Tuberculosis Information Note

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I. Introduction

01 Purpose of this document

The purpose of this Information Note is to provide guidance to applicants choosing what to invest in to end the tuberculosis (TB) epidemic. It is intended to be used in the context of preparing a funding request to the Global Fund. It aims to promote strategic investments, that is, investment in key activities that will have the greatest impact, including for key populations. The Information Note therefore contains recommendations on how to set priorities and targets for TB interventions to achieve the highest impact, based on the country's TB (both drug-susceptible and drug-resistant TB) profile, existing barriers to accessing TB services, and the health system context of the country. The Information Note could be useful for countries that are preparing or revising their national strategic plans (NSP) for TB and is particularly useful for country dialogue and preparation of the requests for funding from the Global Fund.

The Information Note contains brief descriptions of the Global Fund's new Strategy, lessons learned during the first allocation-based funding cycle, priority areas for TB prevention, care and treatment and provides recommendations on how to define or identify TB key or vulnerable populations and set priority interventions for TB to achieve the highest impact. It is designed to complement other guidance and tools for TB strategic planning and interventions including the End TB Strategy, the accompanying guide to Implementing the End TB Strategy; the essentials and the Global Plan to End TB: The Paradigm Shift 2016-2020.

02 Key messages

1. Find the "missing" millions

Of the more than 10.4 million people who become ill with TB each year, more than 4.3 million are not diagnosed, treated, or officially notified by national TB programmes (NTP). The figures are worrying for drugresistant TB (DR-TB) as almost 80% of new DR-TB cases are "missed" every year. Collectively, these "missed" millions are a global public health failure and a top priority for global TB response. The TB epidemic cannot be put to an end unless these missing people with TB are reached, diagnosed, treated and notified. To do so, it is pertinent that barriers to accessing TB services are addressed to ensure quality TB services are available and accessible for all, in particular communities and populations most affected by TB. While utilization of existing tools and services should be intensified, new and innovative approaches and tools including innovative ways of engaging all care providers are required to reach missing patients and end the TB epidemic.

2. Maximize impact against TB

Global Fund will invest in and promote the urgent scale up of diagnosis, prevention and treatment efforts as well as programs to address access barriers, focussing the investment in areas and populations with the greatest burden of disease while strengthening efforts in areas with growing epidemics. Investment will be made in epidemiologically appropriate interventions that are evidence based and delivered with full adherence to the protection and promotion of human rights and with a focus on reaching the "missing" patients. Attention will also be paid to the achievements of clear and measurable results and on implementation of interventions that are targeted and likely to have the biggest possible impact.

3. Build resilient and sustainable systems for health (RSSH)

A focus on RSSH will lead to better results in the fight against the three diseases and for health more broadly, as well as increased financial protection and equity, contributing to universal health coverage. This includes promoting and reinforcing community responses and involvement of affected communities in decision-making.

4. Promote and protect human rights and gender equality is required to accelerate the end of the three epidemics

The promotion and protection of human rights and gender equality in the context of the three diseases is one of the main pillars of the 2017-2022 Global Fund Strategy, *Investing to End epidemics*. Furthermore, the Global Fund Sustainability, Transition and Co-Financing policy states that applications must include, as appropriate, interventions that respond to key and vulnerable populations, human rights and gender-related barriers and vulnerabilities in access to services.

Human rights barriers to accessing TB services, including stigma and discrimination, and gender inequality undermine an effective response. Consequently, addressing human rights and gender-related barriers with concrete programs and gender-responsive and human rights-based programming and implementation is essential to ensuring that quality TB services are available and accessible to all, in particular key and vulnerable populations.

5. Improve program quality

A key component of the 2017-2022 Global Fund Strategy is the mainstreaming of program quality. Within the scale up of service coverage, it is critical to focus on quality to maximize and sustain impact. Countries can achieve greater impact in the fight against TB by scaling up proven interventions, and promoting innovative people-centred quality improvement methods. Healthcare services need to be safe, effective, timely, efficient, equitable and people-centred (the six pillars of quality of care) to result in the desired health outcomes. TB servicers should reach special populations at increased risk, such as people living with HIV, prisoners and people living in over-crowded conditions and extreme poverty.

6. Use data for action

Systematic ongoing efforts and long-term investments in routine data systems are needed to improve the availability and quality of data for analysis and use in strategic decision-making; and to provide capacity for better targeting of programs, improving the quality and the efficiency of the investment.

7. Advocate for increased programmatic and financial resources from diverse sources to accelerate efforts to end the epidemics

Mobilizing increased resources is required for successful scale-up of the response to the three diseases. Most critical is the increased investment of domestic resources for health, which is the sustainable future of health financing for most countries.

8. Challenging Operating Environments

Challenging operating environments (COEs) is one of the key areas of focus for the Global Fund and the Global Fund 2017-2022 strategy commits to improving the effectiveness of Global Fund investments through increased flexibility, support to innovations, and stronger partnerships, with the goal of improving the effectiveness of health investments and reaching key populations. COE applicants should refer to the Operational Policy Note on Challenging Operating Environments, which includes guidance on access to funding and grant management.

9. Differentiate approaches/responses

Innovative approaches to addressing diverse epidemiological contexts within the country are essential to accelerate the end of the epidemics. Successfully engaging with key partners within the increasingly diverse landscape requires a greater emphasis on allocating resources more flexibly and predictably, as well as differentiated approaches based on the epidemiological contexts to allow more focused and targeted interventions to maximize impact.

03 Joint programming and integration

Joint programming will allow to better target resources, to scale-up services and to increase their effectiveness and efficiency, quality and sustainability.

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 high burden of co-infection of TB and HIV**¹ **are required to submit a single TB and HIV** funding request that presents integrated and joint programming for the two diseases. These funding requests need to present prioritized, high impact interventions and activities 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 and HIV co-infection. Countries preparing

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, Papa New Guinea, South Africa, Swaziland, Tanzania (United Republic), Thailand, Uganda, Zambia, and Zimbabwe.

single TB and HIV funding requests should also consider addressing common health system-related constraints, which interfere with the successful implementation and integration of TB and HIV programs as well as other cross-cutting areas for joint TB and HIV programming.

The purpose of joint TB and HIV programming is to maximize the impact of Global Fund and other investments for better health outcomes. These programs will require financing for cross-cutting areas such as building resilient and sustainable systems for health, the removal of human rights and gender-related barriers to TB and HIV services, and more effective use of health information, health personnel and commodities in the course of targeted scale up of integrated TB and HIV services. Joint programming allows for better targeting of resources and harmonization of efforts to increase the effectiveness and efficiency, quality and sustainability of programs. Emphasis should be placed on gaining efficiency through synergized program management and consistent in-country collaboration between the disease programs during the preparation of funding requests, implementation and monitoring of grants, and investment in quality data systems. Furthermore, integrated program planning, budgeting, development of joint activities and sharing resources between the disease programs is strongly encouraged.

Joint programming is an opportunity to strengthen delivery of key services for persons with TB, HIV and TB/HIV infection, including regular screening of people living with HIV (PLHIV) for TB, HIV testing of TB symptomatic people and patients, provision of antiretroviral (ARV) and TB medicines for co-infected patients and provision of TB preventive therapy for PLHIV without active TB. There are several models to provide integrated services to TB and HIV patients including "one-stop-shop" although there is no "one-size-fits-all" approach.

Lessons learned from the development of single TB/HIV concept notes and joint programming during the first allocation-based funding cycle showed that single concept note development processes resulted in greater harmonization of the cross-cutting areas such as procurement and supply chain management, supervision, monitoring and evaluation and delivery of integrated service for TB and HIV. It was also found that a single concept note could ease administrative burden of developing a proposal and simplify the management of grants. A single concept note could therefore be a suitable application tool for countries that seek efficiencies in the application for and management of grants. However, weaknesses identified include independent disease efforts that were only combined at the concept note submission stage with limited in-country collaboration between the disease programs during implementation. Furthermore, TB/HIV activities were rarely classified by target population, despite the fact that groups most affected by TB and HIV often overlap. Programs that do explicitly refer to key populations (e.g., migrants, people who inject drugs or prisoners) or are categorized as joint community based interventions show several best practices.

Country-led dialogue and related decision-making by TB and HIV stakeholders, including civil society organizations and affected communities, firmly built on the principles of human rights and gender equality, are essential for joint TB and HIV programming. The country context determines the scope of joint programming. The epidemiology of the local TB and HIV epidemic, maturity and capacity of programs, diverse health infrastructures and management, as well as barriers to care and client needs should determine the scope and critical areas of joint programming with a flexible approach. Efficiencies can be gained at several levels of the programs, from planning and coordination to service delivery and data collection. This reduces duplication, fosters synergies and targets resources to achieve maximum impact. This will also contribute to an increasingly sustainable program response.

For further details, please refer to the Global Fund Information Note on HIV, the UNAIDS/WHO Technical Guidance Note on HIV/TB, the WHO End TB Strategy, the Stop TB Key Population Briefs and the WHO guidelines Integrating collaborative TB and HIV services within a comprehensive package of care for people who inject drugs and the Report of the consultation meeting to draw lessons from development of Single TB and HIV Concept Notes and defining the way forward for joint TB and HIV programming (Addis Ababa, 2015).

TB and Non-communicable diseases²

Each year, 38 million people die from non-communicable diseases (NCDs), primarily from diabetes, cardiovascular diseases, cancers, and chronic respiratory diseases. Over 75% of these deaths are in low- and

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

middle-income countries, and many countries with the highest burden of TB also face growing epidemics of NCDs (WHO, 2015). 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. Further, 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 and alcohol abuse, leading to an inequitable impact and a double burden of diseases. Addressing these issues requires integrated and coordinated health services, planning and preventive frameworks, and 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 glycaemic control in people with diabetes. Individuals with both conditions thus require careful clinical management. Strategies should be implemented that ensure that optimal care is provided to patients with both diseases. This includes early screening and treatment of TB among people with diabetes and early screening and treatment of diabetes in people with TB depending disease epidemiology and risk factors.

Reproductive, maternal, new-born 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.

The most obvious point of entry into the health system for many children with TB (or those who are contacts of 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 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 in women and children. For further information, see the The Global Fund Reproductive, Maternal, Newborn, Child and Adolescent Health Technical Brief.

II. Global Overview: Progress and Challenges in the Fight Against TB

04 Current status of the global TB epidemic

Overall situation

TB was a leading cause of death among infectious diseases claiming 1.8 million lives in 2015 (an estimated 1.4 million TB deaths among HIV-negative, and 0.4 million deaths among people living with HIV). Worldwide, in 2015 there was an estimated 10.4 million new (incident) TB cases, of whom 5.9 million (56%) were men, 3.5 million (34%) women and 1.0 million (10%) children. During the same year, only 6.1 million (59% of the estimated 10.4 million) new TB patients were reported to national health authorities. That means, globally, 4.3 million TB patients were "missed". The latest treatment outcome data show a global average treatment success rate of 83% for TB (2014 cohort). This is a decline from a treatment success rate of 86% for the cohort treated in 2013. The TB treatment outcomes vary by region and country.

Drug-resistant TB

In 2015, of the estimated 580,000 people with drug-resistant TB (Multi-drug-resistant [MDR] and Rifampicin-resistant [RR] TB) only 125,000 (20%) were enrolled in treatment. In 2015, only 30% (24% of new and 53% of previously treated TB patients) had drug-susceptibility testing (DST) for rifampicin. The highest rates of MDR-TB are found in Eastern European and central Asian countries.

³ When an HIV-positive person dies from TB disease, the underlying cause is classified as HIV in the International Classification of Diseases system (ICD-10).

⁴ Global tuberculosis report 2016.

There were about 250,000 deaths from MDR/RR-TB in 2015. Overall, the proportion of MDR/RR-TB patients in the 2013 cohort who successfully completed treatment was only 52% with a high rate of death (17%) and lost to follow-up (15%).

By the end of 2015, extensively drug-resistant TB (XDRTB) had been reported by 117 WHO Member States. An estimated 9.5% of people with MDR-TB have XDR-TB. The use of the rapid test Xpert MTB/RIF® has expanded substantially since 2010, when WHO first recommended its use. This test has improved the detection of RR/MDR-TB.

The co-epidemics of TB and HIV

An estimated 11% of incident TB cases in 2015 were HIV positive. The proportion was highest in countries in the WHO African Region, and exceeded 50% in parts of southern Africa. A total of 500,564 HIV-positive TB patients were reported by NTPs in 2015. In 2015, 55% of notified TB patients had a documented HIV test result. The proportion of HIV-positive TB patients on antiretroviral therapy (ART) was 78%. Systematic screening for TB among people living with HIV is recommended by WHO as an essential component of the HIV care package. However, only 231,637 (10%) of the almost 2.3 million people who were newly enrolled in HIV care in 2015 were notified as TB cases during the same year. A total of 910 000 people living with HIV were started on Isoniazid Preventive Therapy (IPT) in 2015, as well as 87,000 children under five in contact with TB patients (7% of those eligible).

Research and development: new diagnostics, new drugs and shorter treatment regimens **Diagnostics:**

In recent years, WHO has recommended new tests including LED Fluorescent microscopy, Line Probe Assays including those capable of providing DST results for second line drugs, Xpert MTB/RIF assay and TB Loop Mediated Isothermal Amplification (TB-LAMP) test. Some of these tests such as the Xpert MTB/Rif assay and the Line Probe Assays are rapid and more sensitive diagnostic tests for TB including drug resistant TB. Guidelines for their use are available on the WHO website. These new diagnostics need to be scaled up rapidly and utilized optimally. Further information is available at the following links: Policy Guidance and Framework of indicators and targets for laboratory strengthening under the End TB Strategy.

To illustrate with an example, the Second Line-Line Probe Assay (SL-LPA) detects resistance to second-line anti-TB drugs. WHO recommends the use of the SL-LPA for patients with confirmed rifampicin-resistant TB or MDR-TB as the initial test to detect resistance to fluoroquinolones and the second-line injectable drugs, instead of phenotypic culture-based drug-susceptibility testing (DST). WHO also recommends the rapid diagnostic test for identifying those MDR-or RR-TB patients who can be treated by shorter MDR-TB treatment regimen.

A number of new TB diagnostic tests are under development for use at peripheral, intermediate, and reference level laboratories. This includes, but is not limited to, GeneXpert Omni, GenePOC test, and Xpert Ultra (a new more sensitive cartridge). A full overview of the progress in the development of molecular TB diagnostics can be found in Annex 2. A comprehensive list of existing WHO policy documents on TB diagnostics is available at TB diagnostics and Laboratories.

New drugs, shorter treatment regimens and paediatrics formulations

During the last few years, the addition of two new drugs, bedaquiline and delamanid, for treatment of drugresistant TB cases has been promising for a population of cases in which treatment success rates have remained consistently low. World Health Organization issued conditional recommendations for the use of the new drugs in interim policy guidance documents published in 2013 and 2014, respectively.

A shorter regimen was recommended by WHO in May 2016 for treatment of MDR-TB or RR-TB, regardless of patient age or HIV status. Suitable patients for the short RR- or MDR-TB treatment regimens includes those who have not previously been treated with second-line drugs and in whom resistance to fluoroquinolones and second-line injectable agents has been excluded or is considered highly unlikely (The Shorter MDR-TB Regimen).

The standardized shorter MDR-TB regimen consists of seven drugs given in a 4- month intensive phase and 4 drugs in the continuation phase for a total duration of 9-12 months. Monitoring for effectiveness, harms and

relapse is essential, with patient-centred care and social support to enable adherence. The programmatic use is feasible in most settings worldwide. The cost of drugs is considerably lower at less than US\$1,000 per patient and better treatment outcomes (over 83% success rate) have been reported from observational studies including those carried out in Francophone Africa and elsewhere. The Global Fund supported a number of operational research projects, which informed the WHO recommendation in May 2016 on the use of the shorter MDR-TB regimen as the first choice for treatment of MDR/RR-TB patients. It is important to note that several randomized clinical trials including but not limited to the STREAM trial, are currently being undertaken to provide further evidence to strengthen the recommendation for the use of short regimens for treatment of RR/MDRTB.

Child-friendly TB medicines and paediatrics formulations have been developed recently by partners led by TB Alliance. This is a significant development and facilitates the provision of appropriate treatment for children with TB to improve adherence to treatment and treatment outcomes. Further information can be accessed at TB Alliance site Child-friendly medicines.

05 Global challenges⁵

1. Slow decline in TB burden

The TB incidence declined by less than 2% per year since 2000 and TB mortality fell by 34% between 2000 and 2015. At the current rate of decline in TB incidence the targets to achieve an 80% and 95% fall in TB incidence by 2030 and 2035 respectively is a mirage. The global case fatality ratio is currently estimated to be 17% and it needs to fall to 10% and 6% by 2020 and 2025 respectively for the End TB Strategy targets to be achieved. With an almost flat trend in number of TB patients notified, the achievements over the past decade are far from enough to ensure progress towards elimination of TB. In 2015 alone, 4.3 million people with TB were "missed" due to either failure to report detected and treated cases and/or lack of access to care contributing to sustained transmission. Lack of or poor engagement with private care providers contributes to "missing" cases. Experience from countries such as India suggests that innovative ways of engaging private health care providers including the use of electronic platforms to ease reporting of TB cases by private providers can markedly enhance case notification. Evidence from recent prevalence surveys show that many TB patients may have no symptom and hence do not report to health facilities or are missed by health systems. Current tools and screening approaches are not adequate to diagnose TB among asymptomatic individuals and innovative approaches and better tools are required to reach the missing patients.

2. Drug-resistant TB

Antimicrobial resistance (AMR) poses a great threat to the fight against infectious diseases including TB and remains a major concern for global health security. DR-TB accounts for almost a third of AMR burden globally. In 2015, there were an estimated 580,000 new patients with DR-TB (MDR-TB and RR-TB) and only 20% of these were treated. The treatment outcome of DR-TB has been very low with only 52% of MDR-TB patients successfully treated. Several health system barriers persist, preventing the rapid expansion of programmatic management of drug-resistant TB including the uptake of new diagnostic tools, new drugs and active TB drug safety monitoring and management systems.

3. HIV-associated tuberculosis

The HIV epidemic continues to fuel the TB epidemic. Globally, 45% of all TB patients did not know their HIV status. A significant proportion of PLHIV are not screened regularly for TB. Chemoprophylaxis for TB is still not provided to all who could benefit from it and there is a substantial gap between the number of HIV positive TB patients started on ART, and the estimated total number of HIV-positive people with TB who are in need of both TB treatment and ART. Importantly, in the absence of appropriate care and prevention, a large proportion of people living with HIV die from undiagnosed TB.

⁵ Adapted from: Global strategy and targets for tuberculosis prevention, care and control after 2015, World Health Organization, Geneva, 2014, EB134/12

4. Non-communicable diseases and tuberculosis co-morbidities

Risk-factors of TB such as diabetes, tobacco-smoking, silicosis, alcohol and drug misuse, and malnutrition hamper the fight against TB, especially in low- and middle-income countries. A large pool of latently infected people contributes to a growing proportion of future TB cases.

5. Weak health systems

Inadequate coverage and weak performance of health services limit access to high-quality TB care. Many public and private health providers remain delinked from national efforts to fight TB. Absence of universal health coverage (UHC) aggravates the economic burden on the poor. This hardship is compounded by a lack of social protection mechanisms to address associated income loss and non-medical costs. The following remain weak: regulatory mechanisms essential to ensuring effective infection control; rational use of TB diagnostics and medicines; mandatory disease notification especially among private care providers; functioning vital registration systems; and protection of the legal rights of people with TB.. Furthermore, there is a limited capacity for data collection, quality and use at all levels.

6. Funding gaps

Despite a substantial increase in financing for TB in disease-endemic 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 drug-resistant TB can access diagnosis and treatment without facing catastrophic costs.

7. Underlying determinants and barriers to TB services

The important underlying determinants of the TB epidemic that need to be addressed include poverty and inequity, food insecurity, adverse effects of population movements and complex emergencies as well as other human rights and gender-related barriers, such as stigma and discrimination attached to TB. Effective TB prevention and treatment will require actions resulting in poverty reduction, improved nutrition, and better living and working conditions as well as strategies to address access barriers and mitigate the impact of migration, ageing populations, and chronic diseases such as diabetes that are risk factors for TB.

06 The funding situation

The cost per patient treated for drug-susceptible TB in 2015 ranged from US\$ 100 to \$1,000 in most countries with a high burden of TB. The cost per patient treated for MDR-TB was typically US\$ 2,000 to \$20,000. Therefore, to reach the End TB Strategy milestones and the Global Plan to End TB targets significantly increased upfront investments are urgently needed. Over the next five years, a total of US\$ 58 billion is needed to implement TB programs, of which US\$ 52 billion is estimated to be required in low- and middle-income countries (growing from US\$ 8.3 billion in 2016 to US\$ 12.3 billion in 2020). Another US\$ 9 billion is needed to fund research and development (R&D) for new tools (Global Tuberculosis Report 2016).

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 in order 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. The resource needs in countries that are not members of the Organisation for Economic Co-operation and Development are estimated at US\$ 51.9 billion, while the resource needs in countries eligible for Global Fund financing are estimated at US\$ 29.4 billion over the 2016–2020 period (Global Plan to End TB: The Paradigm Shift 2016–2020).

07 The End TB strategy and the global plan to end TB

The End TB strategy

The global TB epidemic is a development challenge with important biomedical, public health and socioeconomic dimensions. The global response must therefore be part of the overall effort to meet the Sustainable Development Goals. The three pillars of the WHO End TB⁶ Strategy, which guides the global TB response, emphasize country-specific approaches to achieving universal access to high-quality care and support for early and rapid diagnosis and treatment of all forms of TB including DR-TB, TB/HIV, management of comorbidities, and preventive treatment of persons at high-risk. This will require a strategic change in the way that the TB epidemic is addressed, through the following: aggressive scale up of testing; diagnosis and treatment by scaling up new tools and innovations; addressing TB prevention and infection; strengthening community systems to support increased access to health services, especially for vulnerable groups; a focus on working with the private sector and key populations; and protection of human rights and gender sensitive policies.⁷

Intensified action will be needed at different levels of governance and at the level of service delivery. These levels include the NTP or equivalent entities, the health ministry, which oversees these entities, and others in the government responsible for setting the social development agenda, allocating resources and enabling interministerial coordination. Government leaders need to provide the overall stewardship and keep the goal of ending the epidemic high on the development agenda.

The Global Plan to End TB - a paradigm shift and a change in mind-set

The Global Plan 2016-2020 is a 5-year investment plan that represents the roadmap to accelerating impact on the TB epidemic and reaching the targets of the WHO End TB Strategy (Global Plan to End TB: The Paradigm Shift 2016-2020).

The Global Plan sets out ambitious targets of "90-(90)-90" and the actions and resources needed over the next five years to set the world on a course to end the global TB epidemic by 2030, as endorsed by world leaders in the newly adopted Sustainable Development Goals. The Global Plan's investment packages propose interventions tailored to have the greatest impact and to provide the maximum return on investment for the particular setting.

The Plan also makes it clear that what is needed to end TB is a paradigm shift, that is, a change in the way we fight TB at every level, in every community, in every health facility and in every country. Governments of countries with high burden will need to be ambitious, declaring that TB has no place in the future of their societies and that the current paradigm, ending the disease with modest incremental gains, will be replaced by an energized and sustained effort to end TB. Progress as dramatic as that envisioned in the End TB Strategy can only be achieved once a country's leadership announces to its people and its health services that TB will be fought on a long-term campaign basis, similar to HIV or even polio, and that it will dedicate the resources needed to end TB in the country. All stakeholders need to adopt a mind-set of responding to TB in a manner that will end the disease.

III. The New Global Fund Strategy

08 Lessons learned from the first allocation-based funding cycle

Overall, the allocation-based funding model has been a successful change in the operational model of the Global Fund. It has allowed for bigger impact, more predictable funding, an ambitious vision and a more flexible timeline. However there are also areas which need further improvement, including: allocation methodology; unfeasible request for funding, incentive funding not fulfilling purpose; undifferentiated applications/review process; lack of clarity on sustainability and transition; limited integration of programs and services; and slow pace of implementation.

These issues are being addressed in the new funding cycle. The allocation-based funding in which each country eligible for funding is allocated an amount of funding for the period will be continued for the 2017-2019 funding cycle.

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 $^{^6}$ "Ending the TB epidemic" is defined as an average global TB incidence of 10/100 000. The phrase "end TB" is used throughout this document with reference to this operative definition.

⁷ End TB Strategy

The Technical Review Panel's (TRP) observations and lessons learned from the review of the concept notes from the 2014-2016 allocation-based funding model are included in their report available at <u>Technical Review</u> Panel's Consolidated Observations on the 2014-2016 Allocation Based Funding Model.

The lessons learned from the first allocation-based funding cycle and the limitations will be addressed in the new funding cycle. The allocation-based funding in which each country eligible for funding is allocated an amount of funding for the period will be continued for the 2017-2019 funding cycle. Detailed information on the process for requesting funding in the new cycle, including differentiated application approaches, can be found on the Global Fund website.

09 Global Fund 2017-22 strategic objectives

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 a number of 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, 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 barriers including stigma and discrimination undermine an effective response to the three diseases. Addressing those access barriers with concrete programs and human rights-based, gender responsive and community-led programing and implementation is essential to ensuring that the impact of the TB response is maximised. Addressing gender-related barriers, including gender inequality, harmful gender norms and stereotypes is essential as it drives increases in infection rates, and contributes to differential access to health services for men, women and transgender people.

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.

IV. Translating Normative Guidance into a Funding Request

10 Prioritization

Requests for support from the Global Fund should be based on the National Strategic Plan (NSP) for TB and national health sector strategies that are robust.

In preparing for the request for support it is essential to:

- 1. Plan for sustainability and continuity of key interventions that under previous grants have been evaluated as successful and having an impact, while improving prioritization and strategic focus of the Global Fund investment for TB;
- 2. Prioritize interventions that will address priority areas and maximize the impact of the Global Fund investments; and
- 3. Scale up and efficiently and effectively utilize new diagnostics, new drugs, shorter regimens and paediatrics formulations and innovative approaches that maximize impact.

Applicants are strongly advised to review the most recent technical and normative guidance to identify high impact interventions and consider scale up of evidence-based, local and regional good-practices, innovations and successful pilot projects including those supported by TB REACH and other partners. Key guidance documents are listed at the end of this information note. The interventions listed in the box below are illustrative and encompass core functions of health services essential for TB care and prevention that could be tailored to country contexts, epidemiology and experiences. Their implementation requires close collaboration with all stakeholders including the social sector, civil society and communities.

The Global Fund strategy 2017-2022 provides clear direction on how to differentiate the approach to investments, work better in challenging operating environments, incorporate gender considerations into investments more effectively, focus on eliminating human rights barriers, and sustain these gains. The End TB Strategy and Global Plan to End TB provide useful guidance on prioritization of interventions and populations, based on the TB epidemiology and country contexts.

11 Allocative efficiency

The resources required to end the TB epidemic are greater than currently available. Making the greatest impact therefore requires a data-driven approach that focuses programs towards populations most affected by the diseases. This process, often called "allocative efficiency," has been embedded into the Global Fund grant-making process. Countries are encouraged to complete an epidemiological analysis to identify disease trends and data gaps prior to submitting their requests for funding. This aims to focus investment to the right populations in the right places and build better systems of support. To aid this effort, the Global Fund also supports countries to better map and estimate the size of key populations.

NSPs should reflect general principles on the allocative efficiency of investments within programs, namely that cost effective and evidence-based interventions have been selected (among various options) as suitable to the country context; interventions are prioritized given limited resources; and investments are optimally allocated across interventions to achieve maximum health impact. In countries where it is feasible, the allocative efficiency discussion could still be more directly linked to the process of selecting and prioritizing among the numerous key interventions.

Box 1: High-impact TB interventions

- Early diagnosis and prompt treatment of all persons of all ages with any form of TB (drug-susceptible or drug-resistant TB). Providing universal access to TB care and prevention with greater attention to vulnerable and hard-to-reach populations requires access to rapid TB diagnostics and DST to all who need it and prioritized for persons at risk of MDR-TB and HIV-associated TB. This includes optimal utilization of the Xpert MTB/RIF and other new tools, X-ray (including digital x-rays) to ensure access to all people in need; active and intensified case finding among priority populations.
- Systematic screening of high-risk groups including through using digital x-rays and new diagnostics, e.g. contacts of people with TB including children and elderly, PLHIV and workers exposed to silica dust, prisoners, migrants and people living in urban slums. This also includes provision of preventive chemotherapy to high risk groups including PLHIV and children in contact with TB patients.
- Treatment of all people with TB including drug-resistant TB, with patient support. Treatment should be provided to all who need it regardless of age, sex, gender or type of TB disease, bacteriological status, co-morbidities or legal status of the patient. Ensuring all TB patients have access to free-of-charge life-saving treatment is fundamental to minimizing disease and deaths due to TB. This includes introduction and scale up of new drugs and shorter regimen for treatment of MDR-TB and child-friendly medicines and formulations for TB among children. Resistance to anti-TB medicines poses a major threat to global progress and needs to be promptly and adequately addressed including through prevention of transmission (infection control).
- Programs and approaches to address access barriers, including community-based and integrated services: Scale-up programs to support integrated community and family-based approaches to TB and MDR-TB care to remove access barriers, reduce delays in diagnosis and improve management of TB in men, women, children, adolescents and the elderly. This include scale-up of innovative approaches in service delivery, with particular consideration of proven in-country experiences (for e.g., demonstrated through TB REACH supported projects and through the ENGAGE-TB Approach).
- Collaborative TB/HIV 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-centred delivery of effective prevention, early detection, and prompt treatment, as set out within the 12-point collaborative TB/HIV activities.
- **Private Sector TB Care**. Engagement of private care providers in TB diagnosis, treatment and prevention and M&E is very critical. In some countries majority of TB/DR-TB patients consult or access private care providers for their TB-related symptoms due to different reasons. Innovative approaches to engage and collaborate with private TB care providers such as those supported by TB REACH and other partners should be explored and integrated into the effort in fighting TB.
- 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 abuse, smoking, silicosis, chronic obstructive pulmonary disease and other non-communicable diseases including mental health problems. These conditions constitute risk factors for TB and can complicate clinical management.
- Surveillance and data. Quality data are required to inform prioritization, monitoring and decision-making. Strengthening TB surveillance systems including through integrated and electronic recording and reporting systems, digital-health and intensifying diagnostics connectivity solutions is essential.

12 Programme and data quality

Good data is essential for good decision-making. Systematic efforts and long-term investments in routine data systems are needed to improve the availability and quality of data for analysis and use in strategic decision-making; and to provide capacity for better targeting of programs, improving quality and providing for more efficient service delivery.

The Operational Policy Note on Program and Data Quality in the <u>Global Fund Operational Policy Manual</u>, issued in July 2016, provides guidance on monitoring and evaluation (M&E) 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 achievement of grant objective.

13 Critical areas for funding requests to the Global Fund

Key populations

Key populations for TB are people who are vulnerable, underserved or at risk of TB infection and illness. 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 behavioural factors (refer to *Table 1*).

These groups are disproportionately affected by disease, stigma and discrimination and human rights and gender-related barriers. They should be purposively engaged to contribute valuable insights, guidance, and oversight to implementing organizations.

The Global Fund places key populations at the heart of its work and has thus provided a package of supportive strategies, policies, and processes. The Global Fund is increasingly engaging key populations in critical decision-making processes. Members of key populations must be included in Country Coordinating Mechanisms, 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.

Table 1: Key populations for TB8

Table 1: Key populations for 1B°					
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 contacts of TB patients, including children • work in environments that are overcrowded • work in hospitals or are health care professionals				
People who have LIMITED ACCESS TO QUALITY TB SERVICES	Migrant workers, women in settings with gender disparity, children, refugees, or internally displaced people, illegal miners, and migrants. 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				

⁸ The Paradigm Shift 2016-2020; The Global Plan to End TB; Stop TB Partnership, UNOPS, 2015

	face legal barriers to access care			
PEOPLE WHO:				
People at INCREASED RISK of TB	• live with HIV			
because of biological or	 have diabetes or silicosis 			
behavioural factors that	 undergo immunosuppressive therapy 			
compromise immune function	 are undernourished 			
	• use tobacco			
	 suffer from alcohol-use disorders 			
	• inject drugs			

Addressing human rights and gender-related barriers

Many of the factors that increase vulnerability to contracting TB or undermine access to TB services are associated with gender inequality and other human rights violations. The <u>Global Plan to End TB: The Paradigm Shift 2016-2020</u>) to which many countries are committed includes as one of its pillars "protection and promotion of human rights, ethics and equity." Some well documented human rights-related barriers to TB programs are as follows:

- **Stigma:** Overcrowding, poor sanitation, inadequate ventilation and poor nutrition make people vulnerable to TB and also likely to have poor access to TB services. TB-related stigma is often linked to the stigma and marginalization of poverty, as well as to misinformation and unjustified fears about the disease. Health workers should be examples to the community of non-stigmatized TB care, but they are sometimes inadequately informed, judgmental or fearful about TB. PLHIV face high TB risk, and TB is a common cause of mortality among people with HIV. The stigma and discrimination associated with HIV can amplify TB-related stigma.
- **Prison and other forms of detention:** People in prison are at high TB risk because of their living conditions but are often excluded from TB services. People who use drugs in many settings face high TB risk not only because of sharing drug-using equipment such as pipes for inhalation of drugs, but also because they may live in conditions of poverty, may be more likely to have HIV, and are likely to be in prison in their lifetime especially when drug laws include custodial penalties for minor offenses.
- **Involuntary isolation:** TB contagion 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.
- **Gender-related barriers:** Women may not enjoy the economic and decision-making autonomy to seek and sustain TB services. In many places, men are more likely to have jobs such as mining or blasting that expose them to TB risk or to engage in migrant work where sustaining treatment may be difficult. Men may also be more likely to smoke or use drugs, both risk factors for TB.

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

- Stigma reduction measurement tools, training programs and other resources have been developed for health workers, communities, employers, and social and religious leaders and have been shown to be effective, especially when patients are meaningfully involved in the design of programs.
- "Know your rights" or rights literacy programs for patients, their families and communities, and even health workers can be helpful, especially for marginalized people already prone to

⁹.Guidance on ethics of tuberculosis prevention, care and control. World Health Organization Geneva, 2010.

exclusion from services or people who may be subjected to involuntary isolation. These programs are often usefully combined with access to <u>legal services</u>.

- **Reform of laws and policies** that undergird human rights barriers, such as 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 prisoners' access to health services equivalent to those in the community. Laws and policies can be challenged in many ways, e.g. through legislative advocacy, community mobilization and awareness-raising and litigation.
- Training for police, corrections officials, judicial personnel may be useful, especially to improve prison-based services and where key affected populations such as people who use drugs have frequent contact with the police and the courts. Police may be receptive to training that includes information on how to protect themselves from TB on the job.
- **Training for health workers** can focus not only on stigma reduction but also the importance of informed consent, confidentiality and privacy, and meaningful participation of patients in decision-making about their care, as well as understanding involuntary isolation as a last resort.

All programs, in accordance with human rights principles, should be designed, implemented and evaluated with the active participation of affected communities and should be conducted in ways that are respectful, accountable, gender-responsive, and non-discriminatory.

Strengthening community responses

Community and patient driven responses are needed as part of the paradigm shift to end TB. This should go beyond service delivery to include 1) community—drive monitoring and evaluation of TB programs and services, 2) advocacy 3) technical assistance 4) strengthening links and partnerships with key TB stakeholders 5) engaging in the assessments of the legal, policy environment and the gender sensitivity of the response. The community response needs to be comprehensive to contribute to achievement of better health outcomes but also to strengthen community responsiveness. In order for the communities to be equal partners in the response, they require resources, technical assistance, tools and capacity building. Community engagement for TB covers a wide range of activities that contribute to the detection, referral and treatment of people with drugsusceptible and drug-resistant TB, and HIV - associated TB. Community engagement is critical to improve the reach and sustainability of interventions related to TB and to help end TB engagement of communities should be further strengthened. Innovative and successful approaches (such as successful TB REACH funded projects or ENGAGE-TB Approach) that engages communities and civil society organizations could be tailored to country-specific contexts and used to strengthen community responses.

Sustainability and transition considerations

The Global Fund encourages all countries to build sustainability considerations into their program design. In the new 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 (forthcoming).

14 Technical support and capacity building

Technical support

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/updating, development of funding request and implementation. Technical support can be made available to the Country Coordinating Mechanism (CCM), to implementers, and to civil society organizations through partners and the Global Fund.

Several partners including USAID, the UNION, WHO, Stop TB Partnership/GDF, KNCV and others provide technical support to countries to strengthen their TB Programs. USAID works in close collaboration with other USG departments and agencies, implementing partners, the Stop TB Partnership, WHO, and other bilateral donors to plan and coordinate TA to ensure there is no duplication of efforts. USAID supports TB, DR-TB program activities in several countries including Global Fund grant implementations. Further information can be accessed at <u>USAID</u>. The UNION also provides technical support to countries and further information can be accessed at <u>UNION</u>.

Technical support and capacity building for TB and DR-TB responses

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 Memorandum of Understanding (MOU) between the Global Fund and WHO¹⁰ regarding the provision of technical and advisory support relating to the activities of the regional Green Light Committees ("rGLCs") and their respective secretariats was entered into on 1 April 2015. 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 a Principal Recipient receives grant funds from the Global Fund under an active agreement to finance PMDT activities will receive one of the following two TA and advisory support packages coordinated by the rGLC Secretariats:

- a. Core service package (for all countries other than those described on b. below); or
- b. Enhanced service package (for high MDR_TB burden countries as defined by WHOs Global TB Programme in its most up to date report).

The Core Service Package includes the following components:

- assistance in developing, updating, revising, as necessary, the national PMDT expansion plan, in line with the NSP;
- assistance in developing an updating, in relation to the national PMDT expansion plan as part of the NSP, a detailed work plan, budget, monitoring and evaluation plan, and a procurement and supply management plan;
- identification of country capacity needs and assistance for capacity building;
- monitoring of in-country progress with a minimum of one in-country mission per calendar year;
- preparatory activities for in-country missions; and
- supporting the planning for introduction of evidence-based innovative approaches, new diagnostics, new drugs and /or revised regimens for treatment of DR-TB cases as recommended by WHO.

The Enhanced Service Package includes the services listed under the Core Service Package with the following additional services:

- minimum of one additional one in-country mission per calendar year, either to assess the country's performance and progress or provide technical assistance (TA) on specific areas as identified from rGLC reports and country missions or as requested by countries; and
- ongoing provision of support and coordination pf partners to address the bottlenecks identified in the overall PMDDT and the Global Fund supported MDR-TB activities.

According to the MOU the annual payment for each service package is as follows:

- Core service package: US\$ 25,000 per grant per annum;
- Enhanced service package; US\$ 50,000 per grant per annum.

Global Fund and WHO are discussing together with other partners on future mechanism within broader consultations on methods to optimize technical assistance for countries in their response to DR-TB. The special agreement and provision of technical support to countries is expected to continue. Any change in the MOU will be communicated with countries and all stakeholders.

15 December 2016 Geneva, Switzerland

¹⁰ Amended and Restated Memorandum of Understanding (MOU) between the Global Fund and WHO Regional Green Light Committees and secretariats. April 2016

15 National Strategic Plans

The National Strategic Plan (NSP) is the backbone at country level to guide national health authorities in managing and implementing appropriate TB care and prevention activities, and building effective linkages with other programmes and partners within and beyond the health sector. The NSP should be aligned within the national health plan and linked to plans of other sectors. A sound NSP should provide a clear framework that specifies the appropriate strategic interventions to reach the country's TB prevention, care and control goal(s), objectives and targets. Interventions and objectives should be adequately and coherently linked. Moreover, activities and sub-activities inherent to each intervention need to be clearly specified, highlighting clear target(s) for each intervention and identifying where and when each activity or sub-activity should be implemented and who will implement it.

The NSP should include specifications of the technical assistance needed to implement certain interventions and/or activities identified, a clear description of how the implementation of interventions and activities will be monitored and how their output, outcomes and impact will be measured and evaluated; and a detailed budget to implement interventions and activities.

The NSPs need to incorporate an expanded set of baseline assessments of national and subnational TB epidemiology, including identification of key affected populations/communities, health system structure and functions. The NSPs should include specific analyses of procurement and supply systems, resource availability including human resources, access barriers and enablers, including regulatory policies, existing links with social services, and the roles of communities, civil society organizations and the private sector. Such assessments can be linked at least in part with national programme reviews, or joint monitoring mission, undertaken with partners, as outlined in WHO guidance. Detailed guidance can be found in the WHO document Toolkit to develop a national strategic Plan for TB prevention, care and control.

The national strategic plans and strategies should fulfil the following criteria:

- Be up-to-date: based on the latest epidemiological information and knowledge of the adequacy of the current response.
- Be based on an inclusive, multi-stakeholder process.
- Effectively prioritized and budgeted.
- Be based on evidence-based approaches and aligned with international norms.
- Address human rights and gender-related barriers and social determinants of health that make certain groups particularly vulnerable and limit their access to TB services.

The Global Plan to End TB: The Paradigm Shift 2016-2020, provides a set of recommended actions — "investment packages" — designed to achieve the 90-(90)-90 targets described in the plan. These investment packages are tailored to the local characteristics of the TB epidemic, as well as to the health system constraints and socioeconomic situations in various country settings. Similarities exist between countries within a particular region or between countries with similar histories, socioeconomic conditions or health system constraints. As a result, countries can be grouped into different "settings". Countries can be associated with the characteristics of more than one setting, and provinces within a single country can fit into different settings. The Annexes to the Global Plan provide detailed descriptions of relevant key interventions depending on the specific country scenario. These are helpful in determining priorities and priority interventions.

V. Key References

Global Fund Information Notes and Technical Briefs

- Solution Global Fund Information Note: <u>Building resilient and sustainable systems for health through Global</u> Fund investments (2016).
- ➤ Global Fund Information Note: <u>HIV Information Note</u>
- ► Global Fund Technical Brief: Human rights and gender for TB (2016)
- ➤ Global Fund Technical Brief: <u>Addressing Sex Work, MSM and Transgender People in the Context of the HIV Epidemic (2016).</u>
- > The Global Fund Reproductive, Maternal, Newborn, Child and Adolescent Health Technical Brief
- ➤ Global Fund Technical Brief: <u>Strengthening sexual, reproductive, maternal, newborn, child and adolescent health (SRMNCAH) interventions in funding requests to the Global Fund (2016).</u>
- Global Fund Technical Brief: HIV, Human Rights and Gender Equality (2016).
- ► Global Fund Technical Brief: <u>Strengthening Community Systems and Responses (2016).</u>

Further selected Global Fund documents

- ➤ Global Fund Strategy 2017-2022 "Investing to End Epidemics." (2016).
- > Applying for funding
- ► 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)
- The Role of the Global Fund in Supporting Countries to Build Resilient and Sustainable Systems for Health (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

- Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis (2014)
- > WHO: End TB Strategy
- Digital health for the End TB Strategy: an agenda for action (2015)
- ► Electronic recording and reporting for tuberculosis care and control (2012)
- Framework for the engagement of all health care providers in the management of drug resistant tuberculosis (2015)
- Framework of indicators and targets for laboratory strengthening under the End TB Strategy
- Global tuberculosis report 2016
- Implementing tuberculosis diagnostics. Policy framework (2015)
- ➤ <u>Implementing the End TB strategy: The Essentials</u> (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 (2014)
- Policy Guidance
- ➤ WHO: Recommendations for investigating contacts of persons with infectious tuberculosis in low and middle-income countries (2014)
- Report of the consultation meeting to draw lessons from development of Single TB and HIV Concept Notes and defining the way forward for joint TB and HIV programming
- ➤ The Shorter MDR-TB Regimen
- > Systematic screening for active tuberculosis: an operational guide (2015)
- > TB diagnostics and Laboratories

- Toolkit to develop a National Strategic Plan for TB prevention, care and control (2015)
- Towards tuberculosis elimination: an action framework for low-incidence countries (2014)
- > Xpert MTB/RIF Implementation Manual (2014)
- ➤ ENGAGE-TB Approach: Operational guidance (2012)

Stop TB Partnership

- ► Global Laboratory Initiative: <u>GLI quick guide to TB connectivity solutions</u>
- Stop TB Partnership: <u>The Paradigm Shift 2016-2020</u> (2015)
- ➤ Stop TB Partnership: <u>Improving TB Case Detection</u>: A compendium of TB REACH Case studies, lessons learned and a monitoring and evaluation framework
- ➤ Stop TB Partnership: <u>Key Population Briefs</u>
- ➤ Stop TB Partnership: <u>GLI Quick guide to TB diagnostics connectivity solutions</u>
- > Stop TB Partnership: Global Drug Facility

Other key documents

- ➤ The Union: The Unions desk guide for diagnosis and management of tuberculosis in children (2016)
- ➤ UNITAID: <u>Tuberculosis diagnostics technology and market landscape 4th edition (2015)</u>
- ➤ UNAIDS: UNAIDS/WHO Technical Guidance Note on HIV/TB
- ➤ TB Alliance: Child-friendly medicines
- ➤ USAID: <u>USAID Tuberculosis</u>

VI. List of Abbreviations

AMR - Antimicrobial Resistance

ARV - Antiretroviral

ART - Antiretroviral Therapy

DR - Drug-resistant

DST - Drug-susceptibility Testing
IPT - Isoniazid Preventive Therapy
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

PLHIV - People Living with HIV

PMDT - Programmatic Management of Drug-resistant Tuberculosis

rGLC - regional Green Light Committees
RR-TB - Rifampicin-resistant Tuberculosis
SL-LPA - Second Line-Line Probe Assay

TA - Technical Assistance

TB - Tuberculosis

TB-LAMP - Tuberculosis Loop Mediated Isothermal Amplification

UHC - Universal Health CoverageWHO - World Health Organization

XDR-TB - Extensively Drug-resistant Tuberculosis

Annex 1: Top-10 Priority Indicators (Not Ranked) for Monitoring Implementation of the End TB Strategy at Global and National Levels, with Recommended Target Levels that Apply to All Countries

	Indicator	Recommended target level*	Main rationale for inclusion in top-ten
1	TB treatment coverage Number of new and relapse cases that were notified and treated, divided by the estimated number of incident TB cases in the same year, expressed as a percentage.	≥90%	High-quality TB care is essential to prevent suffering and death from TB and to cut transmission. High coverage of appropriate treatment is a fundamental requirement for achieving the milestones and targets of the End TB Strategy. In combination, it is likely that these 2 indicators will be used as tracer indicators for monitoring progress towards universal health coverage (UHC) within the post-2015 Sustainable Development Goals.
2	TB treatment success rate Percentage of notified TB patients who were successfully treated. The target is for drug-susceptible and drug-resistant TB combined, although outcomes should also be reported separately.	≥90%	
3	Percentage of TB-affected households that experience catastrophic costs due to TB** Number of people treated for TB (and their households) who incur catastrophic costs (direct and indirect combined), divided by the total number of people treated for TB.	0%	One of the End TB Strategy's three high-level indicators; a key marker of financial risk protection (one of the two key elements of UHC) and social protection for TB-affected households.
4	Percentage of newly notified TB patients tested using WHO-recommended rapid tests Number of newly notified TB patients diagnosed with WHO-recommended rapid tests, divided by the total number of newly notified TB patients.	≥90%	Accurate diagnosis is a fundamental component of TB care. Rapid molecular diagnostic tests help to ensure early detection and prompt treatment.
5	LTBI treatment coverage Number of people living with HIV newly enrolled in HIV care and the number of children who are contacts of cases started on LTBI treatment, divided by the number eligible for treatment, expressed as a percentage (separately for each of the two groups).	≥90%	LTBI is the main treatment intervention available to prevent development of active TB disease in those already infected with <i>M. tuberculosis</i> .
6	Number of contacts of people with bacteriologically-confirmed TB cases who were evaluated for TB divided by the number eligible, expressed as a percentage.	≥90%	Contact tracing is a key component of TB prevention, especially in children.

7	DST coverage for TB patients Number of TB patients with DST results divided by the number of notified bacteriologically confirmed cases in the same year, expressed as a percentage. DST coverage includes results from molecular (e.g. Xpert MTB/RIF) as well as conventional phenotypic DST results.	100%	Testing for drug susceptibility for WHO recommended drugs is essential to provide the right treatment for every person diagnosed with TB.
8	Treatment coverage, new TB drugs Number of TB patients treated with regimens that include new (endorsed after 2010) TB drugs, divided by the number of notified patients eligible for treatment with new TB drugs, expressed as a percentage.	≥90%	An indicator that is relevant to monitoring the adoption of innovations in all countries. Indicators related to the development of new tools are needed at global level but are not appropriate for monitoring progress in all countries. The definition of which patients are eligible patients for treatment with new drugs may differ among countries.
9	Documentation of HIV status among TB patients Number of new and relapse TB patients with documented HIV status divided by the number of new and relapse TB patients notified in the same year, expressed as a percentage.	100%	One of the core global indicators used to monitor collaborative TB/HIV activities. Documentation of HIV status is essential to provide the best care for HIV-positive TB patients, including ART.
10	Case fatality ratio (CFR) Number of TB deaths (from a national VR system) divided by estimated number of incident cases in the same years, expressed as a percentage.	≤5%	This is a key indicator for monitoring progress towards 2020 and 2025 milestones. A CFR of 6% is required to achieve the 2025 global milestone for reductions in TB deaths and cases.

^{*}target level to be reached by 2025 at the latest.

^{**}cost faced by households of TB patients above 20% of annual household income.

DST – drug susceptibility testing; LTBI - Latent TB infection