Information Note
Tuberculosis

Allocation Period 2023-2025

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THE GLOBAL FUND

Contents

Executive Summary

This information note provides guidance to applicants preparing a funding request to the Global Fund for tuberculosis (TB) grants. It identifies prioritized interventions and program essentials for people-centered TB care and prevention in an efficient, equitable and sustainable manner, enhancing value for money from Global Fund and other investments to achieve the highest impact. It is based on the ambitious new Global Fund Strategy 2023 -2028 (Strategy)[1] to get progress back on track against HIV, TB and malaria and contribute to universal health coverage, while recognizing the disproportionate impact of the COVID-19 pandemic on the global TB response. Priority interventions in the information note are built around the five TB sub-objectives of the new Strategy, described in Section 1.

Early diagnosis, treatment and care, and TB prevention

Priority interventions for TB screening and diagnosis include plans to scale up and improve the quality of systematic screening by using more sensitive digital Chest X-rays and computer-aided detection (CAD) software, expanding testing for TB infection, and decentralizing services across the care cascade. TB screening and testing services should be provided in primary health care facilities, including community-based outreach services and home-based care, while contact investigation should be used as a strategy to find and treat people, including children, for both TB infection and disease. To improve early TB diagnosis, applicants are encouraged to implement intensified case finding in health facilities, conduct active case finding and surge campaigns targeting key and vulnerable populations and high TB prevalence settings. The use of molecular WHO-recommended rapid diagnostics (mWRD),[2] as the initial diagnostic test to replace sputum microscopy should be prioritized. Testing non-sputum-based samples of children, improving bacteriological confirmation of pulmonary TB, and universal rapid drug-susceptibility testing (DST) are other priorities. In addition, diagnostic network strengthening and effective use, including through scaled-up and decentralized services are needed to address the gaps that limit access to and utilization of diagnostic services. Integrated testing for TB with other diseases such as dual (bidirectional) testing for TB and SARS-CoV-2 should be considered in populations at risk for both diseases.

The use of shorter and more patient-friendly treatment regimens for drug-susceptible TB (DS-TB), pediatric fixed-dose combination formulations for children with TB, and shorter, safer, injection-free and all-oral treatment regimens for drug-resistant TB (DR-TB) from the start of treatment are among priority interventions for TB treatment and care. Monitoring and management of adverse drug reactions, management of existing conditions and co-morbidities, psychosocial and nutritional support for key and vulnerable populations, including through linkages to broader social protection services is important to enable treatment adherence and improve treatment outcomes. Scaling up digital tools for

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[1] The Global Fund. Global Fund Strategy (2023-2028): *Fighting Pandemics and Building a Healthier and More Equitable World.* Geneva: The Global Fund, 2021.

[2] World Health Organization. *WHO operational handbook on tuberculosis. Module 3: Diagnosis - Rapid diagnostics for tuberculosis detection 2021 update*. Geneva: WHO, 2021.

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treatment adherence and shift to decentralized, ambulatory, community and home-based services has become even more important in adapting to COVID-19 and future threats.

Activities to promote TB preventive treatment (TPT) should be integrated with ongoing activities as a continuum of care, such as in finding people eligible for TPT as a part of active TB case finding and contact investigations. Priorities include rapid scale-up of screening and evaluation of all household contacts, people living with HIV and other key and vulnerable populations with high-risk for TB infection, improving access to TB infection testing, increasing the coverage and adherence to TPT, strengthening completeness and accuracy of TPT data, and monitoring performance. Addressing provider and recipient hesitancy, provision of newer shorter regimens for TPT and support for treatment completion can generate demand and improve acceptability of TPT. Other priorities are to implement airborne infection prevention and control (IPC) measures at all levels of the health care delivery system, in congregate settings and at the community level in the context of the overall IPC strategy for the health system.

Collaborate to provide accessible, high-quality, comprehensive care and support

Prioritized TB/HIV collaborative activities include testing services for people with TB and those presumed to have TB, for HIV infection. HIV-positive people should be offered antiretroviral treatment and cotrimoxazole prophylaxis. Similarly, people living with HIV should be offered screening for TB at each contact with health care providers. Those with active TB disease should be started on TB treatment while those without the disease who are eligible for TPT should be offered and initiated on TPT. Screening algorithms should be aligned to WHO recommendations and should consider the use Chest X-rays (with or without CAD), C-reactive Protein, LF-LAM test, and mWRD.

To identify all people who have TB and ensure they receive quality and comprehensive care, national TB programs (NTP) must work in collaboration with partners. Engaging with private health care providers, professional associations, regulatory authorities, community-based and led organizations, non-NTP public health care providers is particularly important in countries where they serve as the first point of care for a large proportion people with TB. Innovative private sector engagement models should be considered. This includes contracting, result-based payments and use of intermediary agencies.

Primary health care facilities and community health systems should be supported to improve access and continuity of integrated comprehensive people-centered services and to facilitate community participation in delivering services that advance equity, gender equality and human rights. Collaboration with other health programs and beyond the health systems is needed for effective integrated service delivery and/or referral linkages. Besides HIV, this may include maternal and child health, mental health, and non-communicable diseases programs. Outside of health programs, advocacy and collaboration with relevant ministries, departments and agencies is needed to mobilize political commitment and provide social protection for people with TB, particularly for the poor, undernourished and other key and vulnerable populations.

Maximize equity, gender equality and human rights

Key and vulnerable populations, mostly people who are poor, marginalised, underserved, are particularly vulnerable for contracting TB infection and disease and suffer from the

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poor outcomes (listed in Table 1). As they vary by country, understanding key and vulnerable populations and the barriers they face in accessing TB services in the local context is an important first step, followed by designing, delivering, monitoring and evaluating services that are tailored to overcome the barriers. For example, children with TB need access to testing for non-sputum samples and child friendly anti-TB drugs, while the elderly, mobile populations, and people in prisons and closed settings will benefit from interventions that improve their access. Key and vulnerable populations in countries with high fragility or Challenging Operating Environments (COEs) require special attention, especially internally displaced populations (IDPs) and cross-borders refugees and migrants. Engaging key and vulnerable populations in decision-making and program oversight improves social accountability while better addressing their needs. Community-led and based responses are powerful means to reach key and vulnerable populations, as they go beyond the reach of clinical facilities and biomedical interventions with tailored services to address social and structural barriers to health access.

Efforts to create an enabling environment by addressing human rights and gender-related barriers, stigma, reducing health inequities and social injustice, strengthening community systems and responses should be an integral part of the TB response. Priority interventions related to community systems and responses include strengthening the institutional capacity and leadership of TB community-based and led organizations, increasing community-based services across the TB care cascade, and forming national TB survivor networks. Facilitating links with the formal health system and scaling-up community-led monitoring to gather information from service user experiences, including human rights violations, stigma, and gender related barriers are other priorities. Programming to address these barriers include trainings on stigma reduction and rights literacy programs, reform of laws and policies that restrict access to services or contribute to vulnerabilities for TB particularly for key and vulnerable populations, access to justice and accountability mechanisms, and interventions to address adverse gender norms that may limit access to services.

Strengthen TB surveillance systems, innovations in TB care

The Global Fund promotes data-driven decision-making, enabled by the rapid generation, analysis, and use of high-quality, disaggregated data. Deployment of real-time, digital case-based TB disease surveillance systems that inform decision-making and actions at all levels of services is an urgent priority. Assessments, surveys, and operational research that generate additional evidence to inform policies and practices to improve health outcomes may also be supported, usually jointly with partners and domestic resources.

Potential areas of innovation in TB care during the 2023-2025 funding cycle are presented in Table 3. Applicants are encouraged to include current innovative tools and interventions in their funding requests to scale up for impact.

Program essentials for Global Fund supported services

Program essentials to guide Global Fund investments, derived from WHO recommendations and other international guidance, are listed in Table 4. They represent a

summary which best aligns with the key priority interventions of the Global Fund and are considered critical to accelerate the TB response to meet the global TB targets.

Applicants are expected to consider these program essentials throughout the grant cycle: during country dialogue, funding request development, grant making, implementation and performance monitoring. As a new requirement, applicants will outline in their funding requests how advanced the country is in the implementation of each of the program essentials. In situations where program essentials have been prioritized in funding requests, the Global Fund will support countries throughout the grant lifecycle in achieving and sustaining them.

Global Fund investments aim to contribute to country-owned responses. Therefore, funding requests should be guided by national priorities and updated resource needs set forth in national strategic plan for TB, based on the country context and latest epidemiological situation. In addition, they should be aligned with the wider national health sector strategy, and consideration should be given to the shared health systems constraints impacting programmatic performance. All programs should be rights-based, gender-responsive and informed by and respond to an analysis of equity barriers. Prioritized interventions should be aligned to normative guidance and national guidelines, based on a robust gap analysis, people-centered,[3] [4] and informed by cost-effectiveness and equity analysis when possible. During grant design, resources should be optimally distributed across interventions, populations, and geography to maximize equitable and sustainable impact. Grants should be delivered with high quality and efficiency and strengthen underlying health systems to sustain the gains when the country eventually transitions from Global Fund and other external financing.

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[3] People-centered services consider individuals' health needs holistically. Care is organized around the health needs and expectations of people and sees individuals as participants as well as beneficiaries of trusted health systems. *Source: World Health Assembly, 69. (2016). Framework on Integrated People-Centered Health Services. Geneva: WHO, 2016.*

[4] People-centred framework for TB programming, evaluation, prioritisation and planning tools, information and capacity development resources based on the WHO guidelines can be accessed at https://pcf4tb.org

1. Introduction

This information note provides guidance to applicants preparing a funding request to the Global Fund. It makes recommendations on program essentials and priority interventions for tuberculosis (TB) that will achieve the highest impact in an efficient, equitable and sustainable manner, enhancing value for money. It promotes strategic investments to save lives and achieve economic benefits, based on the country's TB situation, priorities and other contextual factors including the health system.

After many years of slow progress, significant gains were made in the fight against TB, before the COVID-19 pandemic reversed years of progress. TB remains one of the leading infectious causes of death worldwide: an estimated 1.5 million people lost their lives to TB in 2020. Drug-resistant TB (DR-TB) remains a public health crisis with only about one third of estimated people with DR-TB receiving treatment in 2020, while only 5.8 million of the estimated 10 million people who fell ill with TB notified in 2020.[5] With nearly half of the estimated global TB cases missed, finding the missing people with TB continues to be a priority while increasing efforts to prevent further transmission and progression to disease through scaling up preventive activities.

The COVID-19 pandemic disproportionately affected the global TB response. Between 2019 and 2020, TB case notification declined by 18% (22% decline in the case of DR-TB), TPT uptake fell by 21%, while TB deaths increased in 2020 for the first time in over a decade.[5] With less than a decade left to meet the 2030 sustainable development goal (SDG) targets, the world needs to get back on track, and accelerate efforts to meet the ambitious SDG and End TB targets.

To guide its investments, the Global Fund has developed an ambitious new Strategy for 2023-2028 to get progress back on track against HIV, TB and malaria and contribute to the target of achieving universal health coverage (UHC). The Global Fund will put a greater focus on value for money, including efficiency, equity, sustainability, program quality and innovations and take determined action to tackle human rights and gender-related barriers. It will leverage the fight against the three diseases to build more inclusive, resilient, and sustainable systems for health (RSSH), including community systems, better able to deliver health and well-being, and to prevent, identify and respond to pandemics.

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[5] World Health Organization. *Global Tuberculosis Report.* Geneva: WHO, 2021.

2023-2028 Global Fund Strategy Framework Overview[1]

Full Framework [here](#).
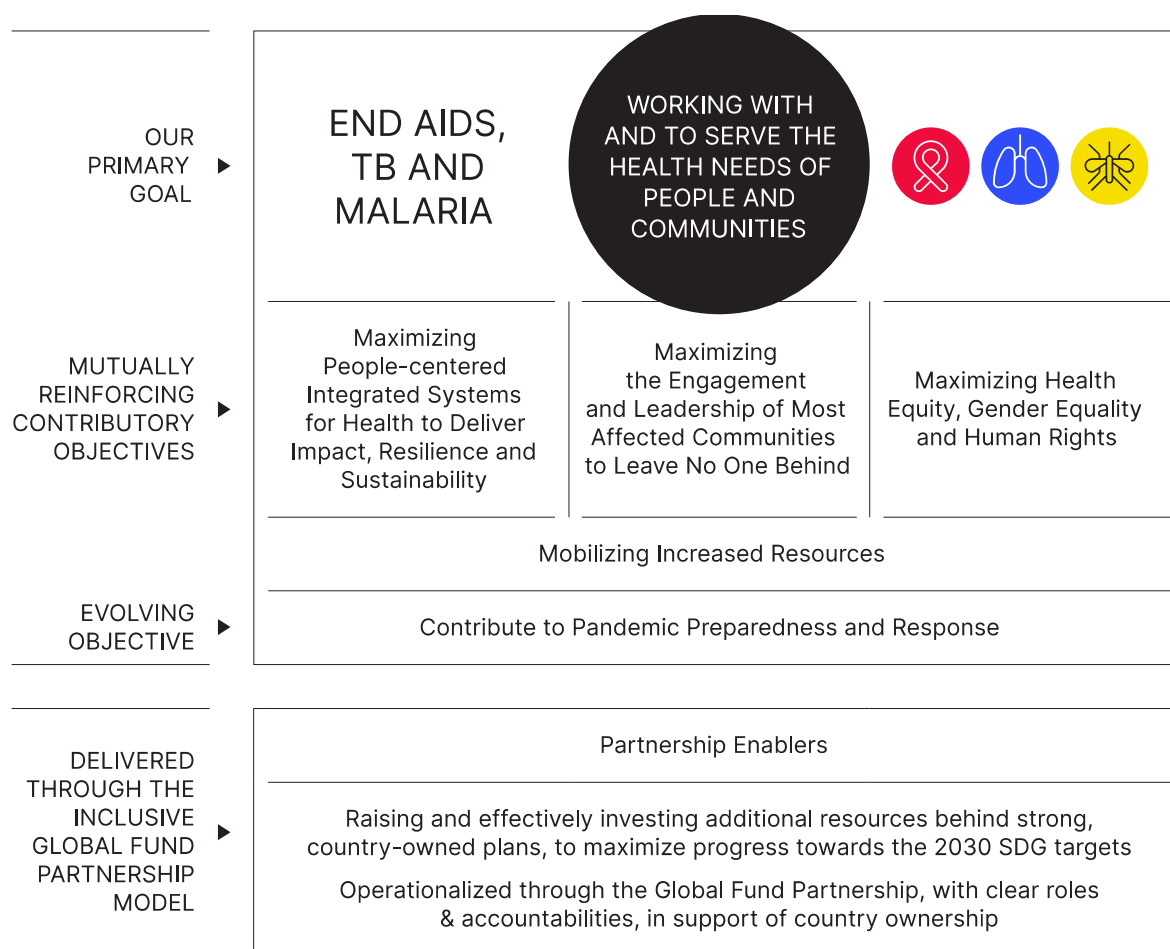
The **five sub-objectives for TB** in the new Global Fund Strategy are:

1. Focus on finding and treating all people with TB, both drug-sensitive and drug-resistant TB, through equitable, people-centered approaches.
2. Scale up TB prevention with emphasis on TB preventive treatment, and airborne infection prevention and control.
3. Improve the quality of TB services across the TB care cascade including through management of comorbidities.
4. Adapt TB programming to respond to the evolving situation, including through rapid deployment of new tools and innovations.
5. Promote enabling environments, in collaboration with partners and affected communities, to reduce TB-related stigma, discrimination, human rights and gender related barriers to care; and advance approaches to address catastrophic cost due to TB.

2. Investment Approach

2.1   Understand: continue to know your epidemic and updated resource needs

Interventions proposed in funding requests should be informed by the latest epidemiological situation disaggregated by sex, age, place of residence, along with socio-economic status and key and vulnerable population groups where possible. TB programming should be informed by a good understanding of the key and vulnerable population in the country context, inequities including gender inequalities, human rights violations, stigma, and other barriers impacting access to TB services. Understanding health and care seeking behavior can inform what services are needed, how to deliver them and the need for engaging other providers, such as the private sector, informal providers, social protection services and service delivery by community-based and led organizations. A clear understanding of how heath systems bottlenecks affect TB program delivery is also needed.

TB care cascade analyses, across the entire continuum of care, can identify and quantify gaps in service delivery across the patient's journey. Data from such analysis can be used to prioritize interventions to improve TB case finding, diagnosis, treatment initiation and completion. The people-centered framework (PCF) and tools aim to facilitate a systematic approach to country-led, data-driven, and people-centered planning, prioritization, and decision-making. A central tenet of the framework is the use of consolidated data along the continuum of care which is presented to and discussed with all key stakeholders in a participatory manner.

Vulnerable populations, including migrants, refugees and IDPs, hosted in COE countries may be at higher risk for TB. Tailored interventions and differentiated program approaches are crucial to achieve results and impact in COEs and host countries. The Global Fund's Operational Policy Note on COE[6] provides guidance on adaptive engagement to ensure access to essential services, maximized coverage and impact in such contexts, based on the principles of flexibility, partnerships and innovation.

Global Fund investments should contribute to country-owned responses. Therefore, requests should be aligned with priorities set forward in national strategic documents and health sector strategies, specifically TB National Strategic Plans (NSPs). Countries should consider updating their NSPs if epidemiological and response data needs an update, or if new tools, service delivery models or policies need to be introduced.

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[6] The COE OPN is being revised. The current list of COE countries includes Afghanistan, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of the Congo, Eritrea, Guinea, Guinea-Bissau, Haiti, Iraq, Democratic People's Republic of Korea, Lebanon, Liberia, Mali, Myanmar, Nicaragua, Niger, Nigeria, Pakistan, Palestine, Sierra Leone, Somalia, South Sudan, Sudan, Syria, Ukraine, Venezuela, and Yemen.

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NSPs can be referenced in place of the funding request narrative when applicants apply through the Tailored for National Strategic Plans application approach. Countries considering this approach are encouraged to include scenario-based projections in their NSPs, specifying the cost and impact for alternative scenarios of funding amount, activities and targets. NSP development should be an inclusive and evidence-based development process that outlines the national vision, key activities and have a robust monitoring and evaluation (M&E) framework with a costed operational plan or scenario-based costed plan for the activities outlined in the NSP.

Technical review criteria to be used by the Global Fund's Technical Review Panel, to ensure that Global Fund investments are positioned to achieve the highest impact, value for money and contribute to the goal and objectives set out in the Global Fund Strategy, are described in Annex 1 of the document accessible through this link.

2.2   Design: develop a mix of interventions that maximizes impact and sustainability

Funding requests are expected to be aligned to national policies and normative guidance. Interventions should be prioritized based on a robust gap analysis and needs assessment supporting the TB investment case. Applications should demonstrate a clear understanding of what the problems are, including access barriers, what is covered through other funding sources, the gaps in funding, and how TB investment will address challenges and lead to better delivery of services. Programming to meet the program essentials described in Section 3.12 will maximize the impact of investments. Adoption and scale up of new TB screening and diagnostic tools, shorter treatment regimen for TB/DR-TB disease and TB infection, engagement with other health providers and community-based service delivery offer opportunities to increase the reach and results of TB interventions. Feasibility and acceptability of new tools, considerations of health equity, gender equality and human rights, particularly to serve the needs of key and vulnerable populations should underpin the design, implementation, and monitoring of TB services.

Where possible, countries can use modelling to project the impact of an optimal mix of interventions (which could change over time) in reducing TB incidence and mortality in the country for given resource envelopes. This may include modelling the impact of interventions implemented by other health programs and beyond the health sector. This can help with prioritization of the most impactful and cost-effective interventions in their country context. Building in-country capacity on modelling and related skills to guide strong national strategic plans can promote better decision making, ownership and commitment.

Accelerating progress towards UHC through integrated people-centered health services for TB, anchored on resilient and sustainable systems for health is critical. The Global Fund's RSSH investments support systems strengthening that underpin TB program quality. This includes integrated supply chains, laboratory and interoperable data systems, polyvalent human resources for health and community health care workers. Encouraging investments in integrated national health systems that address TB, HIV, malaria and COVID-19 is important to enable people-centered care and efficient use of available funds, in addition to tackling other health problems or health service delivery bottlenecks. RSSH

investments can also be used to increase the effectiveness, efficiency, equity and sustainability of disease programs, including through stronger alignment with the national health system and strengthening pandemic preparedness. The RSSH Information Note covers broader health systems investments that also apply to TB programs.

Value for money continues to be a key principle guiding Global Fund investments, as it aims to maximize and sustain equitable and quality health outputs, outcomes and impact for a given level of resources. Applying the principle in funding request development and implementation implies that TB investments shall demonstrate strong and concerted effort across all value for money dimensions, including economy, efficiency, effectiveness (including cost-effectiveness), equity and sustainability. For more information, refer to the Value for Money Technical Brief.

2.3   Deliver: ensure high quality and efficient service delivery for optimal coverage

To end the TB epidemic, more resources are required than are currently available. Making the greatest impact therefore requires a data-driven approach to focus programs on the populations most affected by the disease and efficiently deliver quality services.

The right types and quantities of inputs (e.g., products, human resources, and services) need to be procured at the right prices and utilized through the most appropriate modalities and platforms (i.e., facility or community-based). Grant implementation arrangements need to be fit-for-purpose to successfully, timely and efficiently implement the planned activities. Identifying implementing partners that have strong technical and management expertise, who can convene and coordinate activities with other TB partners and reach key and vulnerable population groups is important to support quality and efficiency of service delivery. Implementing partners should be supported with adequate human resources, their organization policies and procedures should facilitate timely implementation of activities while exercising adequate controls to safeguard the use of Global Fund resources in the most efficient manner. Countries should explore differential contracting modalities under the programs and grants (activity-based contracting, service delivery agreements and program for results) to facilitate engagement of community-based and led organizations, aligned with their capacity to deliver verifiable programmatic interventions and results.

Primary health care facilities and community health systems support countries to explore the possibilities for greater integration to maximize efficiency and effectiveness of people-centered, holistic health services. RSSH investments can be leveraged to alleviate service delivery constraints faced not only by TB programs but by the HIV, malaria and other programs, by removing duplications or misalignments across core health system functions and increasing the efficiency of national health systems.

All grant agreements signed by the Global Fund are expected to meet the following five human rights standards: (i) provide non-discriminatory access to services for all, including people in detention; (ii) employ only scientifically sound and approved medicines or

medical practices; (iii) do not employ methods that constitute torture or cruel, inhuman or degrading treatment; (iv) respect and protect informed consent, confidentiality and the right to privacy concerning medical testing, treatment or health services rendered; and (v) avoid medical detention and involuntary isolation, which are to be used only as a last resort. Global Fund grant recipients are required to advise the Global Fund of risks to these human rights standards. The Global Fund's independent Office of the Inspector General (OIG) has established a mechanism to investigate complaints regarding the standards.[7]

Applicants are also recommended to consider the Protection from Sexual Exploitation, Abuse and Harassment (PSEAH), as well as child protection in the planning and design of program interventions. Program related risks of sexual exploitation, abuse and harassment to beneficiaries and people involved in the service provision, as relevant, should be identified in the proposed interventions. These should also include necessary mitigation measures to ensure that services are provided to, and accessed by, beneficiaries in a safe way. It is also recommended to include PSEAH in community awareness activities, such as outreach strategies, communication campaigns trainings or other activities target grant beneficiaries. More details in the upcoming PSEAH Guidance Note.

2.4 Sustain: strengthen the sustainability of health and community systems

The Global Fund's approach to sustainability focuses on the ability of a health system to both maintain and scale up service coverage to a level that will provide for continuing control of a public health problem and support efforts to eliminate the three diseases, even after funding from external donors come to an end. All funding requests, including from COEs, will be assessed to ensure that they are poised for sustainability.

As part of the Global Fund 2023-2028 Strategy and the implementation of the Sustainability, Transition, and Co-Financing (STC) Policy, the Global Fund strongly encourages all countries to incorporate sustainability considerations in national planning, funding request development, grant design, co-financing commitments, and grant implementation, regardless of where a country is on the development continuum or their proximity to transition from Global Fund financing. While financial sustainability is a critical priority, these sustainability considerations cut across many thematic areas, including financial, epidemiological, programmatic, systems-related, governance and human rights. They will depend heavily on specific country and regional context, including epidemiological context, structure of the health system, and the reliance on external financing for the health sector and national TB response.

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[7] The Global Fund. *The Global Fund Human Rights Complaints Procedure Responding to Community Concerns.* Geneva: The Global Fund, 2015.

Strengthening sustainability is critical to maintaining the gains in the fight against TB given ongoing financing gaps in TB national responses, the continued reliance on external financing for specific interventions critical to ending TB and for significant scale-up to meet programmatic goals. Continued progress in fighting TB will require a combination of scale-up of critical services with increased ownership of national TB responses, including strengthened domestic financing.

In addition to financial sustainability, strategic planning for human resources for health should consider investments needed to take long-term development and support of the health workforce, including capacity development, supportive supervision and mentoring, and career progression. It should promote staff and capacity retainment, and service integration particularly in countries where external financing is used to cover a substantial part of the workforce.

As part of this overall approach to sustainability, strengthening the underlying health systems that serve as the foundation for national TB response is critical to sustaining the gains and supporting successful transitions from Global Fund financing. As applicants develop funding requests, make co-financing commitments and plan for the long-term sustainability of the national TB responses, it is also essential to reinforce strategic investments in health systems and consider strengthening their abilities to provide and finance sustainable services that are affordable and programmatically feasible to scale service coverage in the long run.

The STC Guidance Note provides additional guidance for applicants to consider when developing funding requests. It includes a TB annex that provides additional TB specific sustainability considerations that may serve as a useful resource to support stakeholder dialogue on sustainability.

Finally, as part of the broader sustainability agenda, attention must be paid to how environmental damage and climate change are impacting human health, including the most vulnerable and disadvantaged communities. More information can be found in Global Fund's Statement on Climate Change and Environmental Sustainability and the RSSH Information Note which includes a section on avoidance, reduction and management of health care waste.

3. Prioritized Interventions for Global Fund Investments

3.1 Screening and diagnosis

Screening for TB

Systematic screening for TB disease, including of persons not reporting typical symptoms suggestive of TB, is necessary to find and successfully treat all people with TB and minimize its transmission. It needs to be implemented at nationwide scale going beyond small projects, using sensitive TB screening tools and algorithms. In addition, TB infection testing services need to be available and accessible to those who need them, to drive increased uptake of TB preventive treatment. WHO recommendations and communication on the use of new screening tools and new class of TB skin tests provide an opportunity to scale up screening for TB disease and infection.[8,9]

Applicants are encouraged to consider the following priority interventions:

- Considering the limitations of symptom screening, update policies and plans to significantly scale up systematic screening for TB using digital Chest X-rays (CXR) and computer aided detection (CAD) software. Chest X-rays should be available free of cost to people. CAD is currently recommended for individuals aged 15 years and older.
- Decentralize TB screening and testing into primary health care facilities, as well as community and household levels including through mobile clinics fitted with portable digital CXRs (with or without CAD) and mWRD, along with other priority health services, to offer more accessible, community-based early diagnosis. Monitor cost and performance data of different screening strategies to inform the most cost-effective interventions.
- Integrate contact investigation and other active TB case finding activities with efforts to also identify people with TB infection who will benefit from TPT.
- Expand the network of services offering testing for TB infection to improve access and promote TPT uptake among those who need to be tested. In addition to tuberculin skin test (TST) and interferon-gamma release assays (IGRAs), consider WHO's recent communication on new TB antigen-based skin tests (C-Tb, C-TST, Diaskintest).[9]
- Monitor implementation using key indicators to track progress and make adjustments to improve performance: population covered, screened, tested, diagnosed and started on treatment for TB disease and TPT. Deploy digital innovations to track and link people to appropriate care.

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[8] World Health Organization. *WHO consolidated guidelines on tuberculosis Module 2: Screening – Systematic screening for tuberculosis disease.* Geneva: WHO, 2021.

[9] World Health Organization. *Rapid communication: TB antigen-based skin tests for the diagnosis of TB infection.* Geneva: WHO, 2022.

Diagnosis of TB

To get back on track to meet TB case notification targets, the priority is to find all people with TB, both drug-susceptible (DS-TB) and drug-resistant (DR-TB), including those who may not present TB symptoms, as early as possible and where they prefer to avail of services. Rapid scale up of the latest recommended diagnostic tools, integrated specimen transport systems and rapid communication of test results will increase case finding and improve the quality of TB diagnosis. This is necessary given that globally, the TB treatment coverage in 2020 was only 59%, only 33% of people with TB were tested with mWRD at the time of diagnosis, and only 59% of people with pulmonary TB were bacteriologically confirmed.[5] Early diagnosis and prompt treatment initiation will also help to prevent post TB lung sequelae.

Equally important is to understand existing gaps and barriers (related to human rights, gender and other equity-related issues, including financial ones) that limit access to and utilization of integrated diagnostic services. This knowledge should inform optimal placement of equipment and outreach approaches, design sample referral systems and identify additional needs to maximize impact and generate efficiencies.

Applicants are encouraged to consider the following priority interventions:

- Intensified screening and testing for TB in health facilities, both public and private, so all people presenting to health facilities with TB symptoms or are at risk of TB are promptly identified and tested.
- Active case finding and surge campaigns to increase TB notification by recovering the backlog of TB cases that were missed due to the COVID-19 pandemic, targeting settings where key and vulnerable populations are located, areas where TB case notification is lower than expected, and among the general population in areas with an estimated TB prevalence of 0.5% (500/100,000) or higher.
- Contact investigation should be used as a strategy to find and treat people, including children, with both TB infection and disease.
- Promote decentralized diagnostic networks and integrated testing for TB with other diseases including through multiplex diagnostic testing platforms. E.g., bi-directional testing for TB and COVID-19 in populations at risk for both diseases, integrated sample referral system for TB and HIV programs in high TB and HIV settings.
- Prioritize WHO-recommended diagnostic tools and algorithms that are sensitive, accurate and efficient, including the use of Chest X-ray (with or without CAD) for TB screening, mWRD as the initial diagnostic test, and bacteriological confirmation of pulmonary TB.[10]
- Universal use of mWRDs as the initial diagnostic test for TB to replace sputum microscopy, rapid drug-susceptibility testing (DST) of all people diagnosed with TB to guide appropriate treatment regimen, ensure rapid turnaround times for test results and treatment initiation including through use of digital tools.

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[10] World Health Organization. *WHO consolidated guidelines on tuberculosis. Module 3: Diagnosis - Rapid diagnostics for tuberculosis detection 2021 update.* Geneva: WHO, 2021.

- Interventions to find children and adolescents with TB should be part of the overall case finding efforts including contact investigations. They should have access to child-friendly diagnostics including mWRD testing for non-sputum-based samples. TB programs need to collaborate with and build capacity of providers engaged in childcare.
- Diagnostic scale-up, network strengthening and optimization in the overall context of integrated laboratory services. Understand existing gaps that limit access to and utilization of high-quality diagnostic services to inform intervention to address these gaps. This may include:
    i. Providing TB laboratories with necessary equipment, supplies and trained human resources.
    ii. Appropriate placement of equipment to ensure access while maintaining optimal utilization.
    iii. Sample referral system to cover locations where testing services are not available.
    iv. Ensuring uninterrupted supplies and maintenance of equipment, biosafety, and quality assurance of lab services.
    v. Use of connectivity solutions to enable automated reporting by diagnostic devices.
- Understand, design and implement interventions to close the gaps in the TB diagnosis cascade, so people presenting with TB symptoms in health facilities are promptly diagnosed and started on treatment. In addition, develop systems to facilitate timely investigation and diagnosis of conditions with overlapping chronic respiratory symptoms to facilitate appropriate care.

Note: Specific interventions related to DR-TB, TB/HIV, key and vulnerable populations, private sector and community systems and responses are in Section 3.4 to 3.8. Interventions related to RSSH, including the areas of governance, health financing, human resources for health, laboratory systems strengthening, health information management systems and health products management, are detailed in the RSSH Information Note.

3.2 Treatment and care

Against the global target of ≥ 90%, treatment success rate was 86% among people with new and relapse TB and only 59% among people with DR-TB in 2020.[5] Treatment and care services should be designed and delivered considering the needs and preference of people with TB rather than that of the health care system. These services should aim to maximize the proportion of people with TB who have completed their treatment and have bacteriological proof of cure. Use of shorter, all-oral and patient-friendly treatment regimens recommended by WHO,[11,12] ensuring uninterrupted supply of medicines, managing adverse drug reactions and comorbidities, use of digital tools and psychosocial support are important elements to support a person with TB to access and complete their treatment successfully. Digital adherence technologies and community health workers can

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[11] World Health Organization. *Treatment of drug-susceptible tuberculosis: rapid communication.* Geneva: WHO, 2021.

[12] World Health Organization. *Consolidated Guidelines on Tuberculosis, Module 4: Treatment - Drug-Susceptible Tuberculosis Treatment.* Geneva: WHO, 2022

significantly de-stress the pressure on health care facilities, while meeting the service user needs and preference.

Applicants are encouraged to consider the following priority interventions:

- Use the shorter and more patient-friendly treatment regimen, including the 4-month regimen (2HRZ(E)/2HR) for children with non-severe, drug-susceptible TB (DS-TB), pediatric fixed-dose combination (FDCs) drugs and child friendly formulations of DR-TB medications. The new, 4-month DS-TB regimen (2HPMZ/2HPM) for people aged ≥12 years may be considered when the needs justify the additional costs over the existing standard regimen. Shorter, all-oral treatment regimens for people with DR-TB, including children, should be scaled up to rapidly phase out injection-based regimens (see DR-TB section).[13,14]
- Management of existing conditions and co-morbidities that are disproportionately high among people with TB in the country. This may include comprehensive assessment of patients, integrating care or supporting linkages to appropriate care during and after TB treatment including care for post-TB sequelae and disability, palliative care to alleviate suffering of patients, mental health and other chronic conditions like diabetes.
- Decentralized, ambulatory, community and home-based, people-centered services for TB treatment and care. Multi-month dispensing and home delivery of TB drugs with other medications for chronic conditions, such as antiretroviral therapy (ART) where appropriate, provision for counselling and social support to people with TB by trained community health workers or peers and community-led organizations. Efforts to address barriers to TB treatment adherence, including human rights, stigma and gender-related barriers should be considered.
- Digital tools such as treatment adherence technologies, call-centers and mobile apps could be used to provide home-based support to people with TB for treatment support and monitoring, counselling, treatment monitoring and reporting adverse drug reactions. Digital adherence technologies (DAT) such as video supported treatment (VST), medication sleeves/labels (e.g., 99 DOTS) and smart pill boxes (e.g., MERM) have been successfully used in countries to complement in-person counselling and directly observed treatment. The technical brief developed by the Global DAT Task Force provides an overview of the technologies as well as guidance to applicants on planning, budgeting, and implementation considerations.
- Advocate and mobilize resources to provide financial, nutritional, psychological and mental health support for people with TB and their families particularly through government social protection schemes and corporate social responsibility programs where possible.
- Uninterrupted supply of quality assured anti-TB medicines, including through capacity building and strong procurement and supply chain systems.

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[13] World Health Organization. *WHO consolidated guidelines on tuberculosis, Module 4: Treatment - drug-resistant tuberculosis treatment.* Geneva: WHO, 2020.

[14] World Health Organization. Rapid communication: *Key changes to the treatment of drug-resistant tuberculosis.* Geneva: WHO, 2022.

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3.3   TB prevention

Accelerating actions on TB prevention along with early diagnosis and successful treatment are critical to end TB. While progress has been made in the proportion of people living with HIV initiated on TPT (65% in 2020), the proportion of household contacts under 5 years started on TPT was only 35% and even worse for household contacts older than 5 years at less than 2%.[5] The heightened awareness on airborne infection prevention and control (IPC) due to the COVID-19 pandemic, along with WHO recommendations on the use of shorter TPT regimens and new class of TB skin tests, provide opportunities to scale up efforts on TB prevention.[15]

Applicants are encouraged to consider the following priority interventions:

- Scale up systematic contact investigation, screening and evaluation of high-risk groups for DS-TB and DR-TB infection and disease as defined in national and global guidelines.
- TB prevention, particularly activities to promote TPT, should be designed and implemented as a part of routine activities across the TB care cascade. Integrated approaches to case finding and TPT provision through contact investigation for both TB infection and disease, identifying people eligible for TPT as a part of active case finding by linking algorithms for screening and TPT will maximize efficiency.
- Expand and decentralize testing facilities for TB infection including provisions for collection and transportation of samples for groups requiring testing. In addition to TST and IGRAs, consider the new TB antigen-based skin tests.
- Improve access to digital CXR (with or without CAD) and mWRD to enable providers to diagnose TB disease and rule it out before starting TPT. CXR and mWRD are not prerequisites for initiating TPT and should not be a barrier for TPT.
- Provision of TPT to all eligible people living with HIV (adult and children) and household contacts (all ages) of people with bacteriologically confirmed pulmonary TB, as well as other high-risk groups identified in national guidelines. In situations of limited funding, target groups for TPT may be prioritized based on the strength and certainty in the estimates of effect of the WHO recommendation for the specific population group, and the country context.
- Updated national guidelines to align with the latest recommendations to offer newer, shorter TPT combination therapies (3HP, 1HP, 3HR, and 6 Lfx for DR-TB), using pediatric formulations and FDCs once they become available.
- Multi-month dispensing of TPT including alignment of dispensing TPT medicines pick-ups with other chronic medications dispensing, e.g., ART.
- Supportive activities to improve access to screening and testing for TB infection and adherence to TPT. This may include adoption of digital tools for contact tracing, screening and adherence, strengthening capacity and resources to rule out active TB disease and manage adverse drug reactions and psychosocial support.
- Interventions to strengthen recording and reporting for management of TB infection, starting from contact identification, screening, initiation and completion of TPT and

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[15] World Health Organization. *WHO consolidated guidelines on tuberculosis: module 1: Prevention: tuberculosis preventive treatment.* Geneva: WHO, 2020.

monitoring of adverse events. Strengthen data completeness and accuracy and monitor performance against targets for all groups eligible for TPT.

- Demand creation through sensitization and behavior change and communication approaches to enhance acceptability of TPT among health care providers, communities and individuals who will benefit from TPT.
- Develop and implement appropriate airborne infection prevention and control measures across all levels of the health care delivery system, in congregate settings and at the community level. TB-IPC programs should be part of the wider health system effort to prevent transmission of infections at the health facility and community level.
- Ensure administrative controls are in place and followed to protect health care workers and patients attending health facilities, environmental measures provide a safe working environment and adequate personal protective equipment (PPE) are available and properly used by health care workers and patients.
- Supportive interventions to ensure Bacillus Calmette–Guérin (BCG) vaccination coverage among newborns is adequately maintained.
- Support the introduction and roll out of new effective TB vaccine when it becomes available for use, including assessment of feasibility and acceptability and building linkages with local authorities to monitor adverse events.
- Engage community-based and led organizations to support the development, implementation and monitoring of people-centered TB prevention activities, including through integration of relevant prevention activities in community and primary health care service delivery, behavior change communications and community-led monitoring.

3.4 Drug-resistant TB

Less than half of the estimated DR-TB cases were diagnosed and started on treatment, with only 59% treatment success in 2020. Early diagnosis of DR-TB using rapid molecular test, universal DST for first- and second-line drugs, access to newer and all-oral treatment regimens recommended by WHO.[13, 14] management of adverse drug reactions and support to improve patient adherence to treatment are critical in the management of people with DR-TB.

Much of the interventions covered in earlier sections on screening and diagnosis, treatment and care and prevention apply to DR-TB. Priority interventions of specific relevance to people with DR-TB include:

- Early detection of drug-resistance, including through the use of rapid molecular diagnostics and DST such as GeneXpert, TrueNat, LPA for first and second-line drugs. The GeneXpert 10-colour instrument offers possibilities to identify resistance to Isoniazid, fluoroquinolone and other second-line drugs in one test.
- Decentralize testing and treatment services, with preference for ambulatory care from treatment initiation instead of hospitalization while ensuring close monitoring, follow up and support. Culture and DST should be available at the first referral centers, while second-line drugs and clinical capacity including necessary laboratory tests should be available close to the patients to avoid treatment initiation delays and loss to follow-up.

- Scale up the use of WHO recommended shorter, safer, all-oral treatment regimens for DR-TB (including pre-XDR and XDR-TB) at the start of treatment and rapidly phase out the use of injection-based regimens. Countries should consider transitioning to the shorter, novel 6-month all-oral regimens (BPaLM or BPaL) and the 9-month all-oral bedaquiline-containing regimens following WHO recommendations. Children with DR-TB should benefit from the recommendations on the use of newer drugs like Bedaquiline and Delamanid in all ages.[13, 14]
- Active TB drug-safety monitoring and management (aDSM) using clinical and laboratory tests for people on DR-TB treatment with new and repurposed anti-TB drugs, to timely detect, manage and report adverse drug reactions.
- Support to manage other co-existing conditions and co-morbidities, including mental health and substance dependence.
- Provision for psychosocial support like counselling services, nutritional and transport support.
- Digital technologies for treatment adherence, reporting of adverse drug reactions.
- Identification and management of household contacts of people with MDR-TB based on WHO guidelines.

3.5   TB/HIV collaborative activities

TB remains the leading cause of death among people living with HIV. TB deaths among people living with HIV increased for the first time in 13 years due to the COVID-19 pandemic in 2020. Implementation of TB/HIV collaborative activities will contribute to decrease TB mortality in people living with HIV and reduction in TB incidence, contributing to the End TB and ending AIDS by 2030 goals. To foster collaboration and ensure alignment, countries with a high TB and HIV co-infection are required to submit joint TB/HIV funding requests that present integrated quality programming for the two diseases.

Applicants are encouraged to consider the following priority interventions:

- Provide HIV counselling and testing for all people with TB and presumptive TB. Early provision of ART, cotrimoxazole preventive treatment and TB treatment for people living with HIV with TB disease.
- Systematic screening for TB disease among people living with HIV at each contact with health care (facility and community) and integrated in differentiated service delivery models. Wherever possible, screening algorithms should be adapted to fulfill new WHO recommendations and can include Chest X-Ray (with/without CAD), C-reactive Protein (CRP) or a WHO-recommended rapid molecular assays.
- For TB diagnosis, WHO-recommended rapid molecular assays should be used as the first diagnostic test. LF-LAM tests can assist in diagnosing TB in selected groups of HIV-infected people with presumed TB. The test is fast, bedside and rule-in for HIV-positive individuals, especially in urgent cases where a rapid TB diagnosis is critical for the patient's survival.
- TPT should be provided to all eligible people living with HIV. Countries are encouraged to adopt shorter TPT regimens (3HP, 1HP and 3RH for children) and move to FDCs as they become available.

- TPT should be integrated into HIV differentiated service delivery (DSD) models (e.g., multi month dispensing of ARVs, community adherence groups, etc.). Implementing DSD should not become a reason for delaying or denying benefits of TPT to people living with HIV, and TPT should not be a reason for the patients to become ineligible for accessing DSD.
- Intensify the collaboration between TB and HIV programs, integration of TB/HIV services, joint programming, implementation, supervision and monitoring. Multi-disease platforms are good opportunities to strengthen collaboration and synergize efforts while contributing to building RSSH.

3.6 Key and vulnerable populations

Key and vulnerable population groups for TB vary by country but are all disproportionately affected by the disease, poverty, stigma and discrimination, human rights and gender-related barriers. In all countries, children represent a unique key and vulnerable population - disadvantaged by less sensitive TB diagnostics, without access to economic means, and unable to self-advocate.

Table 1: Key and Vulnerable Populations for TB

People who have increased exposure to TB due to where they live or work	Prisoners, miners, hospital visitors, health care workers and community health workers. People who: • live in urban slums • live in poorly ventilated or dusty conditions • are in contact with TB patients, especially children • work in overcrowded environments • work in hospitals or health care settings
People who have limited access to quality TB services	Migrant workers, women in settings with gender disparity, children, migrants, refugees or internally displaced people, and illegal miners. People who: • are from tribal populations or indigenous groups • are homeless • live in hard-to-reach areas • live in homes for the elderly • have mental or physical disabilities • face legal barriers to access care
People at increased risk of TB because of biological or behavioral factors that compromise immune function	People who: • live with HIV • have diabetes or silicosis • undergo immunosuppressive therapy • are undernourished • use tobacco • suffer from alcohol-use disorder • inject drugs

Source: Stop TB Partnership [16]

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[16] Stop TB Partnership. *Global Plan to End TB (2016-2020): The Paradigm Shift.* Geneva: Stop TB Partnership, 2015.

Many new cases of TB are attributable to five risk factors: undernutrition, HIV infection, alcohol use disorders, smoking (especially among men) and diabetes.

Table 2: Global Estimates of the Number of TB Cases Attributable to Selected Risk Factors, 2020 (Source: WHO Global TB Report 2021)[5]

Risk Factor	Relative Risk (Uncertainty Interval)		Exposed (Millions)	Population Attributable Fraction (%)	Attributable TB Cases (Millions, Uncertainty Interval)	
Alcohol use disorders	3.3	2.1–5.2	291	8.1	0.74	0.30–1.3
Diabetes	1.5	1.3–1.8	496	3.1	0.37	0.15–0.68
HIV infection	18	15–21	38	7.6	0.74	0.65–0.83
Smoking	1.6	1.2–2.1	1050	7.1	0.73	0.25–1.5
Undernourishment	3.2	3.1–3.3	637	15	1.9	1.3–2.6

Sources: Imtiaz S et al. Eur Resp Jour (2017); Hayashi S et al. Trop Med Int Health (2018); Lönnroth K et al. Lancet (2010); World Bank Sustainable Development Goals. Database (http://datatopics.worldbank.org/sdgs/); WHO Global Health Observatory (https://www.who.int/gho); and WHO Global TB Programme.

Key considerations and interventions for key and vulnerable populations:

- Understand the size, location and special needs of key and vulnerable populations in the country. Special considerations, policies and action plans may be needed to address the unique needs of the different key and vulnerable population groups. They should be empowered, deliberately and meaningfully engaged by policy-makers and implementing organizations to contribute insights and oversight, so their needs are considered and addressed.
- Remove barriers to TB services for key and vulnerable populations. This may entail engaging and targeting key and vulnerable populations for TB screening and diagnosis through mobile outreach and community-based or community-led services (e.g., prisoners, miners, people who inject drugs and mobile populations), special allowances for key and vulnerable populations to avail of services, linkage to social protection schemes (food, financial support, nutrition supplements, transport, labor protection etc.), programs to address stigma and discrimination, protect human rights and legal services (more details in Section 3.9).
- In countries with high cross-border movement of people, consider cross-border policies, legal framework and interventions to facilitate continuum of TB care services. In addition to cross-border refugees and migrants, internally displaced populations are often located in hard-to-reach areas with high security threats. Reaching out to these population groups in complex emergencies requires tailored approaches including working with humanitarian partners.
- Training of health care workers on infection prevention and control, access to safe working environment including adequate supplies of PPE, regular screening for TB and support to complete their treatment successfully. Advocate for health workers' labour rights to ensure that they are given paid sick-leave while on treatment and that they can come back to work after completing their treatment.

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- Adopt new tools and innovations that address the needs of key and vulnerable populations. For children, this could include the use of stool sample for mWRD, shorter treatment regimen for non-severe TB and the use of pediatric formulations of first and second-line TB drugs. The use of evidence-based algorithms integrating the use of rapid diagnostics with clinical and radiological features has the potential to address underdiagnosis and reduce treatment initiation delays in children. Among migrant and mobile populations, shorter treatment regimens and digital technology can support treatment adherence and facilitate cross-border collaboration.

3.7 Collaboration with other providers and sectors

In countries with a large private sector, the first point of care for a large proportion of people with or at risk of TB are frequently health care providers outside the national TB programs. In addition, a good proportion of people with TB do not seek health services because they are not aware, may not perceive themselves to be ill or have difficulty accessing services. TB programs need to find all people with TB, ensure the quality of care and improve access to services. This involves working with private health care providers, community leaders, community-based and led organizations and addressing barriers including for gender-sensitive and rights-based service delivery and care. TB also disproportionately affects the poor and marginalized and presents other comorbidities requiring collaboration with other health programs and social protection schemes.

Applicants are encouraged to consider the following priority interventions:

- Understand the size and role of private providers including for-profit providers (e.g., private hospitals, general practitioner, private laboratories, informal providers and pharmacies); not-for-profit sector (e.g., faith-based organizations, civil society); other non-NTP public care providers (e.g., miliary and police hospitals, medical schools) in the care-seeking behavior of the population and the provision of TB-related services. Develop policies and plans for their engagement, aligned with the broader health system private sector strategy, prioritizing those who can contribute the most to early TB case notification and successful treatment.
- Design and implement models of private sector engagement that may be differentiated considering the type of provider and services provided (symptom screening and referrals, diagnosis, treatment etc.). Where appropriate, engage the services of intermediary agencies and consider innovative engagement models including contracting, outsourcing and result-based payments. Build in flexibility to adapt implementation models according to the requirements of each setting and in response to evolving understanding of provider and patient preferences.
- Support and incentivize private providers to deliver quality TB services along the cascade of care. Build their capacity through trainings on the standards for TB care, equip them with tools to facilitate notification and monitor treatment of their TB patients (including through digital technologies), provide consistent and convenient access to government-funded diagnostic tests, and quality assured TB drugs for their patients. Deploy an effective range of powerful incentives and enablers, recognizing both financial and non-financial motivations for provider behavior.

- Strengthen and incentivize reporting of TB data from private providers and integrate such data in the national TB program and health management information system. Monitor and report quality of care and outcomes, as well as notifications, among private patients. Adapt forms and data collection modalities as appropriate for private provider settings, while also serving program needs.
- Strengthen NTP capacity to engage and monitor quality of services through development of appropriate legislation and regulatory systems, inclusion of private laboratories in external quality assurance programs, accreditation of private health facilities, engagements with professional associations and regulatory bodies.
- Strengthen collaboration with other health programs for effective integrated service delivery and/or referral linkages to address coinfection and comorbidities. Besides HIV programs, this may include reproductive, maternal, newborn, child and adolescent health, mental health, and non-communicable disease programs. Develop linkages to investigate and treat conditions other than TB with overlapping chronic respiratory symptoms or those that may be detected during CXR screening.
- Train health service providers to apply TB-relevant health and behavior counselling skills and psychosocial support and to recognize and treat common mental health, neurological and substance use disorders, which can often be managed effectively at the primary health care level. Such training can ideally be complemented by integrated supportive supervision at primary health care level.
- Design and implement collaborative activities to address undernutrition, diabetes, tobacco use, substance use disorders including alcohol and drug use [17,18] and post-TB disabilities.
- Support approaches to address catastrophic costs due to TB, in line with national policies. Provide services at times and in places that are convenient to the poor. Advocate and collaborate with relevant ministries, departments and agencies to include TB services and support for people with TB as a part of UHC packages and social protection schemes, particularly for the poor, undernourished and marginalized communities. Social support may include cash, food, nutrition supplements, health insurance coverage and other social benefits.
- Engage businesses to adopt workplace TB programs, particularly in high-risk occupational sectors, such as mining and construction. This could include building awareness, diagnosis, treatment and prevention services to employees (including daily, casual workers), their families and communities. Businesses may also institute workplace policies to allow employees with TB/DR-TB to take paid medical leave and protect them from discrimination due to TB.
- Support efforts to address antimicrobial resistance (AMR) and zoonotic TB, including through One Health[19] approaches to support more holistic responses that

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[17] WHO and The Union. *Collaborative framework for care and control of tuberculosis and diabetes.* World Health Organization. Geneva: WHO, 2011.

[18] World Health Organization. *WHO package of essential noncommunicable (PEN) disease interventions for primary health care.* Geneva: WHO, 2020.

[19] One Health is a collaborative, multisectoral, and transdisciplinary approach – working at the local, regional, national, and global levels – with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment. Source: https://www.cdc.gov/onehealth/index.html

reinforce linkages between the health of people, animals and the environment. Encourage approaches to minimize the impact of TB program implementation on climate and the environment.

- Contribute to pandemic preparedness and response (PPR) to protect the TB response progress and strengthen the resilience of TB programs and the wider health systems to respond to pandemic threats. Investments in airborne infection prevention and control and in strengthening capacity and infrastructure for the management of respiratory illnesses will serve the needs of people with TB and other respiratory diseases, including post-TB sequelae. This will also strengthen health systems to deal with future threats from airborne pathogens.

3.8   Community systems and responses

Community systems are the processes, structures and mechanisms that communities use to coordinate and deliver responses to their health-related challenges and needs. They are essential to strengthen health systems, improve the TB response and ensure that TB services are designed and delivered to be people-centered, accessible, equitable, cost-effective and accountable. Importantly, community systems and the responses they support are based in and led by communities themselves, while working hand in hand with the NTP and the private sector. They go beyond the reach of clinical facilities and biomedical responses, addressing social and structural barriers to accessing TB care and support services and are powerful means for reaching key and vulnerable populations, with services tailored to meet their specific needs. Community systems and responses should be embedded within the interventions presented in this information note. For key definitions and further details, refer to the RSSH Information Note and Community Systems Strengthening Technical Brief.

Applicants are encouraged to consider the following priority interventions:

- Strengthen the institutional capacity and leadership of TB community-based and led organizations and networks of TB survivors to facilitate their participation in national TB governance and decision-making processes.
- Scale up effective and quality community-led and community-based service delivery to improve access to quality TB services, while improving the sustainability of these interventions via public financing (social contracting).
- Support social mobilization, i.e., enable community-based and led organizations to effectively collaborate among themselves and with the formal health system.
- Support communities, particularly key and vulnerable population groups and TB survivors' networks, to improve the TB response in collaboration with the NTP by identifying and addressing the barriers to accessing TB and other social services (e.g., related to human rights or gender), social determinants of health and progress towards UHC.
- Support community-based and led interventions and outreach services for TB screening, diagnosis, treatment and care, TB prevention, and rehabilitation. Promote

integrated services for TB with HIV and other relevant services. Specific activities are detailed in relevant sections of this document and include identifying people with TB symptoms, facilitating early diagnosis including through TB symptoms awareness campaigns, contact investigation and sample referrals, treatment adherence and psychosocial support, and other activities related to TB prevention.

- Support community-led research to provide a better understanding of the barriers and gaps that inhibit effective, people-centered TB services from the perspective of communities themselves to inform advocacy for change and improvements.
- Scale-up community-led monitoring (CLM) to provide valuable information to the NTP and service providers from service user experiences on issues impacting the availability, accessibility, acceptability, affordability and quality of TB care and support services, human rights violations, and stigma, also from the perspective of different genders and key and vulnerable populations.
- Support social contracting i.e., public financing and contracting of services provided by communities and civil society.

3.9 Equity, human rights and gender-related barriers

Human rights and gender-related barriers, including health inequities, gender inequality, stigma and discrimination, increase vulnerability to contracting TB and undermine access to TB services. TB-related stigma is often linked to the stigma of poverty or other social status as well as misinformation and unjustified fears about the disease. People in prisons and other closed settings face high-risk of developing TB but may be excluded from TB services, health care workers often lack occupational health services support, while involuntary isolation of people with TB may still occur, directly undermining human rights.

While in general, men face higher risk of developing and dying from TB than women, TB is one of the top killers of women of reproductive age. Women's ability to seek and sustain TB services may be undermined by financial, logistical and health literacy concerns, as well as by TB-related stigma. Trans and gender diverse people face multiple challenges and stigma when seeking and accessing TB care. It is important to identify how gender norms and inequities affect the different health-seeking behaviors, as well as accessibility of the TB services for men, women, trans and gender diverse populations.

Applicants are encouraged to consider the priority interventions noted below. In accordance with human rights principles, all programs should be designed, implemented, and evaluated with the active participation of affected communities. They should be implemented in ways that are respectful, accountable, gender-responsive and non-discriminatory. Refer to TB and Human Rights Technical Brief, upcoming implementer's guide on human rights, gender and equity and analysis of 20 national TB community, rights and gender (CRG) assessments. Ideally, prioritized interventions should be informed by the evidence generated by a CRG assessment with disaggregated data and be integrated in the national strategic plans.

- Eliminating TB related stigma and discrimination. Use stigma reduction measurement tools, training programs and other gender-responsive resources that have been developed for health care workers, community health workers, communities, employers, journalists, social and religious leaders. Involve people with TB in these activities. The training should foster mutual empathy and respect among communities, health care workers and TB affected communities. Stigma-

reduction efforts should include mental health support to communities as well as health care workers. CLM efforts should track TB-related discrimination and stigma, with priority settings guided by TB key and affected populations.

- Ensuring people-centered and rights-based TB services at health facilities. Training and other engagement with health care workers focusing on stigma reduction, health communication, the importance of informed consent, confidentiality and privacy and other rights of people with and affected by TB and medical ethics. Key to these activities is sustained support to health care workers beyond the moment of training, for example through supportive supervision, mentoring and counselling.

- Ensuring people-centered and rights-based law enforcement practices. Pre-service and in-service training and other engagements with police to raise awareness of issues such as those mentioned in "access to justice" below. Should ideally include meaningful participation of persons affected by TB.

- Legal literacy ("Know your rights"). These programs for people affected by TB and health care workers may be especially useful for marginalized people already prone to exclusion from services, or people subjected to involuntary isolation. Efforts to ensure access to legal services may complement these programs.

- Increasing access to justice. It may include legal or paralegal assistance, ideally peer-led and community-based, to address breaches of medical confidentiality and privacy, unfair dismissal or exclusion from work and educational opportunities, stigma and discrimination and compulsory treatment or involuntary isolation.

- Monitoring and reforming policies, regulations and laws. This can include advocacy to reform health regulations, policies and laws which hinder access to TB services, including but not limited to policies on involuntary isolation according to WHO guidance. Advocacy, in particular community-led advocacy, to increase access to social protection and TB-associated disability services through policy and legal reforms should be supported. Awareness raising efforts with members of judiciary and parliamentarians should be included here.

- Addressing the needs of people in prisons and other closed settings. People in prison and pretrial detention have the right to access health services equivalent to those in the community and to services that are respectful and accountable. Applicants may also seek support to advocate for less reliance on pretrial detention and other measures to reduce prison overcrowding.

- Reducing TB-related gender discrimination, harmful gender norms and violence. This might include assessing gender-related barriers to services, including through community consultations; CLM; sensitization of community leaders, women, men, trans and gender diverse groups, on harmful gender norms that can impede access to care.

- Community mobilization and advocacy, including support to TB survivor-led groups to strengthen community accountability, including CLM which can document stigma and discrimination in health care and other settings: breaches of medical confidentiality, unlawful imposition of user fees, and unfair exclusion from work and educational opportunities based on TB. Building the advocacy and mobilization capacity of groups led by TB-affected persons is essential.

3.10 New products and innovations

The new Global Fund Strategy places greater focus on accelerating equitable deployment of and access to innovations, working with partners to take an end-to-end view to rapidly address bottlenecks to deployment and scale up, ensuring access to those most in need. To achieve this, it is important to implement and scale up innovative tools and models of care for TB in a timely manner. Table 3 highlights potential new products supporting TB care during the 2023-2025 funding cycle.

Along with new products, non-product innovations in TB care, including in specimen collection and processing, integrated services and quality improvement throughout the care cascade, integrated treatment decision algorithm, digital community-led monitoring and innovative financing amongst others are foreseen.

Applicants are encouraged to include the most recent innovations and tools in their funding requests. Prioritization of the new product or innovation should be guided by due consideration of value for money to be cost-effective, affordable, feasible and substantiable given the country's context. By working with partners, the Global Fund can support countries with preparedness, demand estimation, transition planning and scale up of new guidelines, innovations in care and new products throughout the grant cycle.

Table 3: Potential New Products in TB Care during 2023-2025

	Screening	Diagnosis	Treatment	Prevention
Objective	Systematic screening of high-risk groups	Early diagnosis of all people with any form of TB (DS-TB and DR-TB)	Prompt initiation of, and adherence to appropriate treatment for all people with DS-TB and DR-TB	Prevention and treatment of TB Infection
Innovations and tools for inclusion in funding request	• Digital CXR with or without CAD software • TB antigen-based skin tests	• mWRD • LF-LAM for people living with HIV • LPA for first and second-line TB drugs	• All-oral DR-TB regimens, including 6-month regimens • 4-month DS-TB regimen for children with non-severe TB • Pediatric FDCs and formulations for all forms of TB treatment • Digital adherence technologies	• New shorter, combination therapies (3HP, 1HP and 3HR)
Potential new products within the grant period		• New LF-LAM technologies • Next generation mWRD • New sampling techniques (e.g., tongue swabs)		• Pediatric formulations and FDCs of HP regimens

3.11 Strategic information

The Global Fund promotes data-driven decision-making, enabled by the rapid generation, analysis and use of high-quality disaggregated data. TB programs are still hindered by lack of timely, complete and accurate data. Surveys and assessments are needed to understand the burden of TB, the existing barriers to accessing TB services and other data to inform prioritization and evidence-based programming. Financial data supported through strengthened public financial management systems are key to support strategic planning and efficient and effective program implementation (Annex 3 of VfM Technical Brief provides additional guidance). Operational research is important to assess progress in program implementation and performance, inform improvement of quality and coverage of TB services and test innovations. The RSSH Information Note covers detailed guidance on the essential health management information system (HMIS) and M&E investments and links to additional tools and resources. Applicants should do a thorough assessment of their M&E systems, identify data and system needs and request funding to fill the critical gaps.

Applicants are encouraged to consider the following priority interventions:

- Deployment, scale-up and maintenance of real-time, digital case-based TB disease surveillance systems that are interoperable and able to monitor individual TB cases throughout the care continuum, based on country context and digital readiness.
- Disaggregated data at least by age, sex, place of residence along with socio-economic status and key and vulnerable populations groups where possible, to allow for better understanding of the disease burden and gaps in service delivery to inform differentiated response. Use of a national case-based digital surveillance system will facilitate recording, analysis and use of disaggregated data.
- Build in-country capacity and support for:
    i. Timely data generation, reporting, data analysis and use by local health staff of their own data (e.g., care cascade analysis).
    ii. Inform prioritization, planning and implementation at national, sub-national and health facility levels.
- Private sector, community health services and community led monitoring data reporting and quality assurance, integrated in the national TB program and HMIS.
- Operational research studies to gather evidence to improve access to and quality of services and test new tools and innovations to accelerate implementation and improve services and performance. This may include generating evidence to inform approaches that will address barriers to improve uptake of TPT, modified treatment regimens when this is in line with WHO guidance.
- Population-based and facility-based TB surveys that seek to generate information on prevalence, morbidity, mortality, service coverage and bio-behavioral aspects of the general populations or key populations at risk. Surveys are usually supported jointly with other international agencies and domestic resources when the use of the limited resources that are available clearly justifies the costs.
- Program and epidemiological reviews, surveillance, programmatic and readiness assessments and evaluations, the result of which is needed to design and monitor interventions to improve the availability, accessibility, acceptability, affordability and quality of TB services.

- Activities that strengthen systems for generation of financial data and use to inform costing, budgeting and intervention prioritization for strategic planning and resources tracking to monitor program implementation, improving value for money of investments.

3.12 Program essentials for Global Fund supported services

Program essentials for Global Fund supported TB investments (Table 4) define the essentials for selected TB services, which are considered critical to accelerate the TB response to meet the goal of the new Global Fund Strategy and other global TB targets. These are derived from the latest WHO recommendations and other international guidance and represent a summary which best aligns with the key priority interventions listed in Section 3.1 to 3.11 of this document and the Global Fund's Modular Framework Handbook.

Program essentials are expected to facilitate and support countries to develop and implement high-quality, equitable and impactful programs based on the country's context and priority.

As a new requirement in the 2023-2025 allocation period, applicants will outline in their funding requests how advanced the country is in the implementation of each of the program essentials. In situations where program essentials have been prioritized in funding requests, the Global Fund will support countries throughout the grant lifecycle in achieving and sustaining them.

Program essentials will be operationalized in the following ways:

- Grant applicants are expected to consider program essentials throughout the grant cycle: during country dialogues and funding request development, during grant negotiation and implementation.
- Establish a baseline and monitor progress against the program essentials as a part of routine reviews of the grant portfolio and performance framework.
- Identify bottlenecks, implement measures to address these, and mobilize additional resources needed to make progress in meeting the program essentials.
- Countries are encouraged to establish national program essentials for TB services, institutionalize the use of quality assurance tools, and monitor performance against the essentials as a part of routine supervision and TB program review.
- Institutionalize the use of quality improvement methods that empower program staff to address quality challenges in areas that fall short of meeting program essentials.

Table 4: Program Essentials for Global Fund Supported Services

1. TB screening and diagnosis
1.1 Systematic TB screening is provided for those at highest risk (key and vulnerable populations), including using Chest X-rays with or without computer-aided detection (currently recommended for people aged 15 years and older).
1.2 Multiyear plan to achieve universal use of rapid molecular assays as the initial test to diagnose TB for all people with presumptive TB, with implementation on track.
1.3 All people with bacteriologically confirmed TB are tested for at least rifampicin resistance and for those with RR-TB further tests are conducted to rule out resistance to other drugs.
1.4 TB diagnostic network operates efficiently to increase access to testing and includes specimen transportation, maintenance of equipment, connectivity solutions, biosafety, quality assurance and supply system.
2. TB treatment and care
2.1 Child-friendly formulations, all-oral regimens for DR-TB, and 4-month regimen for non-severe, DS-TB are used for TB treatment in children.
2.2 People with DR-TB receive shorter, all-oral regimens or individualized longer treatment regimens as recommended by WHO and people-centered support to complete their treatment.
3. TB prevention
3.1 TB preventive treatment (including shorter regimens) is available for all eligible people living with HIV (adults and children) and for all eligible household contacts of people with bacteriologically confirmed pulmonary TB.
4. TB/HIV collaborative activities
4.1 All people living with HIV with active TB are started on ARV treatment early as per recommendations.
5. Cross-cutting areas
5.1 Establish, progressively scale-up and maintain a comprehensive, real-time, digital case-based TB surveillance systems and ensure analysis and use of TB data for decision-making at all levels of TB services.
5.2 Prioritized interventions are informed by cascade analysis throughout the pathway of TB care, including for TB preventive treatment.
5.3 Engagement of private health care providers is on a scale commensurate with their role in the provision of TB services.
5.4 Decentralized, ambulatory, community- and home-based, people-centered services are provided across the continuum of TB care.
5.5 All TB programming must be human rights-based, gender-responsive and informed by and respond to analysis of inequities; and include stigma and discrimination reduction activities for people with TB and TB-affected populations; legal literacy and access to justice activities; as well as support for community mobilization and advocacy and community-led monitoring for social accountability.

3.13   Global Fund catalytic investments

Global Fund catalytic investments support programs, activities and strategic initiatives that complement country allocations and that are essential to achieve the aims of the Global Fund Strategy and global partners. There are three modalities for catalytic investments:

- Matching Funds to incentivize programming of country allocations for priority areas.
- Multicountry approaches for critical, pre-defined multicountry priorities in geographic regions.
- Strategic Initiatives that support the success of country allocations but cannot be funded through country grants.

Workstreams and the amount allocated for the different catalytic investment modalities for the current 2020-2022 funding cycle can be found on the Global Fund website.

Priorities for TB for 2023-2025 funding cycle are:

- Matching Fund: find and successfully treat the missing people with drug-susceptible and drug-resistant TB.
- Matching Fund: scale-up TB prevention.
- Matching Fund: country readiness for innovation and quality TB programming.
- Strategic Initiative: technical support to the TB Matching Funds.

Not all Global Fund-supported countries are eligible to receive catalytic investments. Countries that are eligible will be informed and receive further details through their allocation letters.

Tuberculosis Information Note

4. Good Practices

4.1 Country examples and success stories

Countries have adopted innovative practices to address existing challenges while also adapting TB programs to respond to the disruptions caused by COVID-19. Some best practices have been highlighted in the Global Fund quarterly TB updates published on the Global Fund website – October 2021, January 2022, May 2022. For example, Nigeria, a country with high TB burden, has implemented innovative strategies to successfully improve TB case finding, despite the impact of the COVID-19 pandemic. Similarly, Bangladesh has demonstrated a progressive increase in TB case notifications to reach pre-COVID-19 levels, which includes the highest ever notification level for the country in 2021. Bangladesh has implemented innovative measures to address service disruptions and mitigate the impact of the COVID-19 pandemic on TB programs.

Additionally, a recent publication from WHO contains innovative interventions implemented by countries to effectively respond to disruptions of TB services caused or exacerbated by the COVID-19 pandemic. Examples include integrating TB screening in COVID-19 activities in the Philippines, the role of digital treatment adherence tools (99DOTS) in Uganda, and real time public health surveillance projects in three African countries (Kenya, Malawi, Zimbabwe).

4.2 Observations from Technical Review Panel (TRP) reviews

TRP releases reports and observations on funding requests submitted to the Global Fund, identifying key trends, lessons learned and recommendations for each of the three diseases, RSSH, human rights and gender, strategic investments and sustainable finance.

Observations related to TB funding requests from the 2020-2022 TRP report are noted below with the full report accessible through this link. Applicants are encouraged to go through the report and observations related to strategic focus, technical soundness and potential for impact, for guidance in preparing future funding requests. This and other reports from current and past TRP reviews are available here.

- Many TB programs maximized synergies with COVID-19 through bi-directional screenings, digital tools for treatment adherence, accelerating existing tools and innovations, such as GeneXpert and computer-aided diagnosis and deploying TB community members trained to also respond to COVID-19.
- The TRP appreciated that there was a TB cascade analysis in most funding requests and gradual improvement of TB diagnostic and treatment services. While funding requests showed increased prioritization of policies and guidance on TB prevention, the TRP is concerned that implementation of TPT, especially shorter regimens, remains low.

- Applicants are encouraged to access more support to plan and implement interventions to prevent TB, diagnose, and retain key and vulnerable populations in treatment and care, using detailed situational and data-driven analysis.
- Data and approaches for pediatric TB also need more attention, including availability and use of pediatric TB treatment, health care worker training to identify pediatric TB, robust contact investigations that include children and widespread adoption of TPT.
- The TRP is concerned that relatively few civil society and community-led TB organizations are mentioned in the development of TB funding requests and/or implementation. Community mobilization requires more investment, with greater attention to community health workers (CHWs) for TB and community health activities.

List of Abbreviations

aDSM	Active drug safety monitoring and management
ART	Antiretroviral therapy
BPaL	Bedaquiline, Pretomanid and Linezolid
BPaLM	Bedaquiline, Pretomanid, Linezolid and Moxifloxacin
CAD	Computer-aided detection
CLM	Community-led monitoring
CRG	Community, rights, and gender
CXR	Chest X-rays or chest radiography
DR-TB	Drug-resistant tuberculosis
DSD	Differentiated service delivery
DST	Drug susceptibility testing
DS-TB	Drug-susceptible tuberculosis
FDC	Fixed-dose combination
FL-LPA	First-line line probe assay
HMIS	Health management information system
1HP	1-month Isoniazid and Rifapentine
3HP	3-month (12 doses) Isoniazid and Rifapentine
1HR	1-month Isoniazid and Rifampicin
IGRA	Interferon-gamma release assays
IPC	Infection prevention and control
IPT	Isoniazid preventive therapy
6-Lfx	6-month Levofloxacin
LPA	Line probe assay
LF-LAM	Lateral flow urine lipoarabinomannan assay
mWRD	Molecular WHO-recommended rapid diagnostic tests
M&E	Monitoring and evaluation
MDR-TB	Multi-drug resistant tuberculosis
NCD	Non-communicable Disease
NSP	National strategic plan

Tuberculosis Information Note

NTP	National tuberculosis programs
PPE	Personal protective equipment
RSSH	Resilient and sustainable systems for health
RR-TB	Rifampicin-resistant tuberculosis
SDG	Sustainable development goals
SL-LPA	Second-line line probe assay
TB	Tuberculosis
TB-LAMP	Tuberculosis loop mediated isothermal amplification
TPT	Tuberculosis preventive treatment
TST	Tuberculin skin test
TRP	Technical Review Panel
UHC	Universal health coverage
WHO	World Health Organization