Drugs (NDs).
- % of under-5 contacts initiated on TPT
- % of PLHIV contacts initiated on TPT
- % completion of patients initiated on TPT
- % domestic financing for TB (reported annually)
- % of TB households suffering from catastrophic costs due to TB (reported when survey results are available)
- % of facilities with stock-outs of tracer first line and second line ant-TB drugs and GeneXpert commodities (cartridges, falcon tubes and triple packages)
- % of facilities with standard TB infection control measures
- High impact priority interventions (case finding and prevention activities) indicators
    - #/% DS-TB and DR-TB cases notified through Contact Investigation
    - #/% DS-TB and DR-TB cases notified by key population (prison, migrants…) interventions
    - #/% DS TB and DR-TB cases notified through CTBC activities (including presumptive TB referrals)
    - # Specimens referred for GeneXpert, Culture/DST, and SL LPA
    - #/% DS-TB and DR-TB cases notified through high load health facility interventions
- # Of operational research activities, presentations and publications in national and international forums.