USAID Global TB Strategy, 2023-2030
Implementation Approach

Introduction:

Tuberculosis (TB) is one of the world's most deadly infectious diseases. Until the emergence of COVID-19, the bacterium that causes TB was described as, "the most destructive pathogen on the planet," killing more than 4,300 people each day.[1] Despite being preventable, treatable, and curable, this ancient disease continues to kill more people each year than HIV and malaria combined. While a wide range of evidence-based and scientific interventions have been developed to combat TB, due to continued underinvestment and low global prioritization (compared to other diseases), TB persists, resulting in close to 11 million TB cases and 1.3 million deaths annually.[2]

This **Implementation Approach** describes priorities and activities under each Objective of the USAID Tuberculosis Strategy. It provides a brief overview and details of the interventions that have to be in place in order to achieve the Goals and Objectives of the Strategy. It is organized according to the **Reach, Cure, Prevent, Innovate,** and **Sustain** components of the Strategy, with a separate section describing operational principles. It describes *What* and *How* to implement priority TB activities and provides links to the best practices, tools, guidelines and publications. It should be noted that where there is overlap across the strategy components, specific activities may appear more than once. For example, contact investigation is an important activity under both Reach and Prevent, with different aims for each component. Therefore, TB Contact Investigation (TBCI) appears in both sections with a description of why it is relevant to each component.

This is a public version of the Implementation Approach. This document will allow readers to better understand principles and priorities for the USAID TB Program globally and assist National TB Programs to develop and implement innovative and comprehensive TB approaches, with the aim to achieve global and national TB targets and goals.

[1] https://www.economist.com/science-and-technology/most-resistance-causing-mutations-in-tb-have-now-been-identified/21805727

[2] Global Tuberculosis Report 2023, World Health Organization

High-Level Focus of TB Strategy

TB Strategy Vision: A TB-free world

TB Strategy Mission: Provide high-quality TB technical and development assistance through programs founded on principles of diversity, equity, and inclusion, and implemented in partnership with affected individuals and communities.

TB Strategy Goal: The U.S. Agency for International Development (USAID) will work with partners worldwide to reach every person with tuberculosis, cure those in need of treatment, prevent new infections and progression to active TB disease, while scaling-up innovations in detection, care, and treatment, and fostering local ownership to sustain effective TB programs that also contribute to pandemic preparedness.

Strategic Objectives:
1. REACH: Maximize the detection of all forms of TB in all individuals of all ages.
2. CURE: Empower all individuals diagnosed with TB to complete treatment and be cured.
3. PREVENT: Stop the spread of new infections and progression from infection to active TB disease.
4. INNOVATE: Research, develop, introduce, and scale-up new tools and approaches to combat TB.
5. SUSTAIN: Build country-owned TB systems, led by local partners, that accelerate progress and support pandemic preparedness.

Guiding Principles for Priorities and Interventions

This strategy was developed with the understanding that the next eight years may bring a wide variety of developments that could impact USAID's planned activities and targets. However, the following seven guiding principles will remain constant:

1. *Diversity, Equity, and Inclusion (DEI):* USAID's TB program will work to promote, enhance, and sustain diversity and inclusion in all activities. To meet our goal of equity, USAID will prioritize working with underserved communities and those who are in the greatest need.

2. *Local Ownership and Leadership:* USAID will continue to partner with local governments and organizations and support their implementation of TB activities. USAID will actively engage with country leadership to promote program ownership through increased local investments and program monitoring. USAID will continue to support high-level advocacy to actively engage local leaders and communities in eliminating TB at the national level.

3. *Person-Centered Approach:* USAID will continue to place individuals and communities affected by TB at the core of each activity. USAID will support countries in building a holistic, individualized, respectful and empowering health service delivery system for TB that includes TB-affected individuals in decision making regarding the development, implementation, and

evaluation of care and treatment services. USAID will support national TB programs in adopting flexible and tailored approaches that minimize health system barriers and costs to individuals, and to meet the needs and preferences of people affected by TB to improve each person's health outcomes.

4. *Effective and Efficient Programming:* USAID will strive to use funds effectively and efficiently to achieve value for money. The Agency will remain flexible and responsive to adapt to existing and new TB-related challenges and situations in partner countries.

5. *Strategic Partnership:* USAID will continue to work with partners including the WHO, the Stop TB Partnership, the Global Fund, CDC, other USG agencies and others to achieve global goals. As the lead agency for USG international TB efforts, USAID will continue to coordinate USG TB efforts and leverage investments to achieve more.

6. *Evidence Driven Programming:* USAID will support the availability of high-quality, updated, and rigorous systems for TB care across partner countries. USAID will also evaluate systems to generate evidence that will help to improve strategic planning, project design, and resource decisions.

7. *Multisectoral Approach:* USAID will support the implementation of a multi-sectoral approach to achieve effective accountability of governments and all stakeholders–at global, regional, and country levels–in order to accelerate progress to end the tuberculosis epidemic.

Priority Interventions

Strategic Objective 1: REACH

Maximize the detection of all forms of TB in all individuals of all ages. Reaching every person with TB is foundational to USAID's vision of a TB-free world and requires universal access to the most accurate tools to screen and diagnose individuals for TB. REACH includes a broad range of interventions along the patient pathway to care, starting with activities that occur before a person accesses TB testing and continuing through all the steps required to confirm (or reject) a diagnosis of TB. These activities may take place at the household, community and/or facility level. Five key priorities described below and based on international guidance and best practices will help direct USAID strategic and technical design and implementation of activities under the REACH Objective towards achieving USAID's targets of 90% of incident TB and DR-TB cases diagnosed and initiated on treatment.

Priority #1: Ensure optimal coverage of case-finding approaches

Case finding approaches should be tailored to the local epidemiologic, socioeconomic, cultural and health systems context; even within one country, case finding strategies are likely to differ in urban and rural settings and according to local norms. USAID supports the following interventions with the

understanding that they must be adapted to suit local needs, may not be appropriate in all settings and may be combined or implemented in stepwise fashion to achieve maximum impact on TB notifications. Additionally, USAID Missions and partners may need to weigh the potential success of different approaches and prioritize interventions accordingly. For example, if locally generated evidence shows that many people with TB are seeking care in health facilities but are not screened and diagnosed properly, intensified case finding approaches in service delivery settings (both public and private) may need to be prioritized over community based case finding, at least in the short term. WHO's ScreenTB Tool can be used to identify the promising screening strategies based on TB epidemiology, risk factors, screening settings (ex, clinics and communities) and cost effectiveness.

Engage TB-affected communities and civil society to eliminate barriers to access health services. Case-finding along the patient pathway to care should be organized through a people-centered approach reflecting the experiences of TB-affected populations and highlighting the important role of civil society organizations. Interventions may include:

- Creating/maintaining community awareness of TB through interventions that broadly educate communities about TB and generate demand for TB services.
- Designing and implementing people-centered TB services that include access for the most marginalized and vulnerable populations including [Global Plan to Stop TB, 2023-2030 (see Chapter 7)]:
    - People who have an increased exposure to TB due to where they live or work
    - People who have limited access to quality TB services
    - People at increased risk of TB because of factors that compromise immune function
- Eliminating TB-related stigma and discrimination

Expand community-based active case-finding approaches.

Active case finding (ACF) approaches are typically implemented outside formal health care settings and often involve community health care workers or volunteers who are trusted by the population and have direct links to the health care system, facilitating referrals and access to care.

- At a minimum, ACF should include screening individuals for TB symptoms and referring those who screen positive for TB diagnostic testing. Where feasible, community based sputum collection should be implemented.
- Where possible, local partners should provide support to individuals throughout the entire care cascade.
- ACF may also target specific populations at high risk of TB, especially those in congregate settings where exposure to TB is more likely (e.g., prisoners), or occupational settings (e.g., miners, workers exposed to silica),
- ACF at the community (people living in urban slum areas, homeless, nomadic, sex workers, people living in remote and hard to reach areas), displaced persons or crowds (immigrants and refugees) and

- Specific populations at high risk for TB should be prioritized based on approximate group size, TB disease prevalence and number needed to screen to diagnose one TB case. This will ensure effective use of TB resources by targeting populations with the highest TB diagnostic yield.
- ACF activities should be monitored and periodically evaluated to understand which approaches are most effective.

Household and other close contacts of individuals with TB disease should be systematically screened for TB disease. TB contact investigation (TBCI) is an important case finding intervention because household members and others who are exposed to TB due to close contact with someone who is infectious are at high risk for infection and may progress from infection to disease.

Contact investigation is a high yield active case finding strategy to identify persons with TB earlier in the course of their disease as well as an important opportunity to find contacts with TB infection who will benefit most from TPT. A WHO guideline review found a yield of 3.4% (95% CI: 2.9,3.8) among contacts of bacteriologically confirmed (bac+) index cases, 3.9% (95% CI: 2.5, 5.4) among contacts <5 years old, 3.7% (95% CI: 2.4, 5.3) among MDR/XDR contacts, and 11.6% (95% CI: 8.2,15.4) among contacts who were also HIV infected [WHO pg. 17]. Although the WHO recommendation is to perform contact investigation for laboratory confirmed TB cases, a significant number of clinically diagnosed cases would be bacteriologically confirmed if molecular testing was universally available and if all clinically diagnosed cases were tested. Therefore, it is important to consider access to molecular testing and bacteriologic coverage among notified cases in a country when prioritizing cases for TBCI.

The yield of TBCI has been shown to be dependent on the number and timing of follow up visits. In a multicenter prospective study with long term follow up, 81% of new cases were detected within six months, and 92% within 12 months.

- TBCI should be conducted for all bacteriologically confirmed TB cases since they are more likely to be infectious and transmit TB to their contacts, but countries should not limit the scope of TBCI (given the low bacteriological coverage in majority of countries) and consider TBCI implementation for all notified cases, including those who are clinically diagnosed, in order to identify a possible source case (and dependent on resources).
- Source (or reverse) contact investigation should be done for all children (diagnosed clinically or through laboratory confirmed diagnostic testing) and should be prioritized by USAID Missions and implementing partners to identify an adult index case to whom the child(ren) were exposed, which may then lead to identification of additional TB cases.
- TBCI is equally important as a component of prevention, since contacts for whom active TB is ruled out but who are infected and/or continue to be exposed to TB from the index case benefit from TPT, by preventing progression to active disease. Please see PREVENT Priority #1 and #3 for further detail on the role of TBCI in prevention activities.
- USAID programs should support national TB programs to standardize tools to monitor TBCI activities and routinely report on the TBCI cascade.

Effectively utilize facility-based case-finding approaches. Facility-based intensified case finding (ICF) approaches began with the realization that TB programs were missing opportunities to identify individuals with presumptive TB who were seeking care for other illnesses throughout the healthcare system.

- The FAST strategy is an approach initially implemented in outpatient settings to quickly identify and triage symptomatic individuals to minimize TB and other respiratory disease transmission to other clinic attendees (infection prevention), now expanded to encompass rapid referral to TB diagnostic services.
- ICF activities often involve training providers in different services within a facility to actively screen each person seeking care and refer for TB diagnosis services if they screen positive. Some services and populations at higher risk of TB may be prioritized, depending on the context.
- ICF may also include cross referral from services where those seeking care are also at particularly high risk for TB, such as individuals presenting in emergency rooms or attending diabetes clinics (see more info on comorbidities in the sections below).

Engaging all care providers including scaling up public-private mix (PPM) approaches to reach all people with TB. In countries with large numbers of private sector providers, a significant number of people with TB symptoms often seek care outside of public health facilities, including a wide range of settings from private healthcare providers to prisons, workplaces, and military institutions. Special arrangements needed to reach, cure and prevent TB in those settings are outlined under SUSTAIN, priority #4.

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Priority #2: Increased use of chest X-ray to support TB case finding

Chest X-rays (CXR) are an effective screening tool for pulmonary TB due to their ability to identify anomalies consistent with TB disease, especially before the onset of symptoms**.** However, despite being a highly sensitive screening tool, CXR has not been routinely used for active case finding (ACF) in many countries due to financial and logistical challenges and limited technical capacity. Digital radiography, portable equipment and computer-aided detection (CAD) with artificial intelligence (AI) have significantly advanced and expanded the role of CXR technology and provide an opportunity for countries to include it in diagnostic algorithms as a priority screening tool. CXR can also detect other communicable and non-communicable diseases across the spectrum, including pulmonary, cardiac, thoracic, and skeletal conditions. As such, the combined platform of digital portable radiography and CAD with AI has many potential uses, including those which are directly related to individual health and those related to pandemic preparedness and response.

Incorporate CXR into a screening algorithm either in parallel or sequentially to an evaluation of cough/other TB symptoms. The purpose of a screening test is to identify individuals with a higher likelihood of having TB disease; the presence of a prolonged cough (≥ 2 weeks) or any cough is most often used as the primary screening tool for TB. However, screening for TB disease by cough alone

misses up to half of all individuals with TB (see table below). Although a screening test that includes at least one other TB symptom is more sensitive than cough alone, the specificity is much lower - meaning that more people without TB would screen positive, and more diagnostic tests would be needed to identify one true case of TB. CXR screening (for any abnormality or abnormality suggestive of TB) is more sensitive than screening by cough or any TB symptom and has a specificity comparable with screening by cough. In addition, if CXR is used in combination with symptom screening, it should result in a lower number of diagnostic tests needed than with symptom screening alone.

Diagnostic accuracy of symptoms and CXR for screening for TB disease among HIV-negative individuals
(adapted from WHO consolidated guidelines on tuberculosis. Module 2: Screening - Systematic screening for tuberculosis disease. Geneva, World Health Organization. 2021)

Screening Test	**Sensitivity (%)**	**Specificity (%)**
Prolonged cough (≥ 2 weeks)	42	94
Any cough	51	88
Any TB symptom (cough, haemoptysis, fever, night sweats, weight loss, chest pain)	71	64
CXR (any abnormality)	94	89
CXR (abnormality suggestive of TB)	85	96

In addition:

- CXR is an important tool for aiding diagnosis of TB in children. It is important to note that the pattern of TB-associated abnormalities seen on CXR in children may differ significantly from those in adults, and can vary with the age of the child. Identifying subtle changes in CXR images of younger children requires a practitioner specifically experienced in interpreting pediatric chest radiography.
- CXR helps rule out active TB before treating latent TB infection in individuals at risk. In particular, CXR is a valuable asset in diagnosing TB among PLHIV. WHO currently recommends using CXR (where available) in parallel with the WHO four-symptom screen (W4SS) to screen for/rule out TB disease before initiating TPT[3].
- CXR can increase the efficient use of mWRDs for initial TB diagnosis (however, CXR screening shouldn't be a prerequisite for mWRD).

Digital, portable CXR as part of active case finding for TB.
Digital radiography produces a digital CXR image that offers advantages over analog (or traditional) CXR technology: high throughput, decreased radiation dose, improved and more reproducible image quality,

[3] WHO consolidated guidelines on tuberculosis. Module 1: prevention – tuberculosis preventive treatment. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO.

better archiving capacity, possibility of electronically transmitting images, and lower operating costs. Improved portable systems can be used at lower levels of a health system and in mobile units for hard-to-reach communities. They can be operated solely on batteries, emit less radiation, and produce images comparable to stationary machines.

Computer-aided detection (CAD) with AI should be used to complement human reading and interpretation of CXR. CAD software packages are available to automate interpretation of digital CXR images for pulmonary TB disease-related abnormalities. CAD products analyze digital CXR images and generate a continuous numerical score that corresponds to an increasing likelihood of TB as the score increases. CAD can resolve numerous issues related to human interpretation of CXR including the lack or scarcity of trained health personnel to interpret radiographic images for TB screening and substantial intra- and inter-reader variation in detection of abnormalities associated with TB. It also increases workflow efficiency and identifies abnormalities upfront, alerting staff to images that should be prioritized for human reading. WHO recommendations on the use of CAD software to aid in the interpretation of CXR are limited to individuals aged ≥ 15 years. More data should be collected to validate the performance of CAD for TB in children, a process which has already begun, as recently reported in South Africa.

Program planning, site selection and preparation are necessary when implementing digital, portable CXR with CAD-AI.

Advanced planning and preparation is critical to country introduction or scale-up of digital, portable CXR with CAD-AI. The complexity and number of imaging systems, types of machines, and availability of CAD-AI software makes it necessary to have a comprehensive understanding of a country's underlying health system and infrastructure, in addition to its TB epidemiology and screening needs in order to ensure successful implementation. USAID and other stakeholder pilot projects have identified several key considerations when planning to incorporate digital, portable CXR with CAD-AI into a screening algorithm including: availability of electricity and power; portability and set-up; radiation safety and regulatory requirements; data management and privacy; interoperability between CXR and CAD; internet access; privacy for individuals being evaluated. In addition, countries should be supported to conduct an in-depth assessment to determine the parameters, including locations and protocols, to successfully implement the program. Guidance is summarized in this Practical Guide from the Stop TB Partnership.

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Priority #3: Increase access to and use of rapid molecular TB diagnostic tests to diagnose TB and DR-TB

The World Health Organization (WHO)-recommended rapid diagnostics (mWRDs) are highly accurate, reduce the time to treatment initiation, improve treatment outcomes, and are cost-effective. Although the goal is for mWRDs to be used as the initial test for all individuals with presumptive TB by 2025, in 2021, mWRDs are underutilized as the initial test, and access to diagnostics in both public and private

facilities was identified as a critical challenge to detecting TB. Insufficient access, particularly to mWRDs, has also led to a large gap in the detection of drug resistance and it is unethical to limit access to early detection of this deadly form of the disease.

mWRDs are defined as diagnostic tests that employ molecular or biomarker-based techniques for the diagnosis of TB.

Molecular WRDs (to be updated as new dx are approved)		
	Detects drug resistance	**Does not detect drug resistance**
Low complexity automated NAATs	Xpert MTB/RIF Ultra, Xpert MTB/RIF, Xpert MTB//XDR (Cepheid); Truenat MTB, MTB Plus and MTB-RIF Dx tests (Molbio)	TB-LAMP (Human Diagnostics)
Moderate complexity automated NAATs	Abbott RealTime MTB and MTB RIF/INH (Abbott Laboratories); BD MAX MDR-TB assay (Becton, Dickinson and Company); Hain FluoroType MTBDR assay (Bruker/Hain Lifescience); Roche cobas MTB and MTB-RIF/INH assays (Hoffmann-La Roche)	
Biomarker-based WRD		
	Determine TB Lam Ag (Alere)	

USAID supports the following interventions to scale-up the use of rapid molecular TB diagnostic tests within a comprehensive and robust diagnostic network that incorporates diagnostic tools and strategies to help ensure that each person has access to the best available care.

All individuals with presumptive TB are tested with a molecular rapid diagnostic test (mWRD), preferably one that also tests for drug resistance. USAID prioritizes access to and use of mWRDs as the initial diagnostic test for each individual with presumptive TB, including adults, children, and PLHIV (notably, most mWRDs are recommended to test both pulmonary and extrapulmonary forms of TB). Additionally:

- USAID should work to include private sector providers and laboratories in national TB diagnostic networks so that all persons have access to the most accurate and appropriate testing technologies, including mWRDs, regardless of where they receive health care services.
- Children with presumptive TB should receive TB testing in accordance with WHO guidance, including use of mWRD as the diagnostic test of choice, and appropriate use of LAM (see Priority #4 below).
- Low complexity automated NAATs that also test for drug resistance (e.g, Xpert and Truenat) are preferred. Higher throughput moderate complexity NAATs may also be considered but placement should be at higher density test/volume sites that have robust and cost-effective specimen transport with adequate turnaround time. Tests that do not detect drug resistance

(e.g, TB-LAMP) may provide greater access to rapid molecular testing at peripheral sites. In such cases, it is also necessary to refer all individuals in whom TB is detected for resistance testing.

- Since many mWRD testing platforms used to detect TB also offer testing for other infectious diseases, facilitating access to rapid TB testing within communities and primary health care centers could also facilitate increased rapid diagnosis and faster initiation of appropriate treatment and/or referral for other health conditions.
- In countries with centralized testing for TB, USAID programs should continue to support the national TB control program to facilitate early diagnosis and fast initiation of appropriate treatment through use of rapid molecular TB diagnostic tests closer to the community to ensure access and minimize potential challenges with testing turnaround time.

All primary health-care facilities have access to mWRDs either on site or through specimen referral. Rapid molecular tests provide an opportunity to detect TB early, initiate treatment before symptoms progress, and potentially mitigate transmission. This is especially relevant for individuals identified through active case finding, who often have lower bacillary loads than cases identified through passive case finding. Therefore it is critical that mWRDs are available in primary health-care facilities to provide early and accurate detection and to support active case finding approaches. Suggested interventions include:

- Ensure that mWRDs are available at the primary health-care level, and applied as close to the point-of-care as possible. For example, placement of Truenat at peripheral sites could increase access to rapid molecular testing because it is battery operated and portable. Similarly, TB-LAMP could increase rapid molecular testing at peripheral sites that require high throughput testing.
- Strive to achieve a turn-around time of ≤ 48 h for ≥ 80% of samples at all TB testing facilities using mWRD.
- Countries should aim for maximum onsite testing with a mWRD, with specimen referral and sample transport utilized under the following conditions:
    - Individual samples should reach testing sites rapidly to safeguard the quality of samples and potential for accurate diagnoses. To achieve this, countries should develop reliable transport that minimizes turnaround times, prioritizes TB diagnosis, and maintains the necessary conditions, e.g., triple-packaging, temperature-controlled systems. Additionally, collaboration and communication between and among healthcare facilities, laboratories, and public health authorities is crucial. Implementing standardized procedures and protocols, training healthcare workers, and ongoing monitoring using quality assurance metrics are important strategies used to enhance these networks.

Rapid molecular diagnostic sites must be fully functional within a comprehensive and robust diagnostic network. A well-functioning, high-quality decentralized diagnostic network includes a number of components that are the joint responsibility of both the TB program and TB laboratory network. Missions should ensure key performance indicators of diagnostic network functionality are monitored and performance issues should be communicated in a timely manner. Priority interventions include:

- Use of the TB diagnostic network assessment framework to evaluate network capability to adequately address country diagnostic needs and carry out diagnostic network geospatial analysis or optimization exercises to identify whether countries have sufficient testing capacity (including instruments and test kits) based on burden and need. Once ongoing quantification needs are established, plans for routine procurement should be put into place for consumables and reagents.
- Ensure testing equipment service level agreements and maintenance protocols are in place and monitored using key performance indicator based on revised agreements with manufacturers.
- Prioritize implementation of diagnostics data connectivity to optimize data usage and improve coverage and visibility of national diagnostic networks. Diagnostic data connectivity enables the sharing of information that supports service and maintenance of instruments to ensure uptime of the network, procurement data for inventory and stock management, and the application of data analytics for programmatic use to improve clinical outcomes. By implementing data intelligence and connectivity for TB diagnosis and management, programs can improve efficiency and optimize resource allocation for TB diagnosis. Access to and utilization of connectivity data for monitoring and decision-making should be prioritized for relevant stakeholders including USAID TB staff.

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Priority #4: Improve detection of all forms of pediatric TB, including use of alternative specimens when sputum collection is not possible, appropriate use of X-ray and up-to-date treatment decision algorithms, including proper evaluation of extrapulmonary TB.
USAID-supported countries have made great progress in improving TB services for children. The release of WHO's updated guidelines for the management of TB among children and adolescents and accompanying operational handbook in March 2022 served as an impetus for high burden countries to introduce new approaches to TB screening and diagnosis for children, and USAID has provided support for a wide range of activities to improve these services. It is crucial to integrate and coordinate TB services, particularly TB screening activities, with pediatric service delivery at all levels and types of care, as children commonly present with non-pulmonary or non-specific symptoms which may result in a missed diagnosis. Additionally, children should be included in ACF interventions and prioritized for TBCI to ensure that those who have active TB are rapidly identified and treated, and those at high risk of developing the disease receive appropriate preventive treatment.

Providers who see ill children at all service delivery points should screen them for TB disease, if appropriate, especially those who present for care at ART or nutrition clinics, or are admitted as in-patients. TB screening is a critical intervention to identify children who may be at risk, given that TB disease progresses rapidly in children and TB deaths among children often occur before they are diagnosed and initiate treatment. Children identified as close contacts of individuals with TB should be screened for symptoms per WHO guidance (Section 2.3), as should children identified through

community-based approaches to case finding, including those identified as having high risk of TB via existing malaria and nutrition screening efforts that are offered at community level.

Children with presumptive TB should receive TB testing in accordance with WHO guidance, using mWRD as the diagnostic of choice and LAM as appropriate. Additionally, clinical assessment (see below) and collection and testing of samples needed to diagnose extrapulmonary TB, such as fine needle aspiration (FNA) for lymphadenopathy should be performed per WHO recommendations. In recent years, NTPs in high burden countries have introduced stool-based testing as an alternative to sputum due to the challenges of obtaining sputum samples from children. USAID has supported piloting, introduction and scale-up of this approach in multiple countries and maintains up-to-date resources on stool-based Xpert testing, including use of the SOS method for processing specimens, the preferred method due to its simplicity and performance. USAID anticipates guidance on the use of TrueNat for stool-based testing in the near future. USAID also has TA resources available to support National TB Programs to update clinical and programmatic guidelines for comprehensive management of childhood TB (see below).

Chest X-ray is a critical tool for evaluating children with presumptive TB. Given the suboptimal sensitivity of currently available mWRDs to detect TB in children, chest X-ray will remain an important intervention for providers to make treatment decisions for children with presumptive TB for the foreseeable future. For children with bacteriologically confirmed TB, chest X-ray is valuable for determining the severity of illness and eligibility for the 4 month shorter regimen for DS-TB endorsed by WHO. Artificial intelligence applications are not yet finalized for children but may be available relatively soon. USAID supports integration of CXR with updated national guidelines and training materials on management of pediatric TB for clinicians; this component should be integrated with all efforts to improve TB diagnosis for children.

All children with presumptive TB should receive a comprehensive clinical assessment. Although approaches to bacteriologic testing in children have improved with new tools in the last few years, the sensitivity of these tests remains suboptimal. For symptomatic children with a negative bacteriological test or who do not have access to testing, providers should follow WHO's interim treatment decision algorithms, until they are updated in March 2024. Multiple NTPs and technical partners are conducting operations research that will inform the final algorithms, which include one for settings with X-ray and one for contexts where X-ray is not available. USAID encourages Missions to work with NTPs and partners to update their guidelines and encourages the use of available TA resources for this purpose.

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Priority #5: Improved drug sensitivity testing to detect drug resistant TB and support implementation of new drug regimens

Evolving TB drug resistance and improved DR-TB treatment regimens require better and faster methods to detect drug resistance. Timely drug susceptibility testing (DST) is a critical component in the management of TB, as it enables appropriate treatment and care, and minimizes the risk of

transmission. While we have seen important and significant progress in DST tools, 2021 data indicated that only 70% of bacteriologically confirmed cases were tested for resistance to (at least) rifampicin and only 50% of people confirmed with DR/RR-TB were tested for resistance to fluoroquinolones (FQLs). Very little, if any, testing for resistance to other key drugs like bedaquiline (BDQ) and linezolid (LNZ) was reported during this time period. Furthermore, INH mono-resistant TB is associated with worse treatment outcomes than drug-susceptible (DS) TB and higher chances of acquiring additional drug resistance is rarely, if ever, assessed in individuals with RIF-sensitive TB disease.

All individuals with bacteriologically confirmed TB must have drug susceptibility testing consistent with WHO-endorsed national treatment regimens. As described in Priority #3, every person with presumptive TB should be tested with a molecular rapid diagnostic test (mWRD) that can also test for resistance to rifampicin. In situations where the initial test does not include RIF-resistance, it is necessary to include referral to RIF-resistance testing for all detected TB cases. Interventions to improve access to universal DST include:

- Introduce and scale-up the use of rapid, low complexity, automated NAATs for detection of resistance to INH and FQLs, including the Xpert MTB/XDR Assay (Cepheid). The Xpert MTB/XDR test is intended for use as a follow-on–or reflex– test in specimens identified as TB positive and provides an opportunity to improve access to rapid DST, especially in intermediate and peripheral laboratories. Use of low complexity NAATs also provides the fastest turnaround time (TAT), thereby allowing an individual who has tested positive to begin treatment while additional DST is being performed.
- For countries with existing line probe assay (LPA) infrastructure, commercial LPAs should be used as the initial test instead of phenotypic DST to detect resistance to INH and FQLs. However, given the significant infrastructure and biosafety required for LPA, countries should prioritize the use of decentralized rapid molecular testing (such as Xpert MTB/XDR), when possible, to detect resistance to INH and FQLs.
- Targeted next generation sequencing (tNGS) is an emerging solution for DST, with opportunities for use in clinical decision making in many countries. In 2022, WHO commissioned a series of systematic reviews of published and unpublished data on the class of tNGS products that have been commercially developed for TB drug resistance detection. WHO convened a Guideline Development Group (GDG) in May 2023 to discuss the findings of the systematic reviews and make recommendations on this technology including:
    - *Available evidence supports the use of targeted NGS to detect drug resistance after TB diagnosis, to guide clinical decision-making for drug-resistant TB treatment. This class of tests does not replace WRDs that are more accessible, cheaper and easier to perform for detecting resistance to rifampicin, isoniazid and fluoroquinolones. However, this class can be considered an alternative for prioritized populations requiring comprehensive DST with faster results compared with phenotypic DST, or where access to phenotypic DST is limited. Although targeted NGS could provide important early DST results, which may impact treatment decisions in some individuals, the suboptimal sensitivity for selected new and repurposed drugs implies that phenotypic DST is still required.*

Phenotypic DST capacity is still needed and will continue to be an important diagnostic as new drugs are introduced. The current definition of XDR-TB, as well as the regimens designed to treat XDR-TB, requires DST results for FQLs, BDQ and LNZ, making the ability to test for resistance to these drugs a priority. Molecular testing through rapid low complexity automated NAATs or LPA for BDQ and LNZ resistance is not yet available. At this time, phenotypic confirmation is necessary when using sequencing – either whole genome or tNGS – to detect resistance to new and repurposed drugs. Therefore, culture-based phenotypic DST for BDQ and LNZ will need to be performed using either the mycobacterial growth indicator tube (MGIT) or Middlebrook 7H11 (Agar) media for the foreseeable future. Additionally, if capacity exists to perform phenotypic DST for other drugs included in WHO endorsed RR/DR-TB regimens, it may be done using phenotypic methods and will provide valuable information on both individual level drug resistance and broader emerging resistance patterns. Interventions to support culture-based phenotypic DST include:

- Capacity building for staff, as well as mentoring and supervision.
- Ensure biosafety measures for all culture laboratories are in place, in line with a risk assessment approach that considers different types of procedures performed by each lab. Measures should include standard operating practices, safety equipment, laboratory design, health surveillance, training and waste handling.
- Ensure reliable and safe specimen transportation is available for referrals from collection points to regional or national TB reference labs for DST. Monitoring of TAT and specimen quality is required for continuous improvement of the specimen referral and transport system.

DR-TB surveillance should be a routine component of TB programs. Two main approaches to DR-TB surveillance that produce country-wide data include periodic surveys of sampled people with TB and continuous surveillance based on routine DST for all bacteriologically confirmed individuals with TB.

- Conducting periodic nationwide drug resistance surveys (DRS) helps to capture resistance patterns at a specific point in time, but is intensive from both financial and human resources perspectives.
- If a continuous surveillance system is not yet feasible in a country, sentinel site surveillance may be a useful interim approach for monitoring DR-TB if sites are selected per WHO guidance (page 45) to ensure they are representative of all sites likely to be testing people with DR-TB. A phased approach to continuous surveillance may start by targeting certain high-risk groups (e.g., individuals whose treatment failed, previously treated individuals) and expanding as resources permit.

Strategic Objective 2: CURE

Empower all individuals diagnosed with TB to complete treatment and be cured.

Three key priorities listed in this Objective will ensure that USAID programming focuses on key aspects of TB cascade delivery and considers international recommendations and best practices. Treatment initiation and successful completion is one of the critical indicators both for the national TB programs as

well as for USAID and other donors. In the UNHLM targets for 2028, 90% of people detected with TB have to be enrolled in appropriate care. USAID's strategic framework for the 2023-2030 strategy calls for 90% of incident TB and DR-TB cases to be diagnosed and initiated on treatment.

Priority #1: TB treatment initiated promptly and according to the national and international standards

All people with TB who have been diagnosed with TB must be enrolled on an appropriate TB treatment regimen. Frequently individuals with confirmed TB and especially DR-TB are not initiated on appropriate TB treatment. This is referred to as pre-treatment loss to follow-up (LTFU) and occurs for multiple reasons. In some countries, as many as 40% of individuals diagnosed with DR-TB are not enrolled on any treatment, let alone treatment to which their TB disease is sensitive, which leads to disease progression, deterioration of their overall health, further lung damage, and increased mortality. Also, TB transmission continues to occur in people not receiving appropriate TB treatment, especially among close contacts. Early 2022 data suggests that some people with DS-TB are not properly initiated on treatment, especially if the linkage and referral systems for diagnosed cases are not working properly.

Several programmatic solutions can help to address the issue:

- Ensure routine data analysis of diagnosed and enrolled treatment cases, disaggregated by type of TB (DS- and DR-TB), age, sex and location (per province, region, etc)
- Ensure appropriate referral and/or linkages between labs or diagnostic sites, the treatment clinic/site and state/national TB programs. For example, if individuals are diagnosed at the PHC level, via private providers, or at NGO sites and they must travel to initiate treatment, they should not bear out-of-pocket costs (or be promptly reimbursed if such costs are incurred by the individual with TB). When people reach such referral treatment sites, feedback information needs to be given to the referral sites.
- Consider full integration of DR-TB treatment services into the routine TB (DS-TB) network and services (after reviewing DR-TB care delivery to ensure the overall health system and individuals would not be harmed by such changes). Recently WHO-endorsed DR-TB regimens are increasingly simple to provide and for individuals to take (all-oral, short, not requiring hospital care for monitoring). They can be delivered at the same sites, facilities and levels of care as DS-TB services. Where this is not feasible, DR-TB treatment services should be decentralized to primary health care clinics to increase access to treatment enrollment, reduce treatment initiation delays, and improve follow-up and treatment monitoring.
- Utilize test result notification systems to directly communicate results to the providers and utilize community health workers to counsel and encourage rapid treatment initiation.
- Scale-up treatment initiation sites in both the public and private sectors, and at NGO clinics (according to the national regulations).
- Ensure sufficient drug stocks for both DS and DR-TB treatment at the treatment sites. The buffer stock of TB drugs should be available for at least 3 months at TB service delivery sites.

Treatment for people with drug-resistant TB must be provided according to drug susceptibility test results. With the growing number of people diagnosed with resistance to one or more anti-TB medications, it is important to focus on delivering a "precision medicine" approach, where the designed treatment regimen is reflective of diagnosed drug resistance. If individuals are not treated with the drugs to which they are sensitive, the risk of further drug amplification, treatment failure, and transmission of drug-resistant TB all increase significantly.
Several programmatic solutions can help to address the issue (*more details provided in the REACH section of this document, Priority #5*):

- All individuals diagnosed with TB need to be tested at least for resistance to RIF and, if possible, to INH and FQLs (via GX and/or Truenat)
- All individuals with confirmed resistance to RIF, INH or both, must receive further DST to identify an appropriate treatment regimen. This may be done via a combination of LPA, MGIT, and genome sequencing, depending on country context and capacity.
- Individuals diagnosed with resistance to FQLs in addition to RIF and INH should be started on a DR-TB regimen immediately and tested for further resistance to remaining second line medications included in the national guidelines.

People with TB should be provided with the most up-to-date regimen option. Recent developments in treatment options for both DS- and DR-TB mean that countries can now offer short (4-8 month), all-oral, and safer treatment options for all individuals.
Several programmatic solutions can help to address the issue:

- Individuals with DS-TB can be provided with the standard 6-months regimen or enrolled on a novel 4-months regimen (which includes moxifloxacin and rifapentine)
- The vast majority of people with DR-TB are eligible to receive all-oral regimens, and NTPs should aim to treat individuals with DR-TB without injectable agents, except in exceptional circumstances. There are several all-oral treatment options available for individuals without additional FQL resistance as well as with pre- and XDR-TB. Injectable agents should only be used in rare circumstances, for individuals with extensive drug resistance, or when no other medications could be applied.
- Pediatric cases have several all-oral and short treatment options for DR-TB. Additionally, children with non-severe DS-TB qualify for the shorter 4-month treatment regimen (Section 5.2.4, page 92).

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Priority #2: Comprehensive quality TB care delivered

Treatment delivery model is people-centered. While in the past, delivery of TB treatment required daily medicine intake monitoring, the current approach focuses on a people-centered model of care, when TB treatment can be delivered at an individual's home, workplace or other convenient location, as well as monitored remotely. Regardless of the treatment delivery model, it must be convenient to people, minimize costs to individuals with TB, and not create additional burdens including excessive travel and waiting times and costs.
Several programmatic solutions can help to address the issue:

- For TB treatment delivery, a differentiated service delivery shall be established, which can take multiple forms, including variable facility-based DOT, flexible models of care delivery, individualized care and approach for challenging cases, co-scheduling with ART for co-infected individuals, and a variable model of community drug delivery and adherence support.
- TB programming to be open to various person-centered options depending on assessment of the individual and facility/community factors.
- For individuals that have difficulty remaining on treatment, digital solutions such as 99DOTS, SMS reminders, and video-observed treatment (VOT) could be used.
- For people with DR-TB, when monitoring of adverse drug reactions is most important, such monitoring should be a part of treatment at home or communication through VOT.Active and systematic clinical and laboratory-based assessment of all people with DR-TB should be designed and routinely implemented in all USAID supported countries. This should include: Proper and regular laboratory tests, Clinical evaluation. Detection and management of adverse drug reactions. recording and reporting.
- If experiencing high mortality rates, whenever possible, mortality audits should look at the cause of, and not just factors that contributed, death. For example, people may be dying due to acute respiratory failure/hypoxemia and lack of supplemental oxygen. In cases where lack of oxygen is identified as a cause, it is recommended to leverage investments in expanding access to oxygen that USAID and other donors have supported due to COVID-19 for people with TB. Also ensuring pulse oximeters procured with COVID-19 resources are widely available at all in-patients and out-patients facilities where TB cases are managed.

Comprehensive support provided throughout the treatment. Treatment success rates for DS- and DR-TB are still below the 90% target in most countries and require programmatic actions to improve adherence, reduce adverse drug reactions and provide needed psychological and social support to individuals and their family.

Several programmatic solutions can help to address the issue:

- Educational and counseling service for people with TB and their family
- Providing the DR-TB care package as a whole or components of it to individuals, as needed
- Expanding the active drug safety management and monitoring (aDSM) system to all individuals receiving second-line medications
- Linkage with other social support activities and projects, including social protection schemes (see SUSTAIN priority #5)
- Screening for mental health disorders as well as comorbidities, and managing them (See Priority #3 for more details)
- Screening for and diagnosing lung damage during and after TB treatment and providing appropriate therapy if needed

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Priority #3: TB comorbidities addressed

People who are diagnosed with tuberculosis often suffer from additional health conditions and diseases and, in many cases, comorbidities not only increase the risk of developing TB, but also exacerbate

progression of TB, increasing a chance for people to have severe disease and unsuccessful TB treatment outcomes as well as higher chances of suffering from adverse drug reactions. Proper diagnosis of comorbidities at early stages can help initiate appropriate treatment and improve the outcome of TB care. The most common comorbidities among people with TB that require special attention are: diabetes, malnutrition, HIV, hepatitis, mental health disorders, etc. While management of comorbid HIV is often supported by PEPFAR programs, screening for other conditions should be addressed with USAID TB funding, with support from appropriate national disease programs. Designing a response to TB and comorbidities at the national level should be data-driven. Data should be collected and analyzed to identify problems, find solutions and optimize interventions along the continuum of care. NTPs should prioritize interventions for TB comorbidities according to the level of the diseases in the country.

Early screening for TB comorbidities. When people are initiated on TB treatment, an initial assessment and screening for comorbidities should be done. Simplified screening tools and algorithms can be developed and applied by the healthcare worker (HCW) when an individual attends the health facility for TB disease confirmation or TB treatment initiation. Access to digital chest X-ray can play a key role in the early identification of cardiovascular diseases and other pulmonary diseases. It is important to consider coupling these digital X-ray with CAD that can detect tuberculosis, cardiovascular and other pulmonary diseases. If available, laboratory tests can be prescribed to test for common conditions.
Several programmatic solutions can help to address the issue:

- National screening protocols developed to detect comorbidities at TB treatment initiation
- Training and mentoring for HCWs on application of TB screening tools and algorithms
- Close partnership with general and specialized health providers as well as established referral pathways
- Educational sessions to people with TB and families describing identified comorbidities and treatment options

Addressing comorbidities during TB treatment. For people with TB, who have been diagnosed with comorbidities, treatment options have to be provided in addition to TB care. If an individual is treated at the PHC level, initial treatment management of comorbidities can be initiated at the same location. For more advanced conditions, requiring health specialists to be engaged, treatment referral should be organized.
Several programmatic solutions can help to address the issue:

- Development of national guidelines for the treatment of TB comorbidities
- Introduction of data collection as well as monitoring and evaluation measures on comorbidities among people with TB at all levels
- Establishment of a referral network of specialists, managing specific health conditions
- Facilitate availability of treatment options for people with TB and comorbidities
- Training and capacity building for HCWs engaged in managing people with comorbidities
- Engagement of civil society and community leaders and organizations

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Strategic Objective 3: PREVENT

Stop the spread of new infections and progression from infection to active TB disease.

Prolonged exposure to DS and DR-TB such as occurs in communities, households and congregate settings results in high transmission rates of TB infection and active TB disease. Depending on the definition of contacts and the methods used to diagnose the index case, Contact investigation is a high yield active case finding strategy to identify persons with TB earlier in the course of their disease as well as an important opportunity to find contacts with TB infection who will benefit most from TPT. A WHO guideline review found a yield of 3.4% (95% CI: 2.9,3.8) among contacts of bacteriologically confirmed (bac+) index cases, 3.9% (95% CI: 2.5, 5.4) among contacts <5 years old, 3.7% (95% CI: 2.4, 5.3) among MDR/XDR contacts, and 11.6% (95% CI: 8.2,15.4) among contacts who were also HIV infected. TBCI also provides an opportunity when IGRA or TST testing is available to identify persons with TBI who would benefit from TPT and avoid unnecessary treatment for contacts who are uninfected. However, TBI diagnostic testing should not be an obstacle to providing TPT when they are not available.

WHO recommends systematic screening of all household and other close contacts of pulmonary TB disease. Contact investigations should ***always*** be done for: 1) bacteriologically confirmed pulmonary TB, 2) persons presumed or diagnosed with DR-TB, and 3) all children who are clinically diagnosed or bacteriologically confirmed to identify the *'source case'* (reverse contact investigation) [WHO, Sec.2.4.1, pg17]. Contact investigation for clinically diagnosed TB cases should also be considered and encouraged especially when access to molecular diagnostics is limited (see also REACH Priority #1).

Priority #1: Establish robust organizational structures for implementation and scale up of TBCIs

USAID has developed resources to support implementation and scale-up of TB contact investigations. These resources include a toolkit for *Programmatic Implementation of Tuberculosis Contact Investigation* (PI-TBCI), a TBCI implementation checklist, online TBCI trainings for frontline workers and HIV care providers, and indicators in a *Cascade of Care for Contact Investigations* as part of a *Performance-based Monitoring and Evaluation Framework (PBMEF)* for TB. In addition, the WHO Operational Handbook includes a useful stepwise approach to prioritizing, planning and budgeting contact investigations. Stop TB has also developed a useful field guide on how to plan and conduct contact investigations.

Setting up an effective organizational and management structure to plan, operationalize, monitor and evaluate the implementation of effective TBCI operations is crucial, and is a foundational element to build and strengthen a NTP.

A stepwise approach to implementation and scale up will ensure a successful and sustained TBCI program:

- *Establish TBCI policies and guidelines aligned with the NSP.* Leadership at the national level committed to implementation of a comprehensive TBCI program aligned with the NSP is critical for developing a successful program.
- *USAID and WHO have developed resources to guide the implementation and scale up of TBCI* programs suited to a country's current status and context.
- *Establish a TBCI unit in the organizational chart of the NTP*. Front-line TBCI workers who are trained, supported, and fairly compensated with well defined roles and responsibilities and are known and respected in the communities where they live and work are necessary to sustain a TBCI program over time.
- *Ensure initial and refresher contact investigation training of CHWs and other front line workers.* USAID and WHO have developed virtual online training platforms for TBCI along with other resources to support front line workers.
- *A trained TBCI workforce also provides opportunities for integration with primary healthcare* and other disease control activities creating a '*surge capacity*' such as occurred during the COVID-19 pandemic when TB program staff were the first called upon to conduct contact tracing.
- *Develop facility and community TBCI SOPs and Job Aids for staff and individuals. SOPs and* Job Aids support training and high quality service delivery during interventions either in a health facility or in the community.
- *Establish weekly supportive supervision at the health facility level and monthly at subnational (district) levels.* Supportive supervision provides accountability for both the supervisor and the CHW, through the use of routinely collected data that establishes goals, sets targets and monitors performance.
- *Ensure TBCI outcomes measures are aligned with the NSP and the PBMEF core and extended CI indicators with CQI.* USAID has developed core and extended indicators for TBCI in the PBMEF that provides critical information that can be used to inform policy, prioritize resource allocations, and guide supervision and program planning during the implementation and scale up of TBCI activities.

Priority #2: Introduce and scale up TB infection testing for children >5, non-PLHIV contacts and HCWs.

Extension of TPT to meet global requirements creates a need to establish large-scale TB infection testing capacity. TBCI plays a critical role in identifying those contacts who are at risk of progression to active TB disease. WHO has recommended testing for TB infection where feasible, however, it is not required for PLHIV or in household contacts under 5 years old. In **HIV-negative** household contacts aged 5 years and older, and in other risk groups, TB infection tests are recommended but unavailability **should not be considered a barrier to treating people who are judged to be at higher risk of TB with TB preventive therapy** (WHO Sec 2.5, pg. 25). There is some evidence suggesting that the lack of TBI testing presents a barrier to TPT initiation. USAID recommends that countries develop TBI testing capacity and if needed, conduct operational research to generate evidence for use in specific populations, ie, HCWs, contacts to DR-TB, children 5-10 years, and to establish the TBI prevalence among contacts, identify risk factors for progression to active disease, and set policy for initiation of TPT.

When TBI diagnostic testing is feasible WHO recommends using newer diagnostic methods, i.e., antigen-based skin tests and IGRAs. Stop TB and USAID have developed a manual to guide the selection and use of IGRAs for TBI diagnostic testing. USAID-supported countries should support efforts to establish capacity for TBI diagnostic testing with IGRAs and/or TST to inform decisions to offer TPT to adult and adolescent contacts and minimize unnecessary treatment and risk of AEs.

Several programmatic solutions can help to achieve progress in this priority area:

- *Rapidly scale up TBCI implementation.* TBCI requires dedicated staff at the health facility and in the community with regular communication and coordination of activities to ensure prompt initiation of a household visit to screen family members and other close contacts for active TB disease.
- *Establish capacity for TBI diagnostic testing for non-HIV infected child contacts 5-14 years old, adolescents and adult contacts, contacts to DR-TB, and HCWs.* While logistics and high cost of TBI diagnostic testing currently is limiting implementation within countries, demonstration projects or programmatic implementation using an operational research approach focused on these groups should be considered a priority to gather evidence on TBI prevalence among contacts and demonstrate impact on reduction of TB incidence.
- *HCWs are a priority group for annual TB screening and TBI testing* as they are frequently exposed, have higher rates of TB and TBI, and with annual screening and TPT when indicated could significantly reduce their risk of active disease.
- *Ensure availability of TPT including shorter course regimens (3HP, 1HP, 3HR, 4R).* Use of shorter course TPT regimens have been shown to have higher acceptance and completion rates along with lower toxicity. Missions should provide TA in quantification, ordering and supplying TPT regimens to points of delivery to ensure availability of TPT.
- *Ensure quality of TPT delivery through monitoring adherence and completion of TPT.* For preventive therapy to have maximal benefit it is necessary to have a high level of adherence to and completion of the chosen regimen.
- *Monitor for and manage* adverse events (*AEs).* While AEs are uncommon during TPT delivery, it is important to educate people offered preventive treatment to be aware of any signs and symptoms of an AE specific to the medication they are taking and any necessary action they should take if such were to occur.

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Priority #3: Monitor and evaluate TPT scale up to reach 30 million contacts

The USAID strategy to end TB has set a target to provide TPT to 30 million child, adult and adolescent TB contacts by 2030. TBCI will be an essential activity to identify contacts sufficient to meet the 30 million goal and TPT will be essential to reduce the incidence of TB disease among persons with TB infection. TPT has been shown to be highly effective at preventing progress from TBI to active TB disease.

In September 2018, at the United Nations High-Level Meeting (UNHLM) on TB, a target was set to provide TPT to at least 30 million people at risk of the disease globally between 2018 and 2022. Eighty percent of the 30 million people that were meant to receive TPT by 2022 were household contacts of people with TB disease. Unfortunately this target was not achieved due to various reasons, including cost and logistic constraints, lack of clear country level policy and guidelines, individual and provider hesitation, and the COVID-19 pandemic that adversely affected all targets set at the UNHLM in 2018. In September 2023, the UNHLM reconvened Heads of State to recommit and reset TPT and other targets toward achieving the EndTB goal.

To meet the targets for preventive treatment set at the UNHLM in September 2023 will require rapid expansion of TBCI to identify contacts who will benefit from TPT. USAID will review the UNHLM targets and align them with the USAID strategy and provide supported countries with suggested annual targets toward reaching the 2035 TPT target. Annual TPT targets can be used as benchmarks to guide a country's TB Roadmap and operational plan development process toward the new UNHLM TPT target.

Several programmatic solutions can help to achieve progress in this priority area:

- *Develop or strengthen M&E tools for data collection, analysis, sharing of key TBCI indicators.*
- *Establish a robust M&E system to monitor the indicators in the TBCI and TPT cascades preferably as integrated modules in a TB case-based surveillance system.*
- *Monitor the TBCI and TPT cascades on a regular basis, at programmatic level, and individual level, for example through implementation of case and cohort reviews.*
- *Ensuring adequate supply of commodities, medications including shorter course regimens and TBI diagnostic testing reagents and capacity.*
- *Use the data for regularly scheduled supportive supervision with front line workers and for decision making to cover the full spectrum of implementation, from the point of service delivery to district and national levels.*
- *Ensure adequate advocacy and demand creation on TPT in the community.*

Link: WHO operational handbook on tuberculosis: module 1: prevention: tuberculosis preventive treatment

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Priority #4: Implement TB Infection Prevention and Control (IPC) measures at health facility and community levels.

Infection Prevention and Control (IPC) in health care facilities, households and the wider community is an important dimension of services provided by Ministries of Health. The risk of TB among HCWs is high and poses serious health risks to their families and the broader community. A systematic review and meta analysis conducted in 2016 found a pooled TBI prevalence of 47% among HCWs in seven high burden TB countries. In 2021, WHO received reports of 16,931 HCWs with TB from 69 countries that provides compelling evidence for the need to protect HCWs from occupational exposure and risk of contracting TB in the workplace.

WHO IPC guidelines describe critical administrative, environmental, and individual respiratory protection control measures and provide a roadmap to customize, design and implement specific interventions to protect HCWs, individuals and the broader community. Ideally, a facility-based approach that included an Employee Health Program with surveillance for occupational exposures and disease, ie., TB, TBI, Covid-19, hepatitis, etc., and that provides annual screening for TB/TBI as well as HBV vaccinations, PEP for needle stick exposures, adequate PPE including fit testing, etc should be established and monitored by the facility IPC focal point.

A programmatic approach can help to achieve progress in this priority area:

- *Establish or strengthen TB and TBI surveillance among HCWs including annual screening for TBI with IGRAs or TST, or CXR for any HCW known to have a history of TBI.*
- *Monitor and evaluate IPC interventions.* A staff member should be designated and trained at the facility level as the IPC focal point for monitoring and evaluation of interventions and to establish surveillance for TB, TBI, and TPT among HCWs.
- Facility-based health care-associated infection surveillance should be performed to guide IPC interventions and detect outbreaks.
- *Implementation of IPC measures (administrative, environmental, personal protection) at facility and community levels*. A set of administrative, environmental, and personal control measures are essential components of an IPC strategy.
- Guidelines have been developed and can be modified and used to establish IPC program policy and SOPs for use at the national, subnational and health facility levels:
    - Basic Occupational Safety And Health For Respiratory Diseases: A desk guide for health facilities
    - Development of TB Occupational Safety Framework
    - TB Infection Control in Health Care Settings from CDC
    - WHO guidelines on tuberculosis infection prevention and control: 2019 update
    - Guidelines for the control of Tuberculosis in a Healthcare Setting

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Strategic Objective 4: INNOVATE

Research, develop, introduce, and scale-up new tools and approaches to combat TB.

Robust efforts are needed to sustain and improve on the gains made to date, and to address persistent challenges that have led to uneven progress in the fight against TB. The USAID Global TB Strategy 2023 - 2030 results framework demands that major technological breakthroughs are needed and prioritizes a multisectoral approach to developing and equitably disseminating the most appropriate medical and programmatic innovations diagnosing, treating, and preventing TB.
Countries' policies should respond to the needs of individuals and health care systems, to ensure that innovations address both health and non-health determinants of TB, are affordable and accessible, and can be made available sustainably. In promoting TB research, there is a need for mechanisms that steer

innovation towards sustainable, ethically acceptable, and socially desirable interventions, communicated effectively in the affected communities working with community and civil society organizations.

Priority #1: Prioritize the development and implementation of new tools, clinical and programmatic innovative approaches and practices, as well as better use of existing technologies

The USAID TB priority countries' programmatic activities should support the efforts of governments and international and local stakeholders to accelerate TB research and innovations, and improve equitable access to the benefits of research. During the processes of programing, work plan developments, new designs and procurements, the USAID Missions should recognize that to substantially reduce TB incidence and mortality in a country will require developing and introducing new tools and approaches, as well as promoting universal access to, and better use of, existing technologies. The USAID supported activities should strengthen local research capacity, and develop or update the TB research agenda, coherence in existing national priorities, and plans for local health research to produce country-specific research evidence and innovations.

New tools and strategies might include:

1. Rapid point-of-care tests for diagnosing TB infection and TB disease and rapidly screen and diagnose multidrug- and extensively drug resistant TB, HIV-associated TB, and pediatric TB
2. Novel approaches to scale up diagnosis of and access to treatment for MDR-TB and XDR-TB in resource-limited settings and remote areas
3. Shorter, safer regimens for treating TB infection and drug-sensitive TB
4. Shorter, safer, and more effective treatment for DR-TB
5. Preparation activities for new TB vaccines implementation: Focus is on developing tools that countries can use to determine the readiness of their health system to introduce and scale up new vaccines. In addition research will focus on determining factors that affect community acceptability for new vaccines and how to improve that acceptability.
6. Innovative strategies to address the social and environmental drivers of TB
7. Innovative community and health facility models that improve cost effectiveness, sustainability and yield of TBC working with pharmacies, private providers and community leaders
8. Promote and Leverage digital/ emerging technologies use for Tuberculosis Management (in line with USAID Digital Strategy and AI action plan)

WHO: Global Strategy for tuberculosis research and innovation
A Global Strategy for tuberculosis research and innovation (who.int)

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Priority #2: Conduct operational/implementation research to support the effective scale-up of innovative strategies and tools

During the design of a USAID TB portfolio, Missions should consider including operational research and pilot completion for evaluating and improving TB program performance and designing interventions that result in improved policy-making, better implementation in health systems and more efficient and effective methods of service delivery. Social science, organizational psychology of health systems, and understanding of human behavior are equally crucial to maximize the benefits of both existing and new tools and are therefore essential components for the Results Framework targets to be met. USAID Missions, while designing new projects or improving performance of existing bilateral activities, should consider pilots, proof-of-concept, and operational research components to address local problems and recommend appropriate solutions, involving partners at all stages and levels. Research activities could also address the obstacles to integration of HIV, diabetes, mental health and TB care by national programs. Operational research might help to optimize aspects of TB control, including access to accurate diagnosis, effective treatment, and optimal coverage with vaccination against M. tuberculosis, and to address the challenges posed by drug resistance and HIV infection. Operational research could cover a wide spectrum of activities, from local research to assess and improve TB control program performance, to national and international policy-guiding research, including the assessment of new interventions to improve TB control (effective and efficient use of new and existing tools and determination of the conditions and requirements under which they can be effectively implemented). The type and scale of operational research depends largely on the questions being addressed, the level of care and users concerned, and the expected relevance of the results. It is important to engage civil society and affected communities to contribute to TB research, with a view to increasing the quality, relevance and acceptability of innovation by integrating civil society's expectations, needs, interests and values into the research and development process.

Potential types of operation research:

1. Qualitative and quantitative analysis of implementation of interventions, strategies, and tools which produces practical useable knowledge that can be used to enhance the quality, coverage, effectiveness, and efficiency of TB control programs and health services
2. Implementation research for digital technologies and tuberculosis (who.int)
3. The ShORRT research package ShORRT initiative (who.int)
4. Operational Research | The Union

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Priority #3: Facilitate the translation of new evidence and research findings into national and policies on TB prevention, diagnosis, treatment, and care

For the USAID Missions it is important to advocate with the national policy makers for new interventions and approaches being adopted by TB control programs and implemented at a program-wide scale, enhance equitable access to new medicines and technologies, and to advance national TB research capacity and local TB research agenda. It would be important to work with the NTP, community and civil

society organizations to identify and overcome barriers to effective implementation of novel strategies and tools. Supporting activities on implementation of best strategies for early diagnosis, treatment, and prevention of TB, optimized and tailored to various socioeconomic contexts and responsive to local conditions, would help accelerate reaching national and global targets to end TB.

TB research activities could assist countries with the selection or assessment of diagnostic technologies appropriate for their context, which would facilitate the rapid adoption of appropriate tools, contextualization of algorithms and related logistical strategies. The USAID Missions could contribute to the development of local TB research agenda and support research activities, guided by the principles of affordability, effectiveness, efficiency and equity. Effective collaborations between researchers and research institutions are also critical for expediting demand-driven local research capacity-building. Capacity-building initiatives could support the local health professionals and provide practical knowledge and capacity in the analysis of national TB programmatic data (including surveillance data), developing research questions, study protocols and research tools. Enhanced analysis and dissemination of programmatic data are also needed to guide national research agendas. At national level, there is a need to make adequate and timely contributions to national and global data needs for policy-making; to make efficient use of resources in TB research; and to effectively put new knowledge to use without compromising national intellectual property law and the protection of privacy and confidentiality.

TB guidelines (who.int)
WHO consultation on the translation of tuberculosis research into global policy guidelines

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Strategic Objective 5: SUSTAIN.

Build country-owned TB health systems, led by local partners, that accelerate progress and support pandemic preparedness

USAID's TB programs strive to improve the capacity of country health systems to respond to the TB epidemic through its surveillance, prevention, diagnosis, care, and treatment activities. This work, while focused on TB, also strengthens health systems, and has shown great potential as a versatile platform, particularly for airborne and respiratory diseases. In the wake of COVID-19, countries continue to rely on TB infrastructure, expertise, political commitment and partnerships to respond to a range of communicable and non-communicable diseases, particularly airborne diseases. Innovations in approaches and tools to the screening and detection of TB also provide expanded opportunities to leverage the platform to more rapidly identify a broader range of communicable and non-communicable diseases and to facilitate referral to appropriate clinical, supportive, and social services. The TB platform also offers an opportunity to identify the presence of health issues and social determinants that predispose individuals to both TB infection and disease, and to link individuals to related services, such

as those that promote nutrition and address co-morbidities like diabetes. USAID efforts to strengthen TB supply chain management and surveillance systems are a core component of USAID TB programs; this work supports broader supply chain and surveillance networks while building stronger TB networks in-country.

To achieve specific TB goals and overarching TB outcomes, it is critical to outline how health system reforms will have a substantial impact on TB-specific indicators. One critical step is to include all of the components of the TB program in insurance, social protection, and sustainable financing mechanisms to help prevent catastrophic costs and further impoverishment of individuals with or at risk of TB. Efforts in this area would need to build on broader reforms in the health system to achieve specific outcomes for TB.

In addition to efforts geared to improving TB programs and the broader health system, sustainability is inextricably tied to expanding the role of local partners and constituencies, including local organizations, civil society groups, and affected individuals and communities who understand the context–political, social, and economic–in which these programs function, and bring this perspective to identifying resources, developing people-centered responses, and monitoring and assessing impact. Ensuring that local partners and those from affected communities and civil society direct and lead USAID-supported programs helps promote programs that are seen as, and truly are, "of the community" rather than foisted on it, which in turn leads to involvement, commitment and ownership, and eventually, greater likelihood of integration and support by local governments long after external support has ended.

Priority #1: Transparent, inclusive, efficient and effective TB governance that drives people-centered approaches

Transparent, inclusive, efficient and effective governance of a TB program is the foundation for a coherent, well organized and person-centered response. USAID will help countries improve their governance efforts related to TB via:

- Supporting assessments of how National TB Programs are governed, and supporting the NTP to perform at a high level in terms of transparency, inclusiveness, legal framework, and process efficiency and effectiveness. The following are a few fundamental aspects of governance that our implementation approach should capture and address:
    - Sustained technical and managerial leadership at National and Provincial Level.
    - Effective structure at National and provincial level required for program implementation and monitoring and evaluation of progress
    - Transparent domestic financing (actual expenses for TB) at national, provincial and district level, especially in countries which have devolved / decentralized health systems.
    - National Level TB Strategic Plans (with Provincial inclusiveness) for system level interventions
- Promoting governance strategies that will strengthen primary health care and strengthen the TB response in both primary health care and at the community level. Governance forums can support these objectives by including voices of individuals with TB and perspectives in their

deliberations, leveraging existing (and domestically funded) community health cadres, supporting the mobilization of communities on TB issues, and funding the TB activities of community-based organizations – including TB survivor-led organizations. Such community-based interventions are particularly critical in TB, as they are the basis for early TB detection, which reduces morbidity, mortality, and transmission.

- Strengthening political commitment and partnerships via multi-sectoral coordination, to expand and enhance the use of TB services for the detection, treatment and prevention of airborne infectious diseases.
- Supporting investments in communities, rights, and gender, so that civil society, academic, and community-led organizations can enhance their engagement in TB law and policy reform, human rights sensitization, advocacy, and demand generation related to TB. Also, engaging communities will help uncover barriers in TB care and support services, through community-led monitoring and national TB partnerships.

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Priority #2: Sustainable TB information systems that meet country level stakeholder needs to monitor, evaluate and improve programs

A primary goal of TB-related health information systems (HISs) is to produce actionable data for both individual management and program management. For individual management, this requires case-based TB surveillance systems which can facilitate the monitoring of diagnosis and treatment through to completion, and quality of care interventions related to side effect management, treatment of comorbidities, and prevention activities. For program management, high quality TB data can facilitate better targeting of TB human resources (e.g., for active case finding) and of TB commodities, and cycles of quality improvement that are focused on increasing performance against specific priority indicators. USAID supports these objectives via:

- Conducting comprehensive surveillance systems assessments and landscape analyses, and the development of costed plans for electronic TB surveillance and data reporting systems;
- Upgrading TB systems and development of modules to better capture the full spectrum of TB prevention and care activities for electronic data entry and reporting, and improving their utility and reliability, which results in more complete data entry and more accurate data;
- Promoting the use of data for decision making and visualization tools for TB, including the generation of dashboards (which can guide mentoring and supervisory visits), case and cohort reviews, key indicator outputs, and cascades that highlight gaps in the TB response, trends over time for both clinical and programmatic actions that are needed to address gaps and trends;
- Standardizing performance indicators and promoting the use of standard TB indicators from the Performance Based Monitoring and Evaluation Framework (PBMEF);
- Investigating the use of tools for mapping TB outbreaks and directing a localized, geographically targeted response via active case finding;

- Engaging with the development of national digital health strategies and alignment of TB systems digitalization efforts with the national response. USAID will provide technical support to jointly promote these as Digital Public Goods globally.
- Implementing interoperability solutions. This is important on two levels:
    - The first level is interoperability between different types of TB-specific HISs, e.g., between tools that capture either TB diagnostic results from lab instruments, or TB adherence results from community health workers, or TB clinical results from facility-based healthcare workers. Such first-level interoperability allows seamless management of people with TB across the entire cascade of care.
    - The second level is interoperability between TB-specific HISs (as listed above) and general HISs (including HISs used by district health offices to monitor public health programs, electronic medical records (EMRs) used by public and private hospitals, and electronic claims systems used by national health insurance schemes). By allowing data to flow between these systems, this second level of interoperability reduces or eliminates the need for double or triple data entry, thereby reducing the work burden on healthcare workers and increasing the completeness and quality of TB data. This is a particular priority in countries with large health insurance systems, where providers may be more motivated to enter data into an insurance claims system (which will result in a payment) than in a TB-specific data system.

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Priority #3: Sustainable supply chain and procurement systems that ensure quality, available and affordable TB commodities

An effective drug and commodity management system will help ensure that countries have adequate supplies of quality-assured TB drugs and commodities available at all times, while avoiding stock-outs and overstocks. USAID will support country efforts to develop reliable quantification, forecasting, procurement, and distribution systems for all essential TB commodities and supplies via:

- Providing technical assistance to countries through in-country or regional drug management advisors who can facilitate use of an “early warning system” to track drug stock balances and drugs that are about to expire, and enable forecasting and timely orders of TB medicines.
- Supporting the introduction and expansion of regulatory enforcement of both first- and second-line anti-TB drugs.
- Working with country partners to introduce and strengthen pharmacovigilance and support the introduction of new, improved, and internationally recommended TB drugs and regimens.
- Urging countries to make TB and ancillary medications available to all individuals with TB free of charge.
- Encouraging countries to finance procurement of TB drugs and commodities using domestic resources first, relying on Global Fund resources only when there are gaps in drug procurement (USAID should procure TB medicines and supplies only when all other options have been exhausted or for introduction of new tools). Domestic financing of TB drugs will be tracked on a routine basis and considered a key USAID indicator. Grants for first-line drugs should only be

used in very special situations, such as conflict situations or natural disasters. GDF should be used for all USAID procurements since it has the most affordable quality-assured commodities. If GDF procurement is not considered, there should be documentation on the analysis and reason for it including price, quality, etc.

- The same principles as above should apply to TB diagnostic commodities (e.g., Xpert machines and cartridges). However, accurate forecasting of country testing needs should be based on real data and not calculated only on the availability of funding.
- Working at the global level to ensure an adequate global supply of essential TB medicines and supplies. Through the Stop TB Partnership's Global Drug Facility, USAID provides resources to ensure a global, pooled procurement of TB drugs and supplies that includes critical market shaping for first and second-line anti-TB drugs and a strategic stockpile. This support has had a major impact on the availability, affordability, and quality of all TB diagnostics and drugs globally. Where there is a lack of pre-qualified manufacturers of TB drugs (especially second-line anti-TB drugs) or a lone supplier, USAID will continue to offer technical assistance to manufacturers of both active pharmaceutical ingredients and finished pharmaceutical products to obtain WHO/ERP pre-qualification and ensure a second/third supplier allowing competitive pricing and continued availability.
- Ensuring TB commodities are integrated into the government supply-chain management system for drugs and diagnostics to ensure sustainability and thus strengthening the health system.

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Priority #4: TB services accessible to all vulnerable and special populations through public and/or private service providers

Access to the activities of REACH, CURE and PREVENT need to be provided wherever there are individuals with TB or at risk of TB, including in settings that require special or additional service delivery arrangements and considerations, e.g., private healthcare facilities, prisons, informal settlements, and workplaces. Those special arrangements include:

- For private provider engagement, consider the rich set of lessons learned that are outlined in the private provider engagement landscape analysis, the categories of actions described in the Public-Private Mix (PPM) Roadmap, and the national planning guidance in the PPM Action Plan Guide. A majority of clients with TB symptoms start their journey with private providers, and the TB program should take steps to ensure that such individuals are able to access quality-assured diagnosis and treatment as soon as possible. Through such efforts, from 2013-2021, private notifications as a percentage of total notifications have gone up ~2-fold (Bangladesh, Myanmar, Nigeria), ~3-fold (Indonesia, Pakistan, Philippines), or ~5-fold (India), and now represent 20-40% of case finding in all of these "big 7" priority TB PPM countries.
- Private provider engagement for TB services requires both money and human resources. These engagement efforts can be undertaken by staff who are part of the National TB Program, but in many settings this has not been enough to bring this work to scale. PPM has often been more

effective when NGOs or other private organizations act as **intermediaries**, which take their strategic direction from the NTP, but use their own systems for linking with large numbers of private providers. Intermediaries are also able to link private providers to publicly funded TB commodities and to tools that enable quality-assured TB care. In general, all commodities and tools that are used in the public sector should be adapted to and extended to private providers – whether that is training, supervision, or sample transport.

- Other approaches for increasing the quality of TB care from private providers include adding TB requirements to licensing and accreditation frameworks. Regulations, for example, on mandatory notification of TB, can be useful if they are combined with simple reporting approaches (e.g., with few required data fields and a simple electronic portal). All quality improvement efforts (i.e., training, mentoring, and supervision) should, to the extent possible, include both public and private providers, and the hours and modalities should be customized to suit the needs, availability and working hours of private providers. The host government should be supported in establishing a modernized training system.
- For key and vulnerable populations, considerations for programming are outlined in Section 3.6 of the Global Fund's TB Information Note. These include the need to understand the size, location and special needs of key and vulnerable populations, to engage and empower these populations, remove barriers to TB services, and consider legal frameworks for service delivery for internally displaced or cross-border populations. Greater linkages and referral systems should be developed between TB programs and programs that target any of the conditions and social determinants that create critical vulnerabilities to TB, including poverty, malnourishment, diabetes, smoking, alcohol use, and HIV infection to increase awareness and help provide TB interventions quickly to find, treat, and prevent TB, and to better ensure that individuals access care for other health and environmental (e.g., home, work) conditions.
- Engagement with prisons, workplaces (such as mines and factories), and military institutions requires working across ministries to define which parts of the diagnostic and treatment cascade are the responsibility of the Ministry of Health vs the Ministry of Justice, Ministry of Industry, or Ministry of Defense. (refer to Use of Funds guidance for special approvals required)

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Priority #5: Comprehensive TB financing systems that maximize access for all

Health financing provides the money to operate both the clinical and public health functions of a TB program, but it also provides an important source of guidance for providers on what is important, and can motivate them towards best practices. Domestic financing for TB also provides a pathway to a sustainable response, and increases government ownership of the TB program. Specific technical assistance activities are required to ensure that the following are in place for all TB programs:

- A National Strategic Plan that is costed using local unit costs, with geographic and epidemiologic prioritization, coverage targets for each strategic intervention, and with projected funding available and a source of funding for each strategic intervention and activity, with explicitly quantified funding gaps for each strategic intervention and activity.
- A Domestic Resource Mobilization Strategy (DRMS) either specific to TB or inclusive of TB, that includes projections and uses of funding that would be mobilized for TB, if implemented, and that is operationalized at the central and subnational levels. Such a DRMS should consider

diverse TB funding sources, which may include health and non-health ministries/units from both national and sub-national governments, social or national health insurance schemes, and blended financing from the private sector, diasporas, or other philanthropic organizations.

- An evidence-based process that the NTP follows to inform the annual domestic government planning and budgeting process. The NTP should advocate for specific increases in domestic government resources for TB, leading to increased domestic resources for TB from multiple ministries and including budget lines for TB commodities and key TB public health interventions. The Ministry of Health's TB budget allocations plus donor budgets should be sufficient to implement ambitious NSP objectives at the national and subnational levels.
- A government public financial management (PFM) system that is able to accurately track disaggregated TB financing via program-based budgeting categories that align with the NSP objectives. The government should hold subnational levels of government accountable to their TB funding commitments and for using central funds toward agreed-upon TB programmatic targets, and produce an annual, publicly available budget execution report that includes TB financial information.
- A government policy on providing free TB services. In addition, any national or social health insurance scheme should have a benefit package that includes all TB clinical and preventive services; TB care for a high percentage of, if not all, people with TB should be paid by such insurance. Social protection schemes should include most or all people with TB and provide special social support for people receiving DR-TB treatment, which can lead to very high and potentially catastrophic out-of-pocket costs.
- Results-based financing for TB, i.e., domestic financing schemes that pay for TB outcomes/outputs (e.g., treatment completion rates, rapid diagnostic testing volume).
- Social contracting mechanisms to contract TB-related services from not-for-profit NGOs and the for-profit private sector using domestic government funds, based on a robust analysis of the legal and regulatory landscape. This provides a mechanism by which domestic funds can support contributions of non-government organizations towards the TB response.
- TB drug and diagnostic commodities procured from an international pooled procurement mechanism (GF or GDF) or by competitive domestic tenders that are open to both domestic and international vendors.

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OPERATIONAL PRINCIPLES

#1. Locally developed and locally managed activities

Locally led development is the process in which local actors set their own agendas, develop solutions, and bring the capacity, leadership, and resources to make those solutions a reality. To further build TB capacity, increase sustainability, and address this key priority of the Agency, USAID makes direct awards to local organizations via the LON Annual Program Statement. Additionally, the TB Global Strategy 2023-2030 will continue to optimize this mechanism to increase local leadership in TB activities. This will be achieved by adapting the Agency's lines of effort for localization to the TB Global Strategy:

1. Work with Missions and IPs to adapt policies and programs to foster locally led development that is tied to each country's unique political, social, cultural, economic, and environmental conditions, including through local systems practice and local capacity strengthening;
2. Shift power to local actors, including, with an inclusive development lens, those from marginalized and underrepresented groups, and promoting space for them to influence and exercise leadership over priority setting, activity design and implementation, and measuring and evaluating results;
3. Increase and monitor funding directly to local partners while ensuring accountability for the appropriate use of funds and achievement of 50% locally-led TB program outcomes by December 2027 and PBMEF indicators;
4. Use our convening power, partnerships, voice, and other tools of development diplomacy to catalyze a broader shift toward locally led development in TB programs globally including the use of co-creation and building local and regional partner networks.

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#2. Systems and structures established and functioning

Success of the USAID Global TB Strategy is dependent on effective and efficient partnerships between USAID and partner governments, multilateral organizations, non-governmental organizations, research institutions and civil society organizations. Furthermore, efficient program and project management is underpinned by comprehensive oversight and routine monitoring and evaluation. As such, annual strategic planning via the TB Roadmap and bi-annual data reviews ensure TB programming at each Mission aligns with USAID Global TB Strategy. The annual TB Roadmap Guidance document provides the details for the overarching planning and coordination process that should drive partner workplans and MEL plans to ensure a comprehensive and coordinated TB program that delivers and reports on TB strategy goals. It should be developed in collaboration with the NTP and Global Fund to ensure it is prioritizing the gaps and sharing information to maximize our impact. Finally, partners must also promote systematic and structured monitoring and evaluation, close collaboration with USAID/W and Mission staff, and inclusion and input of partners for efficiently-run programs:

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Measuring Success

The USAID's performance-based monitoring and evaluation framework (PBMEF), provides a standardized approach to measure success across USAID's strategic Reach, Cure, Prevent, Innovate and Sustain interventions and investments tracking the progress on achieving the objectives of the USAID Global TB Strategy for 2023-2030 and country and global targets. The PBMEF is part of USAID's efforts to ensure effective accountability of investments in TB at the global, regional, and country levels to accelerate progress to end the TB epidemic. The framework streamlines and prioritizes indicators for monitoring progress toward reaching global TB milestones and targets in USAID TB-supported countries.

The PBMEF presents a set of standardized indicators to measure essential programmatic TB outcomes. Core indicators are critical to understanding the progress made toward TB control in terms of both national targets outlined in national strategic plans and international targets, such as those set at the United Nations General Assembly High-Level Meeting on TB (UNGA/UNHLM).

The PBMEF provides a systematic approach to encapsulating and streamlining the TB reporting processes from the initial critical step of inclusion of standardized Essential List of indicators in the MELs of all Implementing Partners (IPs), and a subset of core indicators in the PPRs for all Missions receiving bi-lateral TB funding. The PBMEF provides a cornerstone for an alignment with the HLM targets and the National Strategic Plans (NSP) M&E frameworks. This approach strengthens USAID's capacities to respond to complex and ever increasing US Congressional reporting requirements and meet the needs of additional to the Annual TB Report to Congress requirements such as the TB prevention Report, the National Action Plan to Combat MDR-TB (NAP), and Research (and other technical areas) related reporting requirements. Most importantly, it facilitates use of data for programmatic and decision making at the national level.