
Tuberculosis Information Note

JULY 2019

Table of Contents

1. Introduction	3
1.1 Purpose of the document	
1.2 Background	
2. Key considerations	4
2.1 Find the “missing” millions	
2.2 Maximize impact against TB	
2.3 Systems for health – accelerate progress towards universal health coverage through the provision of people-centered health services for TB	
2.4 Improve program quality	
2.5 Use data for action and operational research	
2.6 Engaging private providers	
2.7 Advocate for increased programmatic and financial resources	
2.8 Joint programming and collaborative activities	
3. Other critical areas for consideration during funding request development	15
3.1 Lessons learned from the two allocation-based funding cycles	
3.2 Efficiency	
3.3 Challenging Operating Environments	
3.4 Key populations	
3.5 Addressing human rights and gender-related barriers to accessing TB services	
3.6 Community system strengthening (for community-led and -based responses)	
3.7 Sustainability and transition considerations	
3.8 Technical support and capacity building	
3.9 Antimicrobial Resistance	
3.10 New diagnostics, new drugs and treatment regimens and innovative digital technologies	
3.11 The funding situation	
3.12 The Global Fund Strategy	
4. Key References	26
5. List of Abbreviations	28

1. Introduction

1.1 Purpose of the document

This Information Note provides guidance to applicants preparing a Global Fund request for tuberculosis (TB) funding. It makes recommendations on setting priorities and targets for TB interventions that will achieve the highest impact. It promotes strategic investments to save lives and achieve economic benefits, based on the country's TB situation and other contextual factors including the health system:

- Its TB profile: both drug-susceptible [DS-TB] and drug-resistant TB [DR-TB];
- The health system context of the country.
- Existing human rights and gender-related barriers and;
- Socio-economic and other structural barriers to accessing TB services

The note is also useful for countries preparing or revising their TB national strategic plans (NSP).

1.2 Background

The effort to end TB is at a critical stage with global momentum expected to accelerate after the first-ever UN High-level Meeting (UNHLM) on TB held in September 2018, when heads of states and governments, with the support of the global TB community, implementing countries, civil society and affected communities, endorsed a [Political Declaration on TB](#).

The UNHLM Political Declaration on TB contained a number of global targets, including to successfully diagnose and treat 40 million people, including 3.5 million children and 1.5 million people with DR-TB between 2018 and 2022. The declaration also sets ambitious targets for TB prevention for those most at risk of falling ill, including rapid scale-up of access to testing and provision of preventive treatment for at least 30 million people by 2022.

To achieve these ambitious targets, the declaration recognizes the importance of:

- Addressing human rights and gender-related barriers;
- Strengthening and utilizing public health systems as an essential pillar of the TB response;
- Achieve a robust multisectoral partnership including through implementation of the [Multisectoral Accountability Framework](#);
- Support the role of the private sectors and communities to achieve an effective TB response.

[FIND.TREAT.ALL. #ENDTB](#) is a joint initiative of the WHO, Stop TB Partnership, the Global Fund, countries and partners to support the ambitions expressed in the UNHLM Political declaration. The initiative prioritizes enabling access to quality TB care for the millions who miss it each year, focusing on the [30 high burden TB countries](#). Countries will also be encouraged and provided technical support to set up high-level national taskforces, or leverage existing mechanisms, to ensure effective implementation and monitoring of this joint initiative. The taskforce/existing mechanism will bring together implementers and stakeholders to support the tracking of progress and act as an advocacy forum/ platform to learn best practices and innovations. All countries are encouraged to reflect these efforts in their upcoming strategic plans and funding requests to the Global Fund.

2. Key considerations

The Information Note contains descriptions of:

The Global Fund's strategy;

- Lessons learned during the first two allocation-based Global Fund funding cycles;
- Priority areas for TB prevention, care and treatment;
- Recommendations on how to define or identify TB key or vulnerable populations; and
- How to set priority TB interventions to achieve the highest impact.

The note also:

Encourages investment in innovative interventions based on evidence of effectiveness and/or efficiency;

- Highlights how investments on TB can be leveraged to build resilient and sustainable systems for health (RSSH) to support the planning, financing and delivery of health services.
- Complements other guidance and tools from partners for TB strategic planning and interventions including the [End TB Strategy](#), the [Implementing the End TB Strategy: the essentials](#), and the [Global Plan to End TB: The Paradigm Shift 2016-2020](#).

The Global Fund encourages countries to include in their funding requests, the priority and key TB interventions contained in **Box 1** below, subject to:

- Country and epidemiological contexts;
- Lessons learned;
- Local good practices;
- Challenges and limitations documented during implementation of previous grants; and
- International recommendations based on recent evidence.

Implementation of key interventions listed in **Box 1** requires close collaboration of all stakeholders: public/government sector, civil society, private sector and communities.

The [Global Fund strategy 2017-2022](#) provides clear direction on how to differentiate the approach to investments, better work in challenging operating environments, incorporate gender considerations into investments, focus on eliminating human rights barriers, and sustain the gains.

Lessons learned during the two allocation-based funding cycles including the Global Fund [Technical Review Panel's](#) observations and recommendations should also be considered during prioritization for scale-up of best practices, innovations and evidence-based programming.

In preparing the funding request, to maximize the impact of investments, it is essential to:

1. Plan for sustainability and continuity of key interventions that have been successful under previous grants, while improving prioritization and strategic focus.
2. Prioritize interventions that will address priority areas to increase efficiencies in the health system;
3. Scale-up and efficiently and effectively utilize new diagnostics, new drugs, shorter regimens, pediatrics formulations, TB preventive treatment (TPT) and innovative approaches that maximize impact.

Applicants are strongly advised to review the most recent technical and normative guidance listed at the end of this document. The guidance allows the identification of high impact interventions and promotes the scale-up of evidence-based, local and regional good-practices, innovations and successful pilot projects.

Box 1: Summary of high-impact TB interventions

- **Early diagnosis of all people with any form of TB (DS-TB and DR-TB).** Providing access to people who need TB screening, diagnosis and drug-susceptibility testing (DST). This includes improved access and utilization of quality-assured diagnostics such as Xpert MTB/RIF as the initial TB diagnostic test, X-ray (digital x-rays) for screening, engagement of private providers and implementation of functional diagnostic networks. Within health care settings, active case finding and intensified case finding coupled with a robust specimen transport system are needed to ensure people with presumptive TB access early diagnosis when they initially seek care at any point in both the public and private health care sectors.
- **Systematic screening of high-risk groups including through outreach and community-based approaches and using digital x-rays and rapid and more sensitive diagnostics.** This includes all contacts of people with TB, PLHIV and workers exposed to silica dust, prisoners, migrants and people living in urban slums and remote rural areas. Contact investigation should aim to not only diagnose additional people with TB but also as an entry point for provision of TPT for eligible contacts.
- **Prompt initiation of appropriate treatment for all people with DS and DR-TB, using a people-centered approach and with patient support.** Treatment should be provided to all who need it regardless of age, gender or type of TB disease, bacteriological status, comorbidities or legal status. Ensuring all people with TB have access to free-of-charge life-saving treatment is fundamental to minimizing disease and deaths due to TB and interrupt transmission. This includes all-oral regimens for treatment of DR-TB and child-friendly formulations for children with active TB. All people enrolled on treatment should also receive appropriate support including digital adherence technologies and follow-up care and support to ensure successful treatment outcome.
- **Programs and approaches to address access barriers, including community-based and integrated services delivery.** Scale-up programs to support integrated community and family-based approaches to diagnosis, treatment, prevention and care to remove access barriers, reduce delays in diagnosis and improve management of TB/DR-TB. This include scale-up of rights-based, gender responsive programming, innovative quality improvement approaches for the delivery of people-centered health services, with consideration of proven in-country experiences (for example, demonstrated through Global Fund, domestic or partners supported projects). Removing stigma and discrimination based on TB status and improving access to TB information including through community involvement, community monitoring and social accountability for early TB diagnosis and improved treatment outcomes.
- **TB/HIV Collaborative activities.** A significant reduction of TB incidence and elimination of HIV-associated TB deaths can be achieved by adopting and scaling up policies that ensure integrated, patient-centered delivery of effective prevention, early diagnosis, and prompt treatment of TB and HIV. This requires intensifying collaboration between TB and HIV programs, integration of TB/HIV services, joint programming, implementation, supervision and monitoring. HIV testing of all people with TB, screening of PLHIV for TB, provision of ART, Cotrimoxazole preventive treatment and TB treatment for PLHIV with active TB and provision of TPT for PLHIV (including INH and 3HP/3RH). Multi-disease platforms such as GeneXpert are good opportunities to strengthen collaboration and synergize efforts while contributing to building RSSH. As TPT to eligible PLHIV is implemented through HIV programs, funding should be leveraged from HIV grants as well. Scale-up of the latest WHO-recommended diagnostics such as Xpert MTB/RIF and LF-LAM within HIV settings will improve diagnosis of HIV-associated TB. Alignment and synergizing with PEPFAR-supported TB/HIV activities are critically important.

- **Private Sector TB Care.** In some countries, most of TB/DR-TB patients consult private providers for their TB-related symptoms. Private care providers include general practitioners, physicians, private pharmacies, private laboratories, traditional healers, and others. Engagement of these care providers in TB diagnosis, treatment and prevention is very critical. Innovative approaches to engage and collaborate with them including through involvement of interface agents and by providing incentives should be explored and integrated into the effort in fighting TB. Mandatory notification and simplification of the recording and reporting system including through electronic/digital systems facilitates engagement of private providers and maximizes their contribution to ending TB.
- **Prevention and Treatment of TB Infection.** Ending TB transmission in institutional, community and household settings is critical. An estimated 1.7 billion people with TB infection will remain as the main source of active TB. Therefore, ending TB without addressing this group will be difficult. Countries should include treatment of TB infection in their list of priority interventions to high-risk groups such as PLHIV and all household contacts of people with pulmonary TB. Moreover, TPT should be considered as an extension of efforts for early TB case finding including contact investigation in all settings. This includes scale-up of the use of the new combination drugs (such as 3HP and 3RH) including through financial support from domestic sources, Global Fund and PEPFAR. Resources are also needed to interrupt transmission and prevent TB infection.
- **Antimicrobial resistance (AMR) poses a great threat to the fight against infectious diseases including TB and remains a major concern for global health security.** TB accounts for over a third of deaths from AMR. Prevention and control of infection is a core component of the response to AMR and requires concerted and integrated responses including as part of RSSH and disease programs. Early diagnosis and appropriate treatment of DS and DR-TB and TPT contribute to mitigating the threat from AMR.
- **Management of Co-morbidities.** Co-morbidities and health risks associated with TB are important and require integrated patient management. This include undernutrition, diabetes, alcohol or drug misuse, tobacco smoking, silicosis, chronic obstructive pulmonary diseases and other non-communicable diseases including mental health problems. These conditions constitute risk factors for TB and can complicate TB diagnosis, treatment and prevention.
- **Surveillance, Data and Operational Research.** Quality data are required to inform prioritization, monitoring and decision-making. Strengthening TB surveillance systems including through integrated and electronic/digital recording and reporting systems and intensifying connectivity solutions for diagnostics are essential, and countries should progressively develop systems to generate and use case-based and real-time electronic data at all levels. Disaggregated data by age and sex allow better understanding of the disease burden and gaps in service delivery and design differentiated responses. Platforms such as district quarterly review meetings or national annual reviews, whereby surveillance data and findings of operations research would be discussed, successes and gaps identified, and evidence-based actions developed are crucial. Targeted surveys such as cost surveys and inventory studies are critically important. Local capacities including through conducting operational research should be developed to use data at sub-national, facility and community levels, to inform decision making and improve performance and service delivery.
- **Digital Technologies:** These offer cross-cutting solutions for a broad array of activities central to ending TB efforts, including patient care (e.g. digital adherence technologies like medication monitors and video-supported therapy, artificial intelligence to read digital x-rays), surveillance and monitoring (e.g. electronic recording and reporting), program management and eLearning.

2.1 Find the “missing” millions

Of the estimated 10 million people who become ill with TB each year, more than 3.5 million are “missed” because they are not diagnosed, diagnosed but not treated or treated but not officially notified by national TB programs (NTP). Figures for DR-TB show a worrying trend of over 75 percent of people with new DR-TB having been “missed” in 2017. Due to challenges in diagnosing TB among children, limited skilled human resources and suboptimal TB diagnostic tools in this age group, the percentage of missed cases in this population was 69 percent among under-fives and 40 percent among children 5 to 14 years.

Collectively, these “missed” millions are a global public health failure and a top priority for the global TB response. The TB epidemic cannot end unless the missing people with TB are reached, diagnosed, notified and successfully treated. As a first step, critical analysis or operational research would help understand who these missing people are, where they are and why they are missed.

Securing availability and accessibility of quality TB services for all, addressing barriers to access, implementing interventions to address stigma and discrimination, targeting communities and people most affected by TB are essential to ending the TB epidemic. While utilization of existing tools and services should be intensified and maximized, new and innovative approaches, diagnostic tools and technologies including molecular testing, digital x-rays and novel ways of engaging communities and private sectors are required to reach the missing people.

Lessons learned in finding these cases include undertaking prevalence and other surveys and implementing innovative approaches to finding these cases using the example of the [Global Fund’s TB Catalytic Investment](#) which focuses on the 13 selected countries that account for 75 percent of missing people with DS-TB and 55 percent of DR-TB globally. Other initiatives can be considered to inform the prioritization process. As part of the Global Fund’s Catalytic Investment, [a website for sharing experiences](#) and a compendium of tools have been developed to guide efforts in finding the missing people with TB and it includes newsletters, case studies and e-learning modules.

Box 2: Lessons learned from Catalytic Investment for finding missing people with TB

The Catalytic Funding (including matching fund and Strategic Initiative [SI] and multi-country grants) on 'Finding Missing People with TB' was launched in 2017. Through SI, Stop TB Partnership and WHO support countries to find the missing people with TB, by: addressing barriers, developing tools and approaches and the uptake and scale-up of tools including documentation and sharing lessons learned.

Through supporting the countries, the SI aims at finding and treating an additional 1.5 million missing people with TB by 2019, and the initiative has generated momentum worldwide, with the following lessons learned:

- Continuous review of progress towards reaching target has been key for finding more cases
- Countries have shown considerable progress in improving TB case notifications.
- Implementation of innovative approaches and focus on private sector particularly in Asia and quality improvement of practices at health facilities and communities in Africa has been key for finding cases.
- Urgent need to generate and use data at both national and sub-national levels to inform policy and decisions.
- The available [tools](#) developed through the Strategic Initiative will help guide countries during development of funding requests and implementation.
- Making TB diagnosis available in primary health care level in both public and private sectors including through effective sample transportation systems and implementing this approach systematically.

2.2 Maximize impact against TB

The Global Fund will continue to invest in programs that promote the urgent scale-up of diagnosis, prevention and treatment efforts while addressing access barriers both in populations with the greatest burden of disease as well as in areas with growing epidemics. Investments will support epidemiologically appropriate interventions that are evidence-based, scalable, and context-specific. They should also be locally driven and delivered with full adherence to the protection and promotion of human rights, gender-responsive and people-centered approaches. Additional focus should be on reaching the “missing” people with TB including DR-TB.

2.3 Systems for health – accelerate progress towards universal health coverage through the provision of people-centered health services for TB

Programs need to be anchored in universal health coverage (UHC) processes to maximize equitable access to TB/DR-TB services. All people with TB or at risk of developing TB should receive the quality, accessible and affordable prevention, diagnosis, treatment and care services they need without suffering financial hardship. To move towards UHC, countries should make use or capitalize on RSSH that are able to respond to emerging epidemics and provide efficient and effective, integrated, people-centered health services to end TB ([WHO Framework on integrated, people-centred health services](#)).

Many health systems are constrained by inefficiencies, fragmentation and being chronically under-resourced which impacts the delivery of basic primary health care and the ability to deliver high-

quality TB services. System-wide weaknesses collectively impede the delivery of health services in many countries. These can be; health workforce shortages, fragmented health management information systems, poor accountability mechanisms, weak national health product management and supply chain systems that contribute to stock-outs at point of care.

These weaknesses would also lead to specific and significant system bottlenecks for TB programs including; the absence of regulatory mechanisms essential to ensuring effective TB infection prevention and control; the irrational use of TB diagnostics (including continued use of old and insensitive diagnostic tests) and medicines; the absence of mandatory disease notification and more importantly absence of modern, electronic and easy systems for notification especially among private care providers. These weaknesses lead to public sector health governance that focuses primarily on public providers thereby excluding private providers from supervision, linkage to diagnosis and treatment and quality improvement initiatives; supports poorly functioning vital registration systems, and provides minimal protection of the legal rights of people with TB.

Requests for RSSH support should be:

- Based on a joint identification of needs across diseases while addressing health system issues that are bottlenecks in the critical pathway to success.
- Included either within disease-specific funding or as stand-alone.
- Aligned with the specific approaches summarized in the RSSH Information Note (at [this landing page](#)) that outlines guidance on investments in the following areas: (i) health sector governance and planning; (ii) community systems strengthening to support community response; (iii) procurement and supply chain management systems; (iv) health management information systems and monitoring and evaluation (M&E); (v) human resources for health (HRH) including community health workers; (vi) integrated service delivery and quality improvement; (vii) laboratory systems strengthening, and (viii) financial management system.
- Formulated in a way that supports the needs of TB programs and cross-cutting health system issues that are bottlenecks to service delivery overall.
- Used to alleviate service delivery constraints faced by TB and other diseases, increasing the effectiveness, efficiency and sustainability of the programs and facilitating the strengthening of the national health system.

High out-of-pocket payments can also lead to inequitable access to health services, and undue economic burden on the poor. This hardship is compounded by the lack of social protection mechanisms to address associated catastrophic costs including income loss and non-medical costs. As such, improving access to health care through better health financing and social protection systems remains a global priority.

2.4 Improve program quality

A key component of the 2017-2022 Global Fund Strategy is mainstreaming program quality. This includes adopting and implementing quality improvement approaches across the entire cascade of TB care, screening, diagnosis, treatment, care and contact investigation. Healthcare services need to be safe, effective, timely, efficient, equitable, affordable, available, accessible, integrated and people-centered.

TB services should be accessible to special populations at increased risk, such as PLHIV, people with diabetes, prisoners, children and adolescents, mining workers, mobile population and people living in over-crowded conditions and extreme poverty. This can be achieved, for example, by adapting models of care that better serve these populations.

Community-led and based programs to reach hard-to-reach populations with TB information, diagnosis and treatment adherence support are critical components to improve service quality. Improving treatment outcomes, especially of people with DR-TB, is also critical to the global effort and response to AMR.

Scale-up of use of new regimens, including modified shorter all-oral regimens for DR-TB, is an opportunity to accelerate decentralization, people-centered treatment and improve outcomes by among other effects, reducing medicine adverse events. This includes packages of care to support adherence, and active TB drug safety monitoring and management systems (aDSM).

Countries are encouraged to transition to the new regimens as soon as possible, including potentially utilizing operational/implementation research approaches for the introduction of shorter all-oral regimens, and models to promote patient-centered care. This also includes procurement and use of quality drugs. As such, countries are encouraged to procure TB medicines through reliable mechanisms and sources such as the Global Drug Facility (GDF). Applicants may also leverage RSSH investments to strengthen the development and use of tools and quality improvement approaches for the provision of high quality integrated, people-centered health services.

2.5 Use data for action and operational research

Long-term and systematic investments in routine data systems are needed to improve the availability and quality of data for analysis and use in strategic decision-making. High-quality data systems are also needed to provide capacity for better targeting of programs and improving the quality and efficiency of the investment. Countries are encouraged to develop and use existing validated electronic and digital recording and reporting systems so that case-based and real-time data is available to inform decision making at different levels. Countries are strongly encouraged to report disaggregated data (such as by age, gender and HIV status). Furthermore, it is important that NTPs plan to invest in strengthening regular in-country reviews and data use to understand what is and is not working well at various levels, and to inform decisions around improved program performance, quality, efficiency and impact. Applicants should include sufficient funding for their annual or semi-annual reviews at national and quarterly reviews at sub-national levels.

Operational research is important to assess progress in program implementation and performance, identify challenges, inform planning for improvement of quality and coverage of TB services. It should also be conducted when implementing new, innovative interventions for which evidence of impact is incomplete (including use in a very different context from the one in which it was studied) in order to generate more evidence and inform future policy and guidance development.

There is a need to build in-country capacity, including through the engagement of local health staff in actively using their own data, and promoting the use of data to drive planning and implementation at sub-national and health facility levels. The analysis will support the setting of sub-national targets, understand sub-national differences in disease burden and performance, and inform targeted service delivery to at-risk populations to provide a differentiated response.

[TB patients cost surveys](#) provide information on cost barriers to accessing TB services. These should be carried out periodically to inform planning and implementation of interventions intended to eliminate catastrophic costs and to link TB patients with financial safety nets.

[Inventory studies](#) would be useful for assessment of underreporting of TB cases, especially among private providers and can lead to appropriate action as was done in Indonesia in 2018/19. Qualitative

assessments to understand providers' and patients' perceptions, as well as gender and human rights-related barriers, should inform program design and implementation.

The Global Fund Operational Policy Note on Program and Data Quality in the [Global Fund Operational Policy Manual](#) provides guidance on monitoring and evaluation requirements and processes with regards to ensuring program and data quality in Global Fund-supported programs. It outlines the different assessment options and tools available to better identify and manage risks within grants that may prevent the achievement of grant objective.

2.6 Engaging private providers

As highlighted in the public-private-mix (PPM) Landscape Analysis ([Global TB report, 2018](#)), 62 percent of the 3.6 million “missing people” with TB lived in seven countries in which private providers accounted for more than two-thirds of patients initial care-seeking. However, in these countries, private for-profit providers contributed just 19% of the total TB notifications, which is equivalent to only 12% of the estimated TB incidence in 2017.

Global Fund support for PPM activities in these countries has more than doubled during the second funding cycle, with new principal recipients added in some of the countries. To close treatment coverage gaps and ensure early access to diagnosis and treatment, strengthened and expanded engagement of private (for- and not-for-profit) providers is required. Innovative approaches to engage and collaborate with private care providers should be explored and integrated into efforts to fight TB; this can include the use of interface agents, as is being implemented in India and others, providing monetary and/or non-monetary incentives, among other approaches. Mandatory notification and simplification of the recording and reporting system, including through the use of digital systems, facilitates private provider engagement and maximizes their contribution to ending TB.

These interventions may also be applicable to countries other than those seven countries, where the engagement and the contribution of private health care providers are important.

Several countries, including India, Pakistan and Bangladesh, have good lessons learned from engaging the private sector in pilot projects. Other countries could also benefit from sharing those experiences. Strategies for engaging the private sector providers are outlined in the [PPM roadmap](#), a [Stop TB field guide](#), and in a [concept note guiding TB REACH applicants](#).

2.7 Advocate for increased programmatic and financial resources

There is an enormous gap in funding for TB, including for research and development. As new tools, treatment regimens and innovations are introduced, more financial resources are needed to improve uptake, scale-up interventions and optimize utilization. Mobilizing increased resources is one of the main objectives of the Global Fund Strategy and is required for successful scale-up of the response to TB. Most critical is the increased investment of domestic resources for health, which is the future of sustainable health financing for most countries.

Countries are encouraged to explore and come up with innovative approaches to mobilize additional funding, including domestic resource mobilization (DRM) to ensure funding gaps for the TB response are reduced, and to support the transition from donor to domestic funding.

2.8 Joint programming and collaborative activities

Joint health programming can help countries better target resources and scale-up people-centered services to increase effectiveness, efficiency, quality and sustainability. Countries should critically evaluate what packages of services and models of delivery are most appropriate and feasible for specific contexts, and discuss where, how and by whom they should be provided. Achieving people-centered health services can generate significant benefits in all countries, at every point along the development continuum. However, there is no “one-size-fits-all” model for “integrated” health services, and the approach needs to be adapted and implemented across a variety of service delivery models, settings and target populations.

Integration can take different forms and happen at multiple levels of the health system, including at: the governance level to coordinate strategic and operational planning across various health programs; the health financing level to facilitate improved resource mobilization, pooling and strategic purchasing of health services; the health systems management level, for instance to support national procurement and supply chain systems, health management information systems, laboratory systems, and health workforce. Integrated service delivery also requires a defined package of essential health services for each level of care based on a strong PHC and functional referral system.

At the same time, a good TB program requires certain TB-specific interventions that may not be prioritized in fully integrated health programs. This can include active case finding, symptomatic screening in outpatient departments, contact investigation, and adherence support. If joint programming is planned, it is critical to ensure that attention to such public health TB activities is secured and maintained.

2.8.1. TB/HIV joint programming

To optimize investments in TB and HIV programs and maximize synergies between TB and HIV programs for better health outcomes, countries with a high burden of people with both TB and HIV¹ are required to submit a single funding request that presents integrated and joint programming for the two diseases. This funding request needs to present prioritized, high impact interventions for the TB and HIV programs (including collaborative TB/HIV activities) and provide a detailed description on how the two programs will work jointly to address the burden of TB, of HIV and of co-infection., Countries preparing a single TB/HIV funding request should also consider addressing common health system-related constraints, which impede the successful implementation and integration of TB and HIV programs as well as other cross-cutting areas.

Joint programming allows for better targeting of resources and harmonization of efforts to increase the effectiveness, efficiency, quality and sustainability of TB and HIV programs. Joint programming is an opportunity to strengthen delivery of key services for persons with TB, HIV and TB/HIV co-infection, including regular screening of PLHIV for TB, HIV testing of TB symptomatic people and TB patients, provision of antiretroviral (ARV), co-trimoxazole and TB medicines for PLHIV with TB and provision of TPT (including the recently recommended combination shorter regimens such as 3HP and 3RH) for PLHIV without active TB. Multi-disease platforms, such as GeneXpert, which

¹ *The 28 countries with high TB/HIV burden that are eligible for Global Fund funding are: Angola, Botswana, Cameroon, Central Africa Republic, Chad, Congo, Congo (Democratic Republic), Ethiopia, Ghana, Guinea-Bissau, India, Indonesia, Kenya, Lesotho, Liberia, Malawi, Mozambique, Myanmar, Namibia, Nigeria, Papua New Guinea, South Africa, Swaziland, Tanzania (United Republic), Thailand, Uganda, Zambia, and Zimbabwe.*

could be used for TB diagnosis and HIV viral load determination, provide great opportunities to strengthen collaboration between the two programs. Other TB screening and diagnostic tests, including Digital X-rays and LF-LAM, improve TB diagnosis among PLHIV. There are several models to provide integrated services to TB and HIV patients including “one-stop-shops” although there is no “one-size-fits-all” approach. Opportunities for TB/HIV integration such as addressing the TB case-finding and preventive treatment gaps among PLHIV may be bridged through community-based differentiated service delivery to strengthen adherence and ART care.

Lessons learned from joint TB/HIV funding requests and joint programming showed that the process of developing a single funding request resulted in greater harmonization of the cross-cutting areas. This included procurement and supply chain management, supervision, monitoring and evaluation, and delivery of integrated services for TB and HIV. The need to develop only one funding request also eased the administrative burden of developing the funding request and simplified grant management. A single funding request is therefore suitable for countries that seek efficiencies during the process of applying for and managing grants. However, some weaknesses were identified. Independent disease efforts that were combined only at the stage of funding request submission resulted in limited in-country collaboration between the disease programs during grant making and implementation.

The epidemiology of the local TB and HIV epidemic, maturity and capacity of programs, health infrastructure and management, as well as barriers to care and client needs, should determine the scope and critical areas of joint programming. Efficiencies can be gained at several levels of the programs, from planning and coordination to service delivery, data collection and supervision. This reduces duplication, fosters synergies and targets resources to achieve maximum impact. It also contributes to an increasingly sustainable program response.

For further details, please refer to the Global Fund HIV Info Note and Technical Brief on TB/HIV (at [this landing page](#)), [Global Fund Information Note on HIV](#), the [Global Fund TB/HIV Best Practices/Technical Brief](#), the [UNAIDS/WHO Technical Guidance Note on HIV/TB](#), the [WHO End TB Strategy](#), the [Stop TB Key Population Briefs](#) and the [WHO Guidelines on Latent TB infection](#)

2.8.2. TB and Non-communicable diseases ^{2,3}

Risk-factors such as diabetes, tobacco smoking, silicosis, alcohol and drug misuse, mental health disorders and malnutrition hamper the fight against TB, especially in low- and middle-income countries. In 2017, 1.9 million episodes of TB were attributable to malnutrition, 80,000 to smoking, 790,000 to diabetes and 490,000 to harmful use of alcohol. Thus, addressing these determinants will make a considerable impact on reducing the TB burden.

Conditions such as these, in addition to mental health disorders, increase the risk of poor TB treatment outcomes. The double burden manifests itself through susceptibility of those with NCDs to TB and through the negative impact of NCDs on treatment outcomes for TB. Furthermore, poor and vulnerable populations are the ones most affected by TB. There is a strong association of poverty with major NCD and TB risk factors, such as poor diet, smoking tobacco and substance use disorder, leading to an inequitable impact and a double burden of diseases. In addition to PLHIV and household contacts, people initiating anti-TNF treatment, patients receiving dialysis, patients

² Additional information at: <http://www.who.int/nmh/events/ncd-coordination-mechanism/en/>.

³ https://www.theunion.org/what-we-do/publications/technical/english/TheUnion_DMTB_Guide_October2018_Text_AW_02.pdf

preparing for an organ or hematological transplant, and patients with silicosis should also be systematically tested and treated for TB infection including in specialized settings. Addressing these issues requires integrated and coordinated health services, particularly at the PHC level for developing joint planning and prevention frameworks, and harmonizing funding streams.

Diabetes triples the risk of developing TB. Consequently, rates of TB are higher in people with diabetes than in the general population. Diabetes can worsen the clinical course of TB, and TB can worsen glycemic control in people with diabetes. Early screening and treatment of TB among people with diabetes and early screening and treatment of diabetes in people with TB should be intensified.

Smoking and tobacco use are also associated with increased risk of TB infection, progression from infection to active TB disease, increased disease severity, and increased risk of unfavorable treatment outcomes. In addition, tobacco smoking is also associated with an increased risk of recurrence after successful completion of anti-TB treatment. Therefore, strategies that promote smoke free environments in health facilities, as well as tobacco cessation activities, need to be considered and implemented. In addition, strategies to integrate screening and co-management of the above comorbidities within TB care should be developed and strengthened.

Finally a proportion of patients with chronic pulmonary TB may experience chronic morbidity and complications of TB despite achieving “cure” from TB, and programs should consider how to link such patients to appropriate chronic care services.

2.8.3. Reproductive, maternal, newborn and child health

In countries with a high prevalence of TB, women of childbearing age also carry a heavy burden of the disease. TB is one of the top killers of women of reproductive age. Maternal TB associated with HIV is a risk factor for transmission of TB to infants and is associated with premature delivery, low birth-weight of neonates, and higher maternal and infant mortality. In settings with high HIV burden amongst adolescent girls and women of reproductive age (15-49), integration into large-scale prevention and PMTCT programs is a key strategy for reaching women and their children with TB diagnosis and treatment.

Disaggregated data provides programs with better information on TB in children and adolescents, as they face different challenges in terms of detection and successful treatment outcomes compared to adults. The most obvious point of entry into the health system for many children with TB (or those in contact with someone with TB) is at the community level, where the child’s parent, guardian or other household contacts have been diagnosed with TB or where their care is being managed. Maternal and child health, reproductive health and family planning services provide a reliable platform for delivery of TB, HIV and other services including screening/diagnosis and treatment of TB to women and children. An integrated community and family-based approach to TB care would help remove access barriers, reduce delays in diagnosis and improve management of TB, including the implementation of contact tracing and provision of TPT in women and children. The [roadmap towards ending TB in children and adolescents](#) provides more information on addressing TB among children and adolescent, and the “best practices in child and adolescent TB care” provides useful examples from the field. For further information, see [The Global Fund Reproductive, Maternal, Newborn, Child and Adolescent Health Technical Brief](#).

2.8.4. Underlying social determinants and barriers to TB services

Underlying determinants of the TB epidemic that need to be addressed include poverty and inequity, food insecurity, gender, adverse effects of population movements and complex emergencies, as well as other human rights issues, such as stigma and discrimination. Effective

TB prevention, diagnosis and treatment require strategies to address human rights and gender-related barriers. This should also include actions resulting in poverty reduction, improved nutrition, and better living and working conditions, as well as strategies to address barriers to access and to mitigate the impact of migration, aging populations, and chronic diseases like diabetes that are risk factors for TB. There is a need for better, more nuanced and differentiated understanding of the intersection of gender with TB, especially in the context of TB and HIV/TB among those at increased risk, and generally underserved communities. High out-of-pocket payments can also lead to inequitable access to health services, and undue economic burden on the poor. This hardship is compounded by a lack of social protection mechanisms to address other, associated catastrophic costs, such as income loss and non-medical costs. As such, improving access to health care through better health financing and social protection systems remain global priorities and require collaborative and coordinated efforts.

3. Other critical areas for consideration during funding request development

3.1 Lessons learned from the two allocation-based funding cycles

In 2014, the Global Fund moved to an allocation-based funding model in which each country eligible for funding is allocated an amount of funding for the period. The first allocation-based funding period ran from 2014-2016 and was initially referred to as the New Funding Model. The second allocation-based funding period was 2017-2019.

Overall, the allocation-based funding model has been a successful change in the Global Fund's operational model. It has allowed for bigger impact, more predictable funding, an ambitious vision and a more flexible timeline. Following the first allocation-based funding period (2014-2016, previously called the 'New Funding Model') there were improvements made to the allocation methodology; prioritized above allocation requests (instead of "incentive funding"); differentiated application and review process; further clarity on sustainability and transition; and process simplification to allow more time for implementation.

The Technical Review Panel's (TRP) observations and lessons learned from a review of funding requests (called concept notes in the 2014-2016 allocation cycle) from the first two allocation-based cycles are included in their reports available which is available at [Technical Review Panel](#).

The lessons learned from the second allocation-based funding cycle will be addressed in the upcoming 2020-2022 funding cycle, delivering on the key request from applicants and stakeholders to continue to streamline the process to access funds but not change too much. Countries eligible for Global Fund financing will receive their allocation communication in December 2019. Information about the application process for requesting funding in the 2020-2022 cycle, including the refined application material, can be found on the [Global Fund website](#).

3.2 Efficiency

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

There are multiple ways to improve the efficiency of TB response. One is to improve “allocative efficiency” by allocating limited resources strategically across interventions, geographies and population groups to maximize impact. Countries can complete an epidemiological analysis to identify disease trends and data gaps before submitting funding requests. This focuses investment on the right populations, in the right places, with better support systems. To aid this effort, the Global Fund can support countries in better mapping and estimating the size of key populations.

NSPs should reflect the general principles of allocative efficiency in investment in programs. Namely, they should demonstrate that cost effective and evidence-based interventions have been selected as suitable for the country context; interventions are prioritized given limited resources; and investments are optimally allocated across interventions to achieve maximum health impact. When feasible, the allocative efficiency discussion can be more directly linked to selection and prioritization of the key interventions.

Another way to improve efficiency is to design and deliver services that minimize the cost of producing desired health outputs or outcomes, which is known as technical efficiency. There are many ways to achieve technical efficiency throughout the prevention and care cascades and countries are encouraged to identify and implement innovative ways to deliver services in the most effective and efficient manner for their context. Examples include finding missing cases by targeting high risk populations for testing tailored to the country setting; applying appropriate cost-effective diagnostic technology; identifying a cost-effective mix of inputs for service provision at facility level, such as commodities or human resources; promoting community systems or ambulatory care to scale up patient-centered delivery models; promoting service accessibility, including with cost-effective activities to generate demand for economy of scale for diagnostics and treatment services; and developing effective mechanisms to address common bottlenecks in service delivery, such as stock-outs or health worker constraints.

Efficiency can also be achieved through dedicated efforts to improve health system-level efficiency, known as cross-programmatic efficiency. Countries are encouraged to highlight efforts aimed at improving the alignment, integration, and functionality of the health system, to make services available and efficiently delivered to those in need. This can include by removing duplication, overlaps or misalignment across core functions like financing, governance, inputs, and service delivery.

All types of efficiencies have been embedded into the Global Fund grant-making process. For more detailed information on efficiency, please refer to the Global Fund Value for Money Technical Brief at [this landing page](#).

3.3 Challenging Operating Environments

Challenging operating environments (COEs) are one of the Global Fund’s key focus areas. The Global Fund 2017-2022 Strategy commits to improving the effectiveness of health investments and reaching key populations through increased flexibility, support to innovations and stronger partnerships, all important for work in COE environments.

COE applicants should refer to the [Operational Policy Note on Challenging Operating Environments](#), which includes guidance on access to funding and grant management.

3.4 Key populations

For TB, key populations are people who are vulnerable, underserved or at-risk of TB infection and illness. These key populations vary by country and include people with increased exposure to TB

due to where they live or work, people with limited access to quality TB services, and people at greater risk due to biological or behavioral factors (refer to *Table 1*). These groups are disproportionately affected by the disease, stigma and discrimination, and human rights and gender-related barriers. In all countries, children represent a unique key population- disadvantaged by poor or weak TB diagnostics, without access to economic means, and unable to self-advocate.

The Global Fund places key populations at the heart of its work, including by increasingly engaging key populations in critical decision-making processes. Members of key populations must be included in Country Coordinating Mechanisms (CCMs) - the committee of local government, health expert and civil society representatives that develop and guide Global Fund supported programs in a country. When adequately resourced and equipped to do so, communities play an increasingly critical role in monitoring the effectiveness of Global Fund-supported programs; ensuring existing investments are refocused when necessary; and maximizing the impact of the Global Fund investment.

Key populations should be deliberately engaged by implementing organizations to contribute valuable insights, guidance, and oversight. The Global Fund has provided a package of supportive strategies, policies, and processes to this end.

Table 1: Key populations for TB⁴

<p>People who have INCREASED EXPOSURE to TB due to where they live or work</p>	<p>Prisoners, miners, hospital visitors, health care workers and community health workers.</p> <p>PEOPLE WHO:</p> <ul style="list-style-type: none"> • 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
<p>People who have LIMITED ACCESS TO QUALITY TB SERVICES</p>	<p>Migrant workers, women in settings with gender disparity, children, migrants, refugees or internally displaced people, and illegal miners.</p> <p>PEOPLE WHO:</p> <ul style="list-style-type: none"> • 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
<p>People at INCREASED RISK of TB because of biological or behavioral factors that compromise immune function</p>	<p>PEOPLE WHO:</p> <ul style="list-style-type: none"> • live with HIV • have diabetes or silicosis • undergo immunosuppressive therapy • are undernourished • use tobacco • suffer from alcohol-use disorder • inject drugs

⁴ http://www.stoptb.org/assets/documents/global/plan/GlobalPlanToEndTB_TheParadigmShift_2016-2020_StopTBPartnership.pdf

3.5 Addressing human rights and gender-related barriers to accessing TB services

Human rights and gender-related barriers, including gender inequities, stigma, and discrimination, increase vulnerability to contracting TB or undermine access to TB services and gender-related barriers. The [Global Plan to End TB: The Paradigm Shift 2016-2020](#) to which many countries are committed includes “protection and promotion of human rights, ethics and equity” as one of its pillars. Some well-documented human rights- and gender-related barriers to TB programs include:

- **Stigma:** TB-related stigma is often linked to the stigma and marginalization of poverty as well as misinformation and unjustified fears about the disease. Health workers while providing non-stigmatized TB care should be examples for their communities. However, they are not immune from inadequate information/training leading to them being judgmental or fearful about TB. HIV-related stigma and discrimination can amplify TB-related stigma.
- **Inadequate conditions and services in prison and detention:** People in prison are at high TB risk because of their living conditions, and are often excluded from TB services. People who use drugs also fall under this category, particularly when drug laws include custodial penalties for minor offenses leading to imprisonment. People who use drugs also face high TB risk due to sharing drug-using equipment, such as pipes for drug inhalation and due to practices that induce cough. In addition, they also often live in conditions of poverty. Drug use may also lead to higher HIV acquisition risk.
- **Involuntary isolation:** TB transmission is a concern but, as WHO notes, the vast majority of patients, when treated respectfully and with informed consent, will not need to be coerced or detained for treatment. WHO specifies that involuntary isolation “should never be a routine component” of TB programs but rather a measure of last resort when all other efforts are exhausted. Nonetheless, such isolation occurs, and it directly undermines human rights.
- **Inadequate services for health care workers with TB:** Health care workers with TB often lack occupational health services to support them. Where services are available, there are often issues of quality and confidentiality.
- **Gender-related barriers:** Data reveals that men face higher risk of developing TB than women and suffer higher rates of deaths due to TB. In many contexts, male dominated occupations put men at increased TB risk, including mining, blasting and farm work. Men are more likely to engage in behavior with increased risk to TB, including tobacco smoking, alcohol consumption, and drug use. Men are also more likely to be living in prison and other detention settings; they represent 93.1% of the 11 million people incarcerated worldwide.

Nonetheless, TB is one of the top killers of women of reproductive age. Women may have a harder time accessing TB diagnostic and treatment services in some settings than men, due to financial, physical, and health literacy issues. There is growing evidence that women may face more TB related stigma than men, which impacts health-seeking behavior. In many contexts, women may not enjoy economic or executive autonomy to seek and sustain TB services; and stigma affects women and men differently. It is important to identify how gender norms and inequities affect health-seeking behaviors and accessibility of the TB services for both men and women.

In many countries, programs to address these barriers have been implemented with some success (for details see also the Global Fund [TB and Human Rights Technical Brief](#)). Some selected examples are highlighted below:

- **Stigma reduction** measurement tools, training programs and other gender-responsive resources that have been developed for health workers, communities, employers, and social

and religious leaders have been shown to be effective, especially when patients are meaningfully involved in the design of programs.

- **“Know your rights”** and other rights literacy programs for patients, their families and communities, and health workers can be helpful. This is especially true for marginalized people already prone to exclusion from services or people subjected to involuntary isolation. These programs are often usefully combined with access to legal services.
- **Reform of laws and policies** that reinforce human rights and gender-related barriers. This can include health regulations that fail to restrict involuntary isolation; laws or policies that restrict access to affordable generic medicines; health service practices or policies that make it harder for women and young people to benefit from services; policies that restrict access to services for migrant workers or people affected by forced displacement; drug laws that impose prison sentences for minor, non-violent infractions; and policies that impede equal access for prisoners to community health services. Laws and policies can be challenged through legislative advocacy, community mobilization, awareness-raising, litigation and more.
- **Health worker training** can focus on stigma reduction; the importance of informed consent, confidentiality and privacy; meaningful participation of patients in decision-making about their care; and understanding involuntary isolation as the last resort. Key to these activities is adequate training and ongoing educational support to develop and retain expert capacity in supplying care.
- **Addressing gender norms** which are culturally and contextually specific. This might include differentiating clinical and community service delivery for men and women to increase effectiveness; hiring more care providers of a certain gender; ensuring that community outreach and education programs speak to gender-differences and are appropriate for all.
- **Promoting gender equality** in contexts where women, girls, and gender non-conforming communities suffer discrimination and inequality, putting them at higher risk or excluding them from access to services.
- **Community-based monitoring of service quality and other human rights-violations** can ensure that TB-services are delivered in a non-stigmatizing and nondiscriminatory way at facilities and communities, monitor and report on drug side-effects, and stock-outs. Community-led monitoring can also help document and report other violations, such as breach of medical confidentiality, the unlawful imposition of user-fees, and unfair exclusion from work and educational opportunities based on TB.
- **Programs to increase access to justice are important in preventing and addressing human rights violations** in the context of TB. Some major barriers to access TB services include breach of medical confidentiality, privacy, unfair dismissal and exclusion from work and educational opportunities. People may not be able to assert their rights, even if they know them, without assistance from legal or paralegal professionals. In some circumstances, access to legal assistance may be the most direct and effective way for marginalized persons to access TB services, be protected from compulsory treatment, involuntary isolation, or to address stigma and discrimination. Community-based and peer-led legal counseling or services may be particularly effective.
- **Programs in prisons and other closed settings.** People in prison and pretrial detention have the right to health services equivalent to those in the community. Training prison medical personnel, guards and other prison staff on the basics of TB prevention and care can be effective. Coordinating care across prisons and post-release community care can be key to ensuring that those in state custody can begin TB treatment without fear of its

interruption upon transfer or release. Peer-based, patient-centered approaches should be encouraged.

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.

3.6 Community system strengthening (for community-led and -based responses)

Community responses are needed as part of the paradigm shift from top-down efforts to control the epidemic to a multi-sectoral collaboration to end TB. For this reason, collaboration with communities and civil society organizations is a principal pillar of both WHO's End TB Strategy and the Stop TB Partnership's Global Plan to End TB. Community and formal health systems interact and complement each other, as they evolve and adapt to emerging challenges while participating as two parts of the same health eco-system.

'Community systems' is a broad term to describe community structures, mechanisms, processes and actors that support community responses to meet people's health needs; it is often included in the RSSH Modular Framework. For example, strengthening a community-based organization's ability to refer people to a health facility and then be able to monitor and evaluate its outreach program.

'Community response' describes the interventions used by communities to respond to the challenges and needs they face; it is often used in disease-specific Modular Frameworks. Community response can include a wide range of TB, DR-TB and TB/HIV prevention, treatment, care and support services that are complementary to the formal health system, are not otherwise being provided, or are not accessible to key, vulnerable and marginalized populations. For example, a community-based organization doing outreach to find missing people with TB is a community response.

Community responses are essential to ensuring that TB programs are as responsive and comprehensive as possible, provide community-level coverage of basic services, and safeguard the needs of marginalized and excluded groups. Increasing community-led and -based responses can significantly contribute to achieving better health outcomes.

Communities require resources, technical assistance, tools and appropriate organizational, institutional and technical capacity to be equal partners in the response. Community systems strengthening includes interventions that support the development of informed, capable, coordinated and sustainable peer-led organizations, networks and structures. This should go beyond service delivery to include 1) community-based monitoring of TB programs and services; 2) community-driven advocacy; 3) technical assistance to enhance organizational and institutional development, systems development, sustainability planning, leadership and community organizing; 4) strengthening links and partnerships with key TB stakeholders; and 5) engaging in assessments of the legal, policy environment and gender sensitivity of the response. For more information, please see the [Community Systems Strengthening Technical Brief](#) at [this landing page](#).

Community engagement is critical to improve the development and implementation of national strategies and to enhance the reach and sustainability of interventions related to TB. Innovative and successful approaches that engage communities and civil society organizations could be tailored to

country-specific contexts and used to strengthen community responses, such as the successful [TB REACH funded projects](#) and the [ENGAGE-TB Approach](#).

3.7 Sustainability and transition considerations

The Global Fund encourages all countries to build sustainability considerations into their program design. In the [Sustainability, Transition and Co-financing guidance](#), the Global Fund outlines its principles for enhancing sustainability and provides a framework to support countries in transitioning successfully from Global Fund financing, which is differentiated along the development continuum. Additional information for applicants to develop funding requests in accordance with this policy can be found in the [Sustainability, Transition and Co-financing Guidance Note at this landing page](#). The Global Fund in collaboration with partners has developed specific STC annex for TB and health products which can be found [at this landing page](#).

3.8 Technical support and capacity building

Technical support serves to bridge gaps in knowledge, data or expertise at the country level. Countries can request technical support at various stages of the funding process, including NSP development and updating, and development of funding request and implementation. Technical support can be made available to the Country Coordinating Mechanism (CCM), implementers, and civil society organizations through partners and the Global Fund.

Several partners provide technical support to countries to strengthen their TB Programs, including USAID, The Union, WHO, Stop TB Partnership, GDF, KNCV and others. USAID works in close collaboration with other USG departments and agencies, as well as implementing partners, the Stop TB Partnership, WHO, and other bilateral donors to plan and coordinate technical assistance (TA) to ensure there is no duplication of efforts. USAID supports TB and DR-TB program activities in several countries, including those implementing TB interventions with Global Fund grant. Further information can be accessed at [USAID](#). Information about technical support provided by The Union to countries can be accessed at [The Union](#).

In addition to supporting technical assistance through grants, the Global Fund has a special agreement with WHO on provision of technical support and advice to countries to scale up and implement their response to DR-TB. The current 2017-2019 Memorandum of Understanding (MOU) between the Global Fund and WHO regarding the provision of technical and advisory support for activities of the regional Green Light Committees (“rGLCs”) and their respective secretariats was entered on 1 April 2017.⁵ The rGLC secretariats aim to ensure the quality of MDR-TB activities and their scale up in countries by coordinating the provision of technical assistance and advisory support in developing, revising and implementing national Programmatic Management of Drug-resistant TB (PMDT) plans, as part of the overall NSPs.

Countries in which grant funding to a Principal Recipient is part of an active agreement to finance PMDT activities will receive one of two TA and advisory support packages coordinated by the rGLC Secretariats. The packages and associated annual payments, according to the MOU, are:

- **Core service package** for all non-high MDR-TB countries. It includes an annual contribution of US\$25,000 per country.

⁵ *Memorandum of Understanding (MOU) between the Global Fund and WHO on Regional GLC and secretariats. April 2017*

- **Enhanced service package** for high MDR-TB burden countries, according to the most updated WHO Global TB Program report, includes an annual contribution of US\$50,000 per country.

The GLC mechanism supported through the MOU has been evolving based on lessons learned. New features have been incorporated during agreement renewal. To standardize support to countries and ensure quality assurance, terms of references and peer review mechanisms are incorporated into the agreement. The annual contributions (GLC fees) from grants are pooled at the central level and disbursed to WHO in three tranches. The current agreement is performance-based, and grants will be charged only after confirming a country's receipt of technical support from rGLCs.

The lessons learned during implementation of the current MOU include i) Over 90 countries received support from the six rGLCs in 2018; ii) rGLC missions and reports were used for advocacy, NSP funding requests development, iii) quality of the support to countries and mission report quality improved; iv) central payment mechanism facilitated predictability, enabled funding transfer and reduced transaction costs; v) countries benefited from the capacity building component; vi) rGLCs supported countries in the transition to new WHO DR-TB regimens, including scale-up of DST, aDSM and patient support.⁶

3.9 Antimicrobial Resistance

Antimicrobial resistance poses a great threat to the fight against infectious diseases including TB and remains a major concern for global health security. Drug resistance in bacteria, viruses, fungi and parasites makes infections more difficult and expensive to treat. Because the ability to prevent and treat infection underpins all aspects of healthcare, rising levels of resistance to common antibiotics and other antimicrobials is one of the top global health threats. TB accounts for almost a third of AMR-related death globally and could account for 2.6 million of the estimated 10 million deaths from AMR by 2050 and costs to the global economy could reach an estimated US\$16.7 trillion if immediate action is not taken.⁷ Drug resistance in TB is much better understood by policymakers than AMR more generally and is a good example that is important for advocacy purposes.

Resistance to antibiotics is rising because of overuse in human and animal health and in food production. Antibiotics have been used as a substitute for good hygiene practices, diagnosis and care. To address this problem, systems both to prevent and to manage infection must be strengthened. To address the AMR issue, the Interagency Coordination Group (IACG) on Antimicrobial Resistance was convened by the Secretary-General of the United Nations after the UN High-Level Meeting on AMR in 2016. The IACG brought together partners across the UN, international organizations and individuals with expertise across human, animal and plant health, as well as the food, animal feed, trade, development and environment sectors. The reports and recommendations of the IACG can be found at [IACG Report](#).⁸ Implementation of the recommendations is coordinated through the tripartite secretariat, (FAO, WHO and OIE) led by WHO. While this is a multisectoral problem, there is much to be done in human health systems and there can be substantial co-benefits for AMR with minimal additional costs if addressing AMR is incorporated into disease-specific and RSSH investments.

Examples of actions which would have benefit in moving forward both the AMR agenda as well as tackling TB include:

⁶ *Performance-based technical support for drug-resistant TB responses: Lessons from the Green Light Committee. IJTL in press*

⁷ https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf

⁸ <https://www.who.int/antimicrobial-resistance/interagency-coordination-group/en/>

- Incorporate bacteriology and antibiotic susceptibility testing in laboratory and surveillance system strengthening programs.
- Leveraging the expertise developed in medicines supply chain management to ensure a reliable supply of quality-assured appropriate antibiotics (even if Global Fund funds are not being used to purchase the drugs).
- RSSH and investments in quality should include strengthening infection prevention and control to prevent health care-acquired infections compromising care
- Making links between AMR coordination committees and disease programs at the national level to facilitate coordination and realize these potential co-benefits

3.10 New diagnostics, new drugs and treatment regimens and innovative digital technologies

3.10.1. Diagnostics

During the last 10 years, WHO has recommended several new tests for diagnosis of TB and DST including Xpert MTB/RIF, Line Probe Assays (LPA) and TB Loop-Mediated Isothermal Amplification (TB-LAMP) test, as well as lateral flow urine lipoarabinomannan assay (LF-LAM), the latter for TB diagnosis among PLHIV who are seriously ill and with low CD4 count. These and other new diagnostics -need to be scaled up rapidly and utilized optimally, depending on the country contexts/need, and quality assurance mechanisms need to be in place. Globally, only around 20% of public sector health facilities (although with wide range) have onsite TB diagnostics (and only 10% of these diagnostic sites have GeneXpert) as in most countries diagnostics are placed in sites with highest volume outpatient activity. To improve access to TB diagnostics, further expansion of facilities with on-site testing and rapid expansion of integrated sample transportation systems is an urgent priority. Sample transportation can link diagnostic sites to the other 80% of health facilities situated mainly in primary care to ensure earlier diagnosis of TB to find the missing cases. These diagnostic networking schemes should be made available both in the public and the private sectors.

A comprehensive list of existing WHO policy documents on TB diagnostics is available at [TB diagnostics and Laboratories](#). Several new TB diagnostic and DST tests are in the pipeline and programs should be vigilant to introduce and scale up new tools when they become available and recommended for use at different levels. Flexibilities are available within grants including using savings to support scale-up of new and better diagnosis and DST tools. More information on TB diagnostic pipeline could be found at [FIND's](#) website.

3.10.2. New treatment regimens for DR-TB and pediatrics formulations for children

World Health Organization issued new recommendations (through Rapid Communication in August 2018 and the new Guidelines in March 2019) on the treatment of DR-TB. The guideline includes recategorization of the second-line drugs (including new and repurposed drugs), the removal of certain agents (kanamycin and capreomycin) from the list, and an overall preference for all-oral regimens for patients with isoniazid-resistant, rifampicin-resistant, or with multidrug-resistant TB. All-oral regimens shorter than 18 months may be implemented under operational research conditions. For more information, please see [WHO Consolidated Guidelines on DR-TB Treatment](#) and [FAQs](#) on the key changes to the treatment of DR-TB.

Following the release of the Rapid Communication in August 2018, the Global Fund has collaborated and worked with a WHO-convened task force composed of partners including the GDF, USAID and

key technical agencies to support countries to transition to the new regimens. The Global Fund has been encouraging countries to transition to the new regimens, including implementation of all-oral shorter regimen under OR conditions, as these have several advantages especially for patients and the health system. Financial support for transitioning has been leveraged from savings/efficiencies and reprogramming of existing Global Fund grants and through **portfolio optimization**, where over 20 countries have received additional funding from the central pool in 2018/2019. The regional Green Light Committee (rGLC), which is also funded by Global Fund has been providing technical support to countries with a special focus on supporting the preparation of transition plans and the move to the new all-oral regimens including the expansion of laboratory capacity (DST), aDSM, quantification of drugs, and patient support.

Child-friendly fixed-dose drug-susceptible TB formulations were rolled out in 2016 by partners led by TB Alliance. This has facilitated the provision of appropriate and convenient dosing for children with DS-TB to improve uptake and adherence to treatment and treatment outcomes. All children diagnosed with active TB should receive the new formulations. Countries have been accessing Global Fund grants to scale up the use of these formulations. Further information can be accessed at TB Alliance site [Child-friendly medicines](#). Further work is required for the development of similar child-friendly formulations for DR-TB treatment.

3.10.3. Prevention and treatment of TB Infection

WHO published a new guideline on [programmatic management of LTBI in 2018](#) and recommends the use of Tuberculin skin test and/or blood test (IGRAs) for diagnosis of TB infection, although the absence of such tests should not be a barrier to the initiation of TB preventive treatment. The guidelines also recommend the provision of TPT including using the new shorter, combination therapies (3HP and 3HR) as well as INH, especially for high-risk groups including PLHIV and household contacts, regardless of age. The UNHLM declaration on TB also includes a target of providing TPT for 30 million people between 2018 and 2022. This means more attention and resources should be allocated for scale-up of the response to TB infection. IPT has been part of the NSP and most of Global Fund-supported programs, but the coverage and performance have been poor, particularly in children. Following the release of the new WHO guidelines on LTBI in 2018, the Global Fund has been encouraging countries to scale up TPT including using the new combination drugs using existing grants and provided additional funding (through portfolio optimization) for two countries in 2019.

While early diagnosis and treatment of TB including TB infection is critical, ending TB transmission in institutional and community settings should also be prioritized and budgeted. Infection prevention and control consists of evidence-based measures intended to prevent exposure and reduce the risk of transmission of infectious agents including *Mycobacterium tuberculosis*. This requires coordinated and integrated efforts and part of the global response to mitigate the threat from AMR. Further information on TB Infection prevention and control and ending TB transmission could be found at the [WHO website](#) and [End TB Transmission Initiative](#).

3.10.4. Digital technologies

The potential of information and communication technologies to combat TB remains underexploited. Many countries and partners have now tried out various digital technologies in their efforts to improve TB diagnosis (including use of artificial intelligence for reading X-rays), patient care and adherence support (including call centers, mobile apps), surveillance, logistics management and

eLearning. In 2017, WHO released evidence-based recommendations for the use of digital adherence technologies such as medication monitors, video-supported treatment and text messaging to support patients on treatment. In line with these recommendations, these tools need to be implemented more widely to improve program performance and provision of people-centered care. However, the choice and optimal use of these technologies need to be context specific; thus, more evidence regarding implementation and impact is still needed. In 2018, WHO released a [handbook](#) about the practicalities of implementing digital adherence technologies. Countries should also develop systems to gather data about the implementation and impact of innovative digital technologies and interventions.

3.11 The funding situation

Despite an increase in financing for TB in high burden countries, global efforts to fight TB remain under-funded. Funding requirements are likely to increase due to accelerated progress towards the goal of universal health coverage that is required to ensure that all people with TB, including DR-TB and TB infection, can access diagnosis and treatment without facing catastrophic costs. The first-ever UNHLM on TB has contributed to increased commitment for ending TB globally and the momentum should be maintained. To achieve the UNHLM declaration targets, a substantial increase in resources for TB from both domestic and international sources is required. Additional funding is also required for research and development (R&D) as without new tools, achieving the SDG target of ending TB in 2030 would be challenging.

The median cost per patient treated in 2017 was US\$1,224 for drug-susceptible TB and US\$7,141 for MDR-TB. The latter figure was lower than in previous years, following expanded use of a lower cost shortened treatment regimen that was first recommended by WHO in 2016. Therefore, to reach the End TB Strategy milestones and the Global Plan to End TB targets significantly increased upfront investments are urgently needed while efforts in market-shaping including companies to reduce the unit price of diagnostics/consumables and medicines should be intensified. The global funding need is an average per annum of US\$ 13 billion in the period 2018-2022. In addition, US\$ 2 billion per annum is need for R&D. At the global level, currently available funding for TB care and prevention needs to be doubled and for R&D it needs to be tripled. To meet the UNHLM targets for 2022, high burden countries need to significantly increase their budgets for TB. ([Global Tuberculosis Report 2018](#))

For Global Fund-eligible countries, with even the most optimistic domestic funding forecasts and with external funding maintained at current levels, an additional US\$7.4 billion must be mobilized for countries to reach the 2020 milestones. While the bulk of these investments should come from domestic resources and international donors, the mobilization of alternative funding sources such as social impact bonds, micro levies or taxes, and pooled donor trusts could dramatically accelerate the pace of scale-up. ([Global Plan to End TB: The Paradigm Shift 2016-2020](#)).

3.12 The Global Fund Strategy

The [Global Fund Strategy](#) covers the period 2017-2022 and outlines a bold agenda for the six-year period. It is based on an ambitious vision, mission, and four strategic objectives, which are each underpinned by several sub-objectives and supported by two strategic enablers. The core objectives of the Global Fund 2017-2022 Strategy are to: maximize impact against HIV, TB and malaria; build resilient and sustainable systems for health; promote and protect human rights and gender equality;

and mobilize increased resources. The service delivery target for the strategy period for TB is to “Rapidly reduce TB, TB-HIV and MDR-TB incidence and related mortality through universal access to high quality care and prevention in line with the End TB Strategy and Global Plan to End TB”.

Maximizing the impact of investments for HIV, TB and malaria requires differentiated approaches for diverse country contexts, increased alignment, and planning for sustainability of programs. Countries must be supported to implement and sustain impactful programs targeting the three diseases from both a programmatic and financial perspective over the longer term. Successful implementation of this strategy will contribute to progress in the fight against the three diseases aligned with the UNAIDS Fast Track Strategy, the End TB Strategy, and the Global Technical Strategy for Malaria, and to the achievement of the Sustainable Development Goals.

Building resilient and sustainable systems for health are crucial to ensuring that people have access to effective, efficient, integrated, people-centered, safe, timely and accessible services through well-functioning and responsive health and community systems. The existence of strong systems for health is essential to making progress against HIV, TB and malaria, and to ensuring that countries can address the myriad of health challenges that different populations face from global health security threats to non-communicable diseases.

Human rights and gender-related barriers including stigma and discrimination, gender inequities, and the loss of income and other work and educational opportunities based on TB status, undermine an effective response to TB. Addressing access barriers with concrete programs and human rights-based, gender responsive and community-led programming and implementation is essential to ensuring that the impact of the TB response is maximized. Incorporating a gender differentiated approach to TB programs will help to overcome gender-related barriers, including gender-inequality.

Mobilizing increased resources is required for successful scale-up of the response to the three diseases. According to the global technical strategies against HIV, TB and malaria, the global health community must front load investments during the next strategy period to maintain the gains made to date and accelerate progress.

Successfully implementing the Global Fund strategy is dependent upon two fundamental elements, termed the strategic enablers. They include the need to innovate and differentiate along the development continuum and to support mutually accountable partnerships.

4. Key References

Global Fund Information Notes and Technical Briefs (these are being updated/finalized and could be accessed at [this landing page](#))

Further selected Global Fund documents (some of these documents are being updated/finalized and could be accessed at: [this landing page](#) and [Global Fund website](#))

- [Global Fund Strategy 2017-2022 “Investing to End Epidemics.” \(2016\).](#)
- [The Applicant’s Handbook. A practical guide to preparing a funding request \(2016\)](#)
- [Funding Request Instructions \(2016\)](#)
- [Global Fund Modular Framework Handbook](#)
- [Frequently Asked Questions. The 2017-2019 Funding Cycle \(2016\)](#)

- [Framework for Financing Co-infections and Co-Morbidities of HIV/AIDS, Tuberculosis and Malaria \(COIM\) \(2015\)](#)
- [Global Fund Operational Policy Manual](#)
- [Scaling up programs to remove human rights barriers to health services \(2016\)](#)
- [The Global Fund Sustainability, Transition and Co-Financing Policy \(2016\).](#)
- [The Challenging Operating Environments Policy \(2016\).](#)
- [Technical Review Panel's Consolidated Observations on the 2014-2016 Allocation Based Funding Model](#)

WHO guidelines and key documents

- [Handbook for the use of Digital Technologies \(2017\)](#)
- [WHO Consolidated Guidelines on DR-TB Treatment \(2019\)](#)
- [Global TB report, 2018](#)
- [End TB Strategy](#)
- [PPM roadmap \(2018\)](#)
- [ENGAGE-TB Approach](#)
- [Programmatic management of LTBI in 2018](#)
- [Framework of indicators and targets for laboratory strengthening under the End TB Strategy](#)
- [Roadmap towards ending TB in children and adolescents \(2018\)](#)
- [Implementing tuberculosis diagnostics. Policy framework \(2015\)](#)
- [Implementing the End TB strategy: The Essentials \(2015\)](#)
- [Integrating collaborative TB and HIV services within a comprehensive package of care for people who inject drugs](#)
- [Monitoring progress towards universal health coverage at country and global levels: framework, measures and targets](#)
- [Recommendations for investigating contacts of persons with infectious tuberculosis in low and middle-income countries](#)
- [Framework on integrated, people-centred health services](#)
- [Systematic screening for active tuberculosis: an operational guide \(2015\)](#)
- [TB diagnostics and Laboratories](#)
- [Compendium of standards](#)

Stop TB Partnership

- [GLI quick guide to TB connectivity solutions](#)
- [The Paradigm Shift 2016-2020 \(2015\)](#)
- [Improving TB Case Detection: A compendium of TB REACH Case studies, lessons learned and a monitoring and evaluation framework](#)

- [Key Population Briefs](#)
- [GLI Quick guide to TB diagnostics connectivity solutions](#)
- [Global Drug Facility](#)
- [TB REACH funded projects](#)
- [Strategic Initiative - Finding the missing people with TB – how to do guides](#)
- [Legal environment assessment](#)
- [Gender assessment](#)
- [Framework for data on TB Key Pops.](#)

Other key documents

- The Union: [The Unions desk guide for diagnosis and management of tuberculosis in children – Africa and Asia](#) (2016)
- UNITAID: [Tuberculosis diagnostics technology and market landscape - 5th edition](#) (2017)
- UNAIDS: [UNAIDS/WHO Technical Guidance Note on HIV/TB](#)
- TB Alliance: [Child-friendly medicines](#)
- USAID: [USAID Tuberculosis](#)

Other useful documents (Global Fund)

- [Program Quality and Efficiency Case Study](#) (2018)
- [Best Practices on TB Case Finding and Treatment: Reflections and Lessons from West and Central Africa and Beyond](#) (2018) – [English](#) and [French](#) versions
- The Global Fund TB/HIV Best Practices/Technical Brief

5. List of Abbreviations

aDSM	-	Active drug safety monitoring and management
AMR	-	Antimicrobial Resistance
ARV	-	Antiretroviral
ART	-	Antiretroviral Therapy
CCM	-	Country Coordination Mechanism
DR-TB	-	Drug-resistant TB
DST	-	Drug-susceptibility Testing
GDF	-	Global Drug Facility
3HP		3-month (12 doses) Isoniazid and Rifapentine
Hr-TB	-	Isoniazid-resistant (rifampicin-susceptible) Tuberculosis
IPT	-	Isoniazid Preventive Therapy

LF-LAM		Lateral Flow urine lipoarabinomannan assay
LTBI	-	Latent Tuberculosis Infection
M&E	-	Monitoring & Evaluation
MDR-TB	-	Multi-drug resistant Tuberculosis
MOU	-	Memorandum of Understanding
NCD	-	Non-Communicable Disease
NSP	-	National Strategic Plan
NTP	-	National Tuberculosis Programs
PHC	-	Primary Health Care
PLHIV	-	People Living with HIV
PMDT	-	Programmatic Management of Drug-resistant Tuberculosis
PPM	-	Public-Private Mix
rGLC	-	regional Green Light Committees
RSSH	-	Resilient and Sustainable Systems for Health
3RH		3-month (12 doses) of Rifampicin and Isoniazid
RR-TB	-	Rifampicin-resistant Tuberculosis
SL-LPA	-	Second Line-Line Probe Assay
TA	-	Technical Assistance
TB	-	Tuberculosis
TB-LAMP	-	Tuberculosis Loop Mediated Isothermal Amplification
TPT	-	Tuberculosis preventive treatment
TRP	-	Technical Review Panel
UHC	-	Universal Health Coverage
USG	-	United States Government
WHO	-	World Health Organization