IMPLEMENTING THE END TB STRATEGY: **THE ESSENTIALS**

THE END TB STRATEGY

World Health Organization

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Contents

Abbreviations

aDSM	active TB drug-safety monitoring and management
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
BCG	bacille Calmette-Guérin
CFR	case fatality ratio
CHW	community health workers
COPD	chronic obstructive pulmonary disease
CSO	civil society organization
CV	community volunteer
DR-TB	drug-resistant TB
DST	drug susceptibility testing
FBO	faith-based organization
FDC	fixed-dose combination
HIV	human immunodeficiency virus
IGRA	interferon-gamma release assay
IPC	infection prevention and control
LTBI	latent TB infection
MCH	maternal and child health
MDGs	Millennium Development Goals
MDR-TB	multidrug-resistant TB
NCD	non-communicable diseases
NGO	nongovernmental organization
NSP	national TB strategic plan
NTP	national TB programme
PHC	primary health care
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
PPM	public-private mix
RMNCAH	reproductive, maternal, newborn, child and adolescent health
SDG	Sustainable Development Goals
TST	tuberculin skin test
UHC	universal health coverage
WHA	World Health Assembly
WHO	World Health Organization

Foreword

In order to end the TB epidemic, countries will need to strengthen their health and social sectors by achieving universal health coverage and social protection, which are also emphasized within the framework of the new SDG agenda.

The global resolve for intensifying the fight against TB and achieving an end to the global epidemic is illustrated by the adoption of the WHO's End TB Strategy by the World Health Assembly (WHA) in 2014, its endorsement in several WHO Regional Committee meetings during 2015, and the inclusion of "ending the TB epidemic" as a target within the health-related Sustainable Development Goal (SDG) 3 by the United Nations General Assembly in September 2015. The Global TB Report of 2015 substantiates how timely and essential this resolve is by highlighting that TB now ranks as a leading infectious disease killer globally alongside HIV.

Through the implementation of the DOTS strategy (1994-2005) and the Stop TB Strategy (2006-2015), countries – especially those with a high burden of TB – established the basics required for providing high-quality TB diagnosis and treatment. These efforts contributed greatly to meeting the TB-related target of the Millennium Development Goals (MDGs) of halting and beginning to reverse the TB epidemic. Between 2000 and 2014, improvements in quality-assured diagnosis and treatment of TB contributed to saving 43 million lives worldwide. It was apparent, however, that while enhancing access to diagnosis and treatment remarkably improved outcomes in terms of reducing suffering and death, it had very little effect on achieving the desired impact in terms of declining the incidence rates and driving down the TB epidemic. This is not entirely surprising: TB is not only a biomedical and a public health problem but also a disease associated with poverty; TB will continue thriving as long as poverty persists. The End TB Strategy, whose aim is to end the TB epidemic, therefore combines a holistic mix of health and social interventions. Importantly and in keeping with one of the underlying principles of the Strategy, this mix of interventions will need to be adapted to regional, national and local contexts. The End TB Strategy envisions universal access to high-quality TB care and goes beyond it to promote TB prevention. In order to end the TB epidemic, countries will need to strengthen their health and social sectors by achieving universal health coverage and social protection, which are also emphasized within the framework of the new SDG agenda. While this comprehensive approach may help to drive down the TB epidemic more rapidly, it may not be enough to end it. Ending the TB epidemic will also require new tools – a point-of-care test for diagnosing infection and disease; shorter and better regimens to treat disease and infection; and, ideally, a pre- and post-exposure vaccine.

This document describes the essentials of operationalizing the principles, pillars and components of the End TB Strategy after

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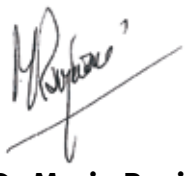
The Essentials emphasize that transitioning from "stopping TB" to "ending the TB epidemic" will call for major transformations, beginning with a transformation of outlook of those in charge of national TB control efforts.

first providing an understanding of the vision, goal, targets, and milestones of the Strategy, and the suggested operational indicators to measure progress. While the Strategy adopted by the WHA presents what needs to be done in the coming decades to achieve the SDG and the WHO targets in 2030 and 2035 respectively, The Essentials outline how it could be done and by whom depending on where the Strategy is going to be implemented. WHO operational guidelines and tools are available for most, but not all aspects of the three pillars of the Strategy. The Essentials explain the concepts and provide examples of early experiences of countries that have already begun the transition to the End TB Strategy.

The Essentials emphasize that transitioning from "stopping TB" to "ending the TB epidemic" will call for major transformations in national TB control efforts. Ending the TB epidemic will require national TB programmes to not only expand and innovate to allow TB diagnosis, treatment and preventive services for all who need it (Pillar 1 interventions), but also to work with all government and non-governmental agencies, communities and civil society organizations to ensure that the design and implementation of relevant health and social sector programmes are TB-sensitive (Pillar 2 interventions). While introducing innovative approaches, tools and technologies will require considerable operational research, countries will also need to participate proactively in research to develop and deploy new tools essential to ending the TB epidemic (Pillar 3 interventions). National TB programmes will require greatly enhanced support from all stakeholders for proper implementation of the End TB Strategy. The task ahead for all of us essentially demands long-term multisectoral engagement. As the world embarks upon the SDG era, we hope all those concerned about global health keep the elimination of TB, an ancient scourge of humanity, at the top of their agenda and help sustain the fight against it until we see the end of the epidemic.



Dr Mario Raviglione
Director, Global TB Programme
World Health Organization

Executive Summary

AIM

The aim of this document (The Essentials), is to guide actions that are needed at national level to adapt, launch and implement the World Health Organization's End TB Strategy. The Strategy, approved by the 67th World Health Assembly in 2014, is designed to achieve a health-related target under the United Nations SDG 3 that calls for ending the TB epidemic. Pursuing this ambitious but achievable goal will require new ways of working, building on the national and global efforts of the past two decades and seizing the opportunity to draw in many new stakeholders to join the endeavour.

This document was developed by the WHO's Global TB Programme. It has benefitted from the collective inputs of WHO's Strategic and Technical Advisory Group for Tuberculosis and in-depth consultations with many stakeholders during the two-year development of the Strategy and during the year after its approval. It also builds on the early experiences of countries preparing to introduce the Strategy.

This document, designed for use mainly by national TB programmes (NTPs) and equivalents within ministries of health, is intended for all stakeholders engaged in TB care and prevention. The NTPs must engage with a wide range of stakeholders to implement the Strategy. Using this document as a starting point, country officials may need to prepare detailed national operational guidance on the implementation of the Strategy to meet the needs of diverse stakeholders.

As countries adapt and implement the End TB Strategy and share their experiences, WHO will provide additional guidance and tools and revise The Essentials as appropriate. This is therefore a "living" document and will be enriched by supplementing it further with country examples and case studies available online.

STRUCTURE

This document is organized into three parts:

Part I discusses the overall approach, underlying principles and essential steps in implementing the End TB Strategy.

Part II explains the global targets, advises on setting national targets and provides priority indicators that can be used by countries to monitor progress.

Part III introduces approaches to implementing the three pillars of the Strategy.

Chapters on Pillar 1 (Integrated, patient-centred care and prevention) and Pillar 2 (Bold policies and supportive systems) are organized to address the "what", "who" and "how" of country-level action by outlining:

- National policies needed to implement each component;
- The main actors engaged in helping implement each component;
- Health system requirements to enable implementation;
- Principal implementation steps.

The chapter on Pillar 3 (Intensified research and innovation) proposes steps to help implement the research pillar at country level. Throughout the document, country examples are used to illustrate the implementation of specific aspects of the Strategy.

KEY MESSAGES

PART I. APPROACH, PRINCIPLES AND ESSENTIAL STEPS

- Ending the global TB epidemic will be achievable over the next 20 years only if there is intensive action by all countries which have endorsed the End TB Strategy and its ambitious targets. It requires a paradigm shift from focused actions that gradually reduce the incidence of TB to enhanced, multisectoral actions that have been shown to drive down the epidemic at a rapid pace.
- Ending the TB epidemic is a target under the SDGs that requires implementing a mix of biomedical, public health target and socioeconomic interventions along with research and innovation.
- The End TB Strategy encompasses a package of interventions that can be fully adapted at country level. It has ten components organized under three pillars and four underlying principles that necessitate government stewardship, a strong coalition with communities and civil society organizations, a human rights-based, ethical and equitable approach to implementation, and adaptation of the strategy and targets at the country level.
- Implementing the pillars and components of the End TB Strategy while adhering to its underlying principles requires intensified action from and beyond the ministries of health, in close collaboration with all stakeholders including other ministries, communities, civil society and the private sector.
- Facilitating and coordinating genuine multisectoral collaboration at national and subnational levels may require the establishment of a high-level national coordinating mechanism.
- Designing and operationalizing an effective country-specific response to end the TB epidemic should be founded on sound baseline assessments that include mapping the epidemic, the preparedness of the health system and the TB programme as well as resources available for the ambitious work ahead.

PART II. VISION, GOAL, INDICATORS, TARGETS AND MILESTONES

- The End TB Strategy includes a vision, a goal, and three high-level indicators with corresponding targets for 2030 and 2035 and milestones for 2020 and 2025.
- The 2035 targets are to reduce the TB incidence rate by 90% to 10 cases per 100,000 population per year and to reduce the absolute number of TB deaths by 95% compared with a baseline of 2015. They correspond to the overall goal of ending the global TB epidemic by 2035. The 2030 targets (reductions of 80% and 90% respectively compared with 2015)

correspond to the end date of the post-2015 UN SDGs. The third high-level target is the elimination of catastrophic costs faced by TB-affected families. This target is set to be achieved by 2020.

- Strategy targets and milestones were defined based on projections of what could be achieved in two phases: 2016-2025, and 2026-2035.
  - » Key elements of the first phase include optimum use of existing interventions, achievement of universal health coverage (UHC) for essential prevention, treatment and care interventions as well as efforts to address the social determinants and consequences of TB.
  - » The second phase requires, in addition, the availability and wide use of new tools, including pre- and post-exposure vaccines; point-of-care diagnostic tests for infection and disease and shorter treatment regimens for TB disease and LTBI.
- Countries can adapt the global targets and milestones to their own settings using guidance provided in this chapter. Particular attention is given to how to set targets for 2020 and 2025, since these years are especially relevant for nearer-term strategy and planning.
- Reliable measurement of progress in reducing TB incidence, TB deaths and catastrophic costs is essential. High-performance TB surveillance within national health information systems and national vital registration systems must be in place to monitor TB incidence and TB mortality, while special surveys are the most appropriate way to measure catastrophic costs.
- A top ten list of priority indicators relevant to global and national monitoring of progress in implementing all components of the End TB Strategy is provided, along with recommended target levels. As a minimum, countries will need to define the year(s) by which these targets can be met and ensure that monitoring systems are in place to allow for reliable measurement of progress. It is recommended that the target date for these ten indicators should not be later than 2025.

PART III. THE THREE PILLARS

Pillar 1 – Integrated, patient-centred care and prevention

- Pillar 1 of the End TB Strategy builds on the DOTS strategy (1994-2005) and the Stop TB Strategy (2006-2015) and encompasses all core functions of health services essential for TB care and prevention. Their implementation requires close collaboration with all stakeholders including the social sector, civil society and communities.
- The human and financial resources required for implementation should be commensurate with the enhanced scope of core functions that are integrated effectively within delivery of general health services.
- Early diagnosis and prompt treatment of all persons of all ages with any form of drug-susceptible or drug-resistant TB is fundamental. WHO-endorsed rapid TB diagnostics and drug susceptibility testing (DST) should be available to all who need it and prioritized for persons at risk of multidrug-resistant TB (MDR-TB) and HIV-associated TB. DST for anti-TB medicines other than rifampicin should be offered.
- Appropriate treatment of drug-susceptible and drug-resistant TB should be available and accessible to all who need it. Proper drug safety monitoring and management should be pursued. All relevant care providers should be engaged in the delivery of TB care. Palliative and end-of-life care should also be available when all curative treatment options are exhausted.
- Joint TB and HIV programming should be pursued for integrated and decentralized delivery of services for TB and HIV; the latest WHO recommendations on collaborative TB/HIV activities and on management of LTBI should be followed.

- As part of patient-centred care and depending on needs, all patients should receive educational, emotional and economic support to enable them to complete the diagnostic process and full course of required treatment.
- Close contacts of people with TB, people living with HIV (PLHIV) and workers exposed to silica dust should be systematically screened for TB and considered for preventive therapy.
- All persons with TB need to be assessed for nutritional status and receive nutritional counselling and care according to need. All persons with TB should also be screened for diabetes. Further, depending on local epidemiology, all persons with TB should be assessed for other co-morbidities and related risk factors such as smoking and alcohol or drug abuse.
- TB infection control measures should be applied in all settings.
- Proven digital health tools need to be progressively introduced to improve efficiency of implementation, monitoring and evaluation.

Pillar 2 – Bold policies and supportive systems

- Effective implementation of the End TB Strategy requires effective government stewardship, high-level political commitment and enhanced resources.
- Active coordination across government ministries as well as engagement and collaboration with communities, civil society and all public and private care providers are essential.
- A sound, fully budgeted national TB strategic plan should be developed and implemented with all stakeholders, in line with overall national health and social sector plans.
- The linkages necessary to advise on and secure TB-sensitive UHC strategies and schemes should be developed.
- The regulatory framework should be strengthened and enforced to enable mandatory TB case notification; wider efforts are needed to strengthen vital registration, quality assurance and rational use of drugs, and infection control.
- Practical steps by government agencies and all stakeholders are required to ensure that TB is addressed in social protection, poverty alleviation and related social policy agendas and programmes, with special attention to the needs of affected communities and vulnerable populations.

Pillar 3 – Intensified research and innovation

- In order to end the TB epidemic, new diagnostics, drugs, vaccines and innovative delivery methods are necessary. Countries that carry a moderate or high burden of TB can play a critical role in stimulating and pursuing research along with high-income, low TB-burden countries.
- A coherent national TB research plan that includes a country-specific prioritized research agenda across a continuum from basic to operational research is a core requirement for the development of TB research capacity in countries with moderate or high TB burden.
- Mechanisms should be in place to allow for effective collaboration among the various research and health institutions, the national TB programme and other public health programmes, ideally through the establishment of a national TB research network.
- National TB research networks should establish links with recognized international stakeholders, including scientists, research institutions, other research networks and donors.
- Sustained public investments are the key to developing infrastructure and capacity for TB research.

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PART I

Approach, principles and essential first steps

KEY MESSAGES

- Ending the global TB epidemic will be achievable over the next 20 years only if there is intensive action by all countries which have endorsed the End TB Strategy and its ambitious targets. It requires a paradigm shift from focused actions that gradually reduce the incidence of TB to enhanced, multisectoral actions that have been shown to drive down the epidemic at a rapid pace.
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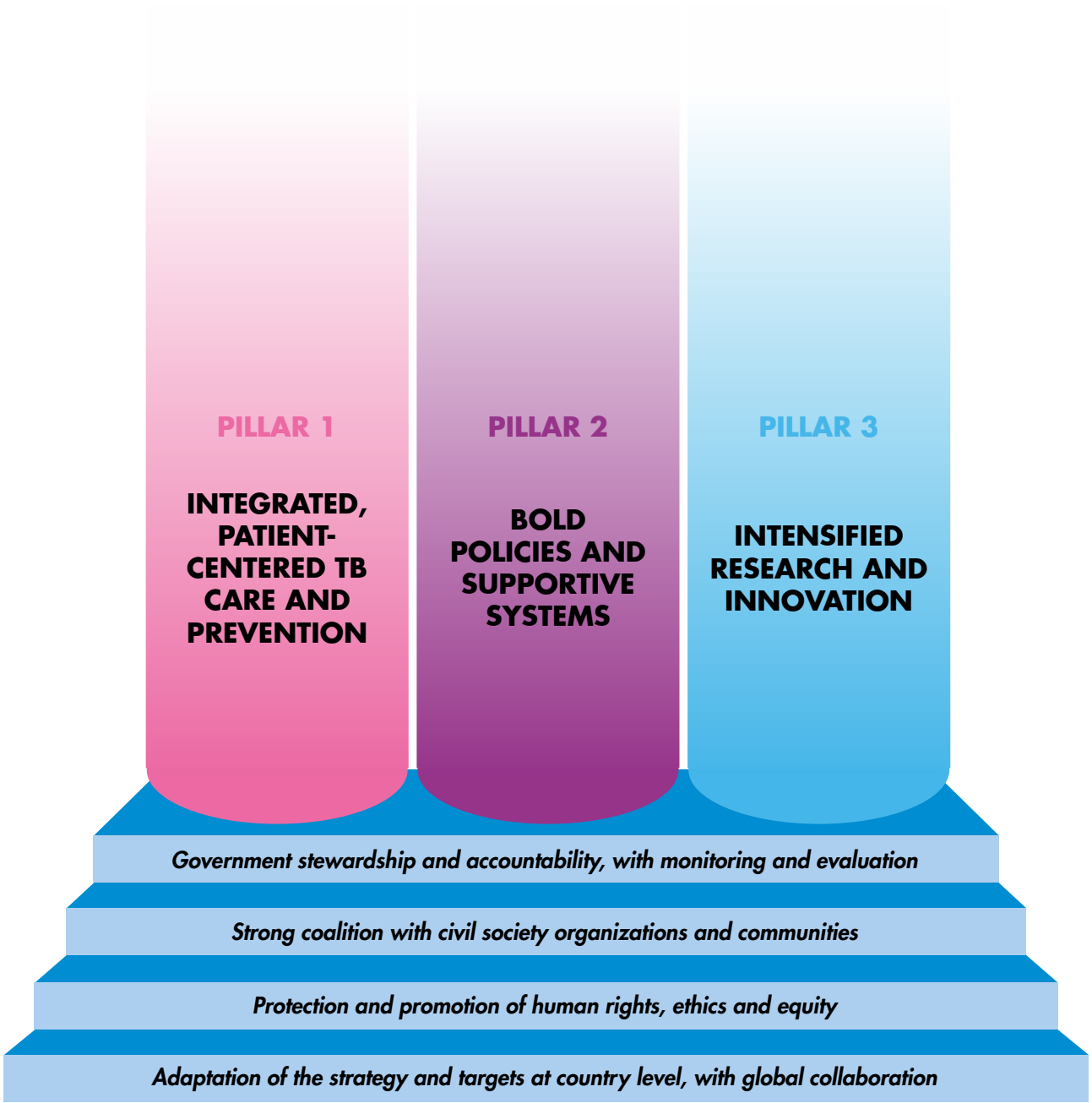
- Facilitating and coordinating genuine multisectoral collaboration at national and subnational levels may require the establishment of a high-level national coordinating mechanism.
- Designing and operationalizing an effective country-specific response to end the TB epidemic should be founded on sound baseline assessments that include mapping the epidemic, the preparedness of the health system and the TB programme, as well as resources available for the ambitious work ahead.

THE END TB STRATEGY: ***PILLARS AND PRINCIPLES***



THE END TB STRATEGY: *AT A GLANCE*

VISION: A WORLD FREE OF TB
Zero deaths, disease and suffering due to tuberculosis

GOAL: END THE GLOBAL TB EPIDEMIC

INDICATORS	MILESTONE		TARGETS	
	2020	2025	**2030***	**2035**
Reduction in number of TB deaths compared with 2015	35%	75%	**90%**	**95%**
Reduction in TB incidence rate compared with 2015	20% (<85/100 000)	50% (<55/100 000)	**80%** (<20/100 000)	**90%** (<10/100 000)
TB-affected families facing catastrophic costs due to TB (%)	0	0	**0**	**0**

PRINCIPLES
1. Government stewardship and accountability, with monitoring and evaluation
2. Strong coalition with civil society organizations and communities
3. Protection and promotion of human rights, ethics and equity
4. Adaptation of the strategy and targets at country level, with global collaboration

PILLARS AND COMPONENTS

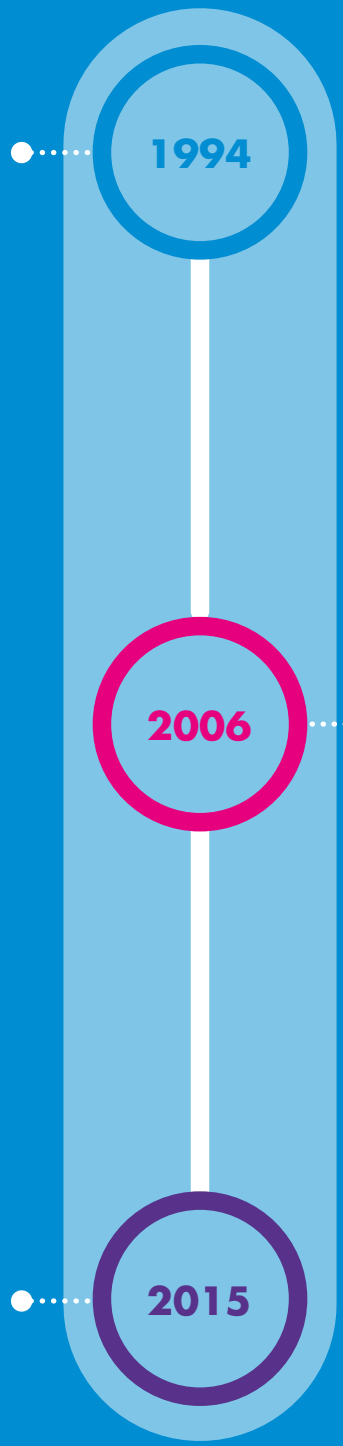
1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION
A. Early diagnosis of TB, including universal drug-susceptibility testing and systematic screening of contacts and high-risk groups
B. Treatment of all people with TB, including drug-resistant TB, and patient support
C. Collaborative TB/HIV activities, and management of co-morbidities
D. Preventive treatment of persons at high risk, and vaccination against TB

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS
A. Political commitment with adequate resources for TB care and prevention
B. Engagement of communities, civil society organizations, and public and private care providers
C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
D. Social protection, poverty alleviation and actions on other determinants of TB

3. INTENSIFIED RESEARCH AND INNOVATION
A. Discovery, development and rapid uptake of new tools, interventions and strategies
B. Research to optimize implementation and impact, and promote innovations

* Targets for the United Nations Sustainable Development Goals.

FIGURE 1.1 **EVOLUTION OF WHO GLOBAL TB STRATEGIES**



THE DOTS STRATEGY

1. Government commitment
2. Case detection through predominantly passive case finding
3. Standardized short-course chemotherapy to at least all confirmed sputum smear positive cases of TB under proper case management conditions
4. Establishment of a system for regular drug supply of all essential anti-TB drugs
5. Establishment and maintenance of a monitoring system, for both programme supervision and evaluation

THE STOP TB STRATEGY

1. Pursue high-quality DOTS expansion and enhancement
2. Address TB/HIV, MDR-TB and other challenges
3. Contribute to health system strengthening
4. Engage all care providers
5. Empower people with TB and communities
6. Enable and promote research

THE END TB STRATEGY

1. Integrated, patient-centred care and prevention
2. Bold policies and supportive systems
3. Intensified research and innovation

Ending the TB epidemic is a Sustainable Development Goal target that requires implementing a mix of biomedical, public health and socioeconomic interventions along with research and innovation.

Introduction

The End TB Strategy, developed in the context of the UN SDGs, is a logical evolution and a paradigm shift from past global TB strategies (1,2). The DOTS strategy of 1994 helped revitalize NTPs and equivalent entities by putting in place the essential basics to address the TB epidemic (3). The Stop TB Strategy of 2006 broadened the response by addressing the emerging challenges of HIV-associated TB and MDR-TB (4). It aimed to improve access to quality TB care by engaging all public and private care providers, civil society organizations and communities. The Stop TB Strategy also encouraged investment in research for better tools and approaches (4) (Figure 1.1).

The World Health Organization's (WHO) annual global TB reports chronicle progress made through widespread implementation of the global TB strategies, and the achievements towards TB-related targets under the Millennium Development Goals (MDGs). The 2015 MDG target to halt and reverse TB incidence has already been achieved on a worldwide basis. TB mortality has fallen 47% since 1990. TB incidence is now 18% lower than the level of 2000. In all, effective diagnosis and treatment of TB saved an estimated 43 million lives between 2000 and 2014. Though significant, this progress is insufficient. In 2014, TB killed 1.5 million people and 9.6 million people fell ill with TB. TB ranks alongside HIV as a leading infectious disease killer. Several challenges remain to be addressed to end the TB epidemic as envisaged under the End TB Strategy (5).

1.1 A holistic approach to end TB

Ending the TB epidemic is a SDG target that requires implementing a mix of biomedical, public health and socioeconomic interventions along with research and innovation (Figure 1.2).

Progress in ending the TB epidemic will depend on:

- Optimizing current strategies and interventions for TB care and prevention;
- Achieving universal access to TB care and support within UHC and social protection and addressing social determinants of TB – all as a part of the global development framework of eliminating poverty and addressing inequity;
- Investing in research to develop new, better and rights-based tools and strategies for diagnosis, treatment and prevention of TB.

The End TB Strategy encompasses a package of interventions that can be fully adapted at country level. It has ten components organized under three pillars and four underlying principles. Implementing the pillars and components of the End TB Strategy while adhering to its underlying principles requires intensified action from and beyond the ministries of health, in close collaboration with all stakeholders including other ministries, communities, civil society and the private sector.

FIGURE 1.2 **UNITED NATIONS SUSTAINABLE DEVELOPMENT GOALS**

The imperative of multisectoral collaboration

Multisectoral collaboration is the key to successful implementation of the End TB Strategy. Clearly, the mix of biomedical, public health and socioeconomic interventions, combined with research and innovation, results in a portfolio far beyond the remit of NTPs. With high-level support, the NTP leadership will need to cultivate and steer the engagement of a wide range of collaborators across and beyond government. These collaborators include a range of ministries such as social welfare, labour, justice, education, transport and science and technology; technical and scientific institutions; financial partners and development agencies; civil society; and the private sector.

In practical terms, 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 within which it is embedded, and others in the government responsible for setting the social development agenda, allocating resources and enabling inter-ministerial coordination.

NTPs or their equivalent may be better placed to coordinate the delivery of TB care and prevention through general health services, while ministers of health and directors-general of health services or equivalents can provide the leadership needed to reinforce and enforce a regulatory framework, and facilitate inter-ministerial and intersectoral collaboration. Government leaders need to provide the overall stewardship and keep the goal of ending the TB epidemic high on the development agenda. The paradigm shift needed to end the epidemic requires resource mobilization which is energized, sustained and involves actors across government and beyond, as has been seen in the response to HIV/AIDS and other health security threats.

1.2 Principles underlying the End TB Strategy

All actions under the three pillars of the Strategy are founded on the following four principles, essential to achieving the Strategy's vision and goal.

A strong coalition that includes civil society organizations and communities can help by giving patients and vulnerable populations a voice and active roles, accelerating the response to the TB epidemic.

1) Government stewardship and accountability with monitoring and evaluation

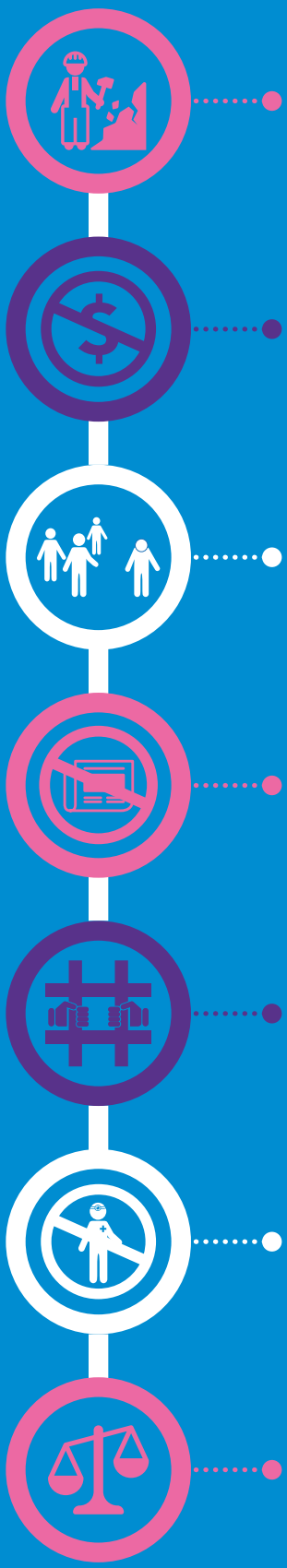
Government stewardship is fundamental to implementing and achieving the targets and goal of the End TB Strategy. A comprehensive response will require involvement of authorities from health and social sectors as well as from other ministries. Stewardship responsibilities may be shared by all levels of government – central, provincial, and local. Within the ministries of health, disease control divisions and NTPs may continue providing technical and strategic support for TB care and prevention services, while eliciting active engagement of higher authorities within the health ministry and their counterparts in other ministries. Further, governments need to create and support mechanisms to actively involve TB-affected communities, patients and health workers in responding to the TB epidemic.

Monitoring and evaluation have to be regular and systematic to ensure accountability. Joint review processes need to include data collection and validation in addition to independent assessments. They should use quantitative and qualitative information and engage those targeted and served. The use of digital tools should be progressively introduced, and systems to improve performance and impact should be well-defined and supported. At the same time, deficiencies in fulfilling roles and responsibilities should be promptly addressed.

2) Strong coalition with civil society organizations and communities

The beneficiaries of the End TB Strategy should also drive its implementation. Their engagement and participation will improve understanding of their perspectives, priorities, awareness, needs and expectations. A strong coalition that includes civil society organizations and communities can help by giving patients and vulnerable populations, a voice and an active role; accelerating the response to the TB epidemic; improving the use of quality services; expanding investment in research and innovation and strengthening grassroots advocacy – all essential to mainstream TB into the development agenda.

BOX 1.1 **ILLUSTRATIVE HUMAN RIGHTS AND ETHICS CONCERNS IN TB CARE AND PREVENTION**



Living and working conditions that increase the risk of exposure, infection and disease may violate human rights (such as for inhabitants of slums, persons living in severe food insecure areas, miners, informal factory workers, truck drivers, migrants, refugees, health workers etc.);

Lack of access to patient-centred quality care may be due to financial cost, limited health service availability and working hours workplace restrictions or failure to follow the International Standards of TB Care and the Patients Charter for TB Care. This can also involve lack of access or inequitable access to new tools, care for co-morbidities, and social support services, including social protection;

Some groups at high risk for, or with, TB face stigma and discrimination and may avoid seeking out care for fear of social or legal repercussions (such as migrants, illicit drug users, women in some cultural settings);

Some groups may lack adequate access to information (such as children and their caregivers, migrants, prisoners);

Some persons ill with TB may face involuntary isolation or detention, without legal protections such as patient-friendly models of care and enablers for treatment adherence, or regular infection control support - they may also lack access to legal redress and due process;

There may be failures to provide care, counselling, and proper infection control measures when no effective TB treatment options remain;

Research may be pursued without ethical standards or the engagement of research subjects and their communities.

Representatives of TB-affected communities and civil society organizations should participate actively in all stages of implementation including programme planning and design, service delivery, and monitoring and evaluation. This engagement is also essential in disseminating information, providing education and support to patients and their families, and in research and advocacy. It is critical that government authorities make concerted efforts to engage and support civil society in TB care and prevention.

3) Protection and promotion of human rights, ethics and equity

The third principle of the End TB Strategy is the use of a human rights-based approach that includes respect for ethical values and promotion and pursuit of equity (6). Health is a human right, along with access to high-quality care and social protection. Progress on these rights will help reduce risk factors for TB infection and disease and enable far better outcomes for those affected. For all interventions in this document, applying a human rights-based approach means a pursuit of non-discrimination and equality, participation and inclusion, and accountability. In practical terms, this means that policies, services and practices should protect and promote individual human rights as well as address the underlying inequities of the poor and marginalized communities who bear a greater burden of TB infection, disease, deaths and social impacts.

BOX 1.2 **ADDRESSING THE SPECIAL NEEDS AND HUMAN RIGHTS OF MIGRANTS UNDER THE END TB STRATEGY**

Adapting the End TB Strategy applies not only to individual countries and local areas, but also to specific communities and populations who are particularly vulnerable to disease transmission or who face access barriers to quality care or poorer treatment outcomes. For example, in 2014 the International Organization for Migration and the World Health Organization proposed actions consistent with the End TB Strategy framework to respond to the global and local challenges of TB among migrants. This constitutes a significant undertaking given the numbers: an estimated one billion migrants worldwide, including 232 million international migrants and 740 internal migrants with complex South-South, South-North, North-North and North-South migration flows, often linked to profound social and economic crises.

The proposed actions include:

- Migrant-inclusive NTPs: addressing issues with epidemiological assessments and programme reviews in national planning consultations, and in monitoring systems;
- Migrant-sensitive care and prevention: sensitizing health workers, patient care models that recognize their needs, cross-border referral systems, and targeted health communications;
- Bold intersectoral policies and systems: enabling policy coherence across immigration, labour and health; adopting policies and regulations enabling access to care regardless of status and eliminating legal and administrative barriers; inclusion of TB prevention and care in bilateral and regional agreements on migration;
- Operational research: on social determinants of TB in migrant communities, assessing effectiveness of local implementation strategies and innovative tools to enable access;
- Global support: by enabling further collaboration across agencies and technical partners, and across sectors.

Source: http://www.who.int/tb/publications/WHOIOM_TBmigration.pdf.

Examples of human rights and ethics concerns in TB care and prevention are presented in Box 1.1. Efforts should be made to identify and eliminate human rights violations that could affect access to quality care or prevention, directly or indirectly. For example, migrants, detainees, prisoners or persons who use drugs may face restrictions on their freedom which can prevent access to care and full treatment, without due process or potential for redress. See Box 1.2 for an example on the situation of migrants.

NTPs, their partners and relevant stakeholders should identify, acknowledge and address practices that are not based on sound ethical standards, and that fail to protect and promote human rights. These should be guided by globally recognized principles and values, sensitive to local values and traditions, and be informed by debates among all stakeholders.

4) Adaptation of the strategy at country level, with global collaboration

The End TB Strategy is not "one size fits all" and must be tailored to diverse country settings. It requires a new or updated medium-term, prioritized and costed national TB strategic plan (NSP). For this reason, baseline assessments will be needed around the following processes: mapping of persons at a greater risk, understanding socioeconomic contexts, analysing access barriers especially for vulnerable populations, and a grasp of the health system context including underserved areas and inequitable service delivery. A sound NSP may not be enough. Robust and effective implementation of the Strategy may also require inclusive, multisectoral engagement that ensures active participation of all stakeholders, under government stewardship. The baseline assessments will help prioritize interventions and approaches and clarify diverse needs and capacities on the ground (Box 1.1). Adoption of the Strategy should be immediately followed by its national adaptation and the development of clear guidance on how to implement its different components, based on local evidence and opportunities. As explained in the following section, countries also need to set their own national targets guided by the ambitious global goal, but taking into account national circumstances.

Tackling the global TB epidemic effectively also requires close collaboration among countries, essential for national health security. Countries within a region can benefit from regional collaboration. Migration within and between countries poses challenges and addressing them will require both in-country coordination and cross-border collaboration (Box 1.2). Global coordination is also essential to mobilize resources for TB care and prevention from diverse multilateral, bilateral and domestic sources.

BOX 1.3 PRIORITIZING INTERVENTIONS IN IMPLEMENTING THE END TB STRATEGY: THE THAI EXAMPLE

To develop a sound NSP for 2015-2019, Thailand embarked on a prioritization exercise during 2013-2014. A first step was to identify major gaps in TB care and prevention by asking key questions:

- What are the major weaknesses in current programme implementation?
- How can performance be improved?
- Which populations and geographical areas have higher TB burdens?
- Who are the most vulnerable and underserved?
- Which interventions are the most cost effective and which ones can be scaled up and sustained nationally?

This gap analysis received critical input from diverse sources: a thorough epidemiological assessment; the recommendations of a national programme review by a Joint Monitoring Mission; several stakeholder consultations at the national and provincial levels; review of data from the National Health Security Office; a review of results of research studies including those conducted as part of the Health Intervention Technology Assessment Programme; and a full costing of the NSP.

The prioritization exercise identified the need to strengthen basic programme operations while expanding and refining their scope. Intervention areas included ensuring early and accurate diagnosis and improving treatment outcomes; mandatory case notification; setting up an efficient surveillance system; and ensuring access to care for migrants and cross-border populations. At the same time, specific focus was required on the elderly (which constitute more than a fifth of case notifications), as well as those living with HIV (with 15% HIV-TB co-infection rates), prisoners (TB prevalence among prisoners being six times higher) and unregistered migrants (a large proportion of the four million hosted by Thailand). Data also revealed that the northeast of the country and the capital Bangkok carried nearly two-thirds of the national TB burden. Of Thailand's 76 provinces, 23 were also high-burden provinces for HIV and TB, requiring intensified efforts.

Not every issue identified was expected to be addressed within the NSP 2015-2019. Consequently, the NSP has prioritized specific investments in transitioning to molecular methods for early diagnosis, while maintaining a network of laboratories with high-quality microscopy and culture facilities. Systematic screening of contacts will be undertaken. Special attention will be paid to key populations such as PLHIV, prisoners, migrants, children and the elderly. Investments in nationwide programme management of drug-resistant TB will also be enhanced. Programme innovations will include adherence support strategies through mobile phones and video technology as well as a web-based and case-based electronic reporting system.

All Thai citizens benefit from universal access to health care, and the NSP 2015-2019 (to be fully supported from domestic resources by 2016) has set an ambitious goal of reducing TB by 25% by 2030.

The initial steps of internal advocacy, baseline preparations, and a national multisectoral coordinating mechanism are the 'ABC' of putting the End TB Strategy into practice.

1.3 Essential steps

Implementing the End TB Strategy requires a thorough understanding of the WHA resolution, strong knowledge of government commitments, and a good grasp of the NSP with details of what has already been planned and what still needs to be done to achieve a seamless transition to the End TB Strategy. The new or modified NSP should be aligned with the End TB Strategy (Box 1.4). The initial steps of internal advocacy, baseline preparations, and a national multisectoral coordinating mechanism could well be the 'ABC' of putting the End TB Strategy into practice (Figure 1.3). With high-level support, the NTP managers and their teams would be well-placed to plan and implement these initial steps.

Such a high-level mechanism that includes communities and civil society and is hosted by the NTP or similar can be based either on an existing body or established specifically to "end the TB epidemic", a SDG target. The creation of a national mechanism for coordination and leadership would help publicize the new Strategy, elevate the leadership of national efforts to end TB, and raise the profile of the TB programme. Similar mechanisms can be established at the provincial and lower levels. Viet Nam presents one possible approach to adapting and launching a national End TB Strategy (Box 1.5).

BOX 1.4 ALIGNING THE NATIONAL STRATEGIC PLAN AND OVERALL HEALTH SECTOR PLAN WITH THE END TB STRATEGY

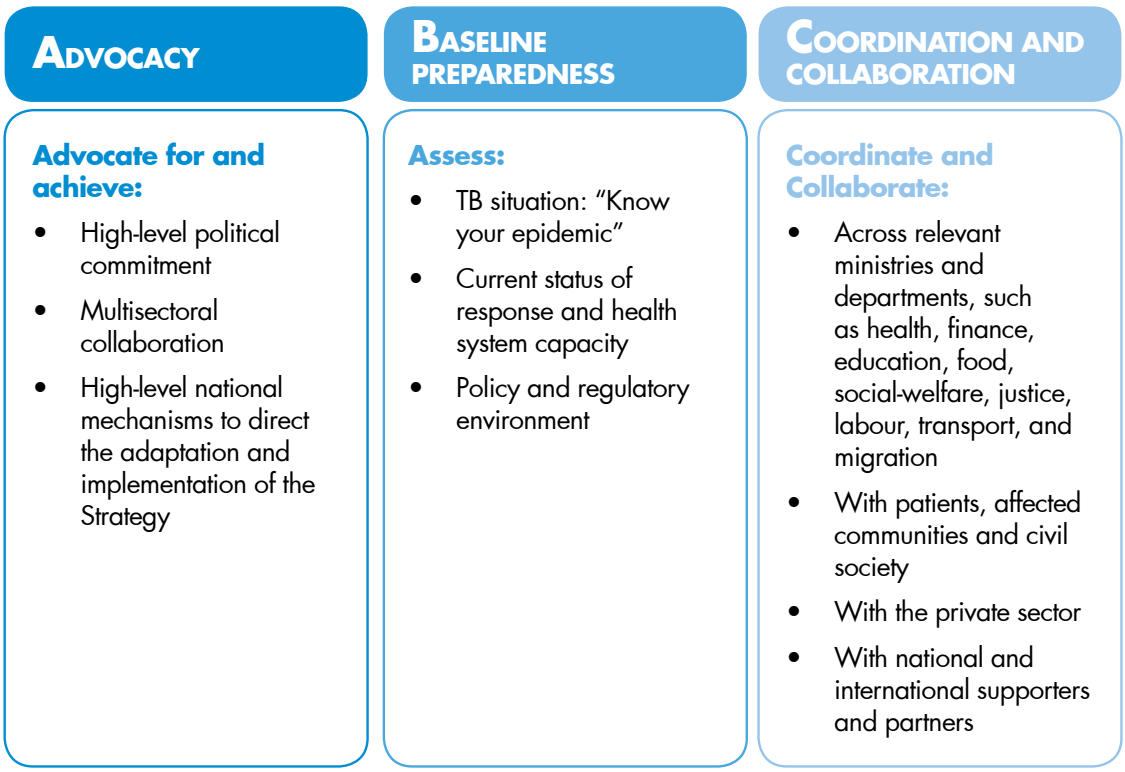
While launching the End TB Strategy at country level could well be a high-profile event, its national implementation is expected to be a planned and phased process of strengthening ongoing interventions and introducing new ones.

NSPs to address TB are generally an integral part of overall national health sector plans, which are prepared every four or five years, and may be introduced as either new interventions or mid-term revisions. Concept Notes for Global Fund financing must also be based on sound NSPs developed through dialogue with all relevant stakeholders.

The End TB Strategy was developed through an inclusive process involving NTP managers, their advisors and partners, and other stakeholders. As a result, many NTPs (or equivalent) were exposed to the thinking behind the new Strategy and have taken advantage of preparing or updating their NSPs to introduce relevant new interventions. For example, NSPs of Ghana, Malawi and Vietnam for 2015-2020 or Kenya's NSP for 2015-2018 explicitly mention and incorporate relevant new interventions foreseen in the End TB Strategy. Thailand's TB NSP for 2015-2019, while based on the current Stop TB Strategy, factors in the End TB Strategy by addressing UHC, social protection, and the elimination of catastrophic costs due to TB, while placing greater emphasis on patient-centred care and community engagement.

New NSPs or updates in line with the End TB Strategy should be based on thorough baseline epidemiological and health systems assessments and informed by recommendations of in-depth programme reviews. These assessments are also essential to determine the selection and prioritization of interventions that are proposed in the NSPs.

FIGURE 1.3 INITIAL STEPS (ABC) TO IMPLEMENT THE END TB STRATEGY IN COUNTRIES



A. Advocacy

Effective implementation of the End TB Strategy will require, from the start, the involvement of all stakeholders, including different government departments across ministries. In some countries this may be beyond the current capacity and authority of the NTP.

To begin implementing the End TB Strategy, national governments should take early visible steps coordinated by the health ministries through their NTPs or equivalent entities. These initial steps, supported by all stakeholders, should raise the profile of national TB efforts. This will send a clear message that the government and its partners are adopting a far more comprehensive approach that will build on and significantly expand current TB efforts.

Ministries of health should encourage and empower NTPs to begin consulting across relevant departments and among all stakeholders to advocate for the new Strategy and to enable a smooth transition.

Building a convincing case can be done through listing current constraints and suggesting practical solutions, as well as by justifying why and how the capacity, scope and reach of the TB response is needed. Approaches best suited to the country's context and a summary of key initial actions will also be required.

B. Baseline preparedness

In parallel, ministries of health may need to enhance their support to NTPs by realigning their NSP to the new Strategy and to the SDGs through inclusive stakeholder consultations and collaboration (6). The current status of interventions listed under the three pillars of new Strategy may have to be defined. This would require a comprehensive health system assessment and epidemiological

mapping. These assessments would help identify and prioritize populations at risk and communities with poor access to services (Boxes 1.6, 1.7).

In addition to TB-specific interventions, baseline assessments would highlight coverage of new TB diagnostics, treatment for drug-resistant TB, and related general health and social sector initiatives. This would also provide a better understanding of the place of TB in, for example, health-related regulatory frameworks, the national plan for UHC and various social welfare schemes.

C. Coordination and collaboration

A high-level multi-stakeholder coordinating mechanism led by the national government can significantly enhance the implementation of the End TB Strategy by enabling:

- Proper oversight of the implementation of the new strategy;
- Advocacy for required resources;
- Development of a participatory platform for all health and non-health stakeholders;
- Facilitating intersectoral collaboration and;
- Advising the NTP through frequent stakeholder consultations, ongoing internal monitoring and periodic independent external evaluations.

Establishing and maintaining a high-level coordinating mechanism should be informed by lessons learned from similar efforts in other health and social sector programmes.

BOX 1.5 **HIGH-LEVEL COMMITMENT: FIRST STEPS FORWARD IN VIETNAM**

When endorsing the new End TB Strategy at the WHA, Viet Nam's representative declared that, inspired by ongoing global discussions leading to the WHA resolution, the country had already launched its post-2015 national TB strategy. This sets ambitious targets for 2020 and 2030, in line with the End TB Strategy and targets. High-level commitment was evident throughout the Viet Nam strategy's development. First, the strategy was launched by the Deputy Prime Minister at a gathering of all stakeholders. Second, and notably, the Prime Minister directly assigned specific, well-identified responsibilities to key stakeholders including ministries of health, finance, planning and investment, labour, social affairs, education and training, information and communication, public security, defence, internal affairs and culture, sports and tourism. Social mobilization and supervision responsibilities were assigned to the members of Viet Nam Fatherland Front, while the People's Committees of Provinces were asked to provide adequate infrastructure and allocate sufficient provincial resources for TB control. Third, the 2014-2015 domestic investments for TB increased by 30% over previous years and all provinces began establishing steering committees for TB control. A national TB strategic plan with representatives of all stakeholders was developed in collaboration with Viet Nam's own Stop TB partnership. The plan provides a blueprint to achieve national milestones for the year 2020.

BOX 1.6 **MAPPING THE EPIDEMIC AND ACTING ON IT**

1. Undertake a thorough epidemiological assessment based on available national and subnational data with the objective of understanding the distribution of the burden of disease and identify geographical areas (urban, rural) or subpopulations (vulnerable, hard to reach) or sectors (mining, prisons) with especially high TB burden.

2. Undertake a through health system and services assessment at all levels based on available information and findings of national and subnational studies with the objective of understanding patient pathways, availability of required services along the pathway and sociocultural and economic barriers that people with TB face from before the onset of symptoms to beyond completing TB treatment.

3. Match the epidemiological and health service assessment to identify actions that need to be taken prioritizing interventions that are likely to have greater effectiveness and higher impact and use this analysis to allocate or reallocate available resources or mobilize new resources.

BOX 1.7 **MONGOLIA - USING EPIDEMIOLOGICAL DATA TO INFORM NATIONAL STRATEGIC PLANNING**

The Ministry of Health and Sports of Mongolia, with support of WHO, carried out a TB epidemiological review, building on preliminary results from the 2015 TB prevalence survey and routine data. The objectives of the exercise were to understand characteristics of the national TB epidemic and inform the National TB Programme's new National Strategic Plan (NSP) 2016-2020. In 2014, the population of the country was 2.9 million and the TB notification rate was 154 per 100,000 population. MDR-TB was estimated at 1.4% among new TB cases but 34% among retreatment cases. Nearly three-quarters of notified TB patients knew their HIV status, and HIV positivity among these patients was under one percent. Rates of bacteriologically-confirmed TB in urban areas were higher among men compared with women (833 vs 293 per 100,000 population). Alcohol dependency is almost four times higher in men than women, and half of all men smoke compared with 5% of women.

Urbanization increased dramatically between 2010 and 2015; by 2015, over 50% of the population resided in the capital Ulaanbaatar and other urban areas. Sixty-two percent of newly notified TB cases were from the capital city alone. Urban areas have high levels of air pollution, which are worse in the winter due to coal and wood combustion. Notifications of bacteriologically confirmed TB were higher among people living in densely populated areas compared with other areas, and also higher among prisoners. In 2015, systematic screening was undertaken in prisons and also for students entering higher education. It was recognized that further research was needed on other risk groups, such as miners.

The epidemiological analysis helped shape the new NSP, with country adaptation of the three pillars of the End TB Strategy. The TB screening criteria have been expanded to include use of chest X–ray and more sensitive diagnostic tools such as LED microscopy and Xpert MTB/RIF. The Government will work to strengthen contact investigation policy. It will incorporate home visits for household contacts of TB patients and source case finding for children as well as contacts of drug-resistant TB cases, with prioritization of geographical areas with the highest case notification rates and social settings associated with transmission. It has been recognized that the new policies require orientation and training of healthcare providers. Community engagement to raise awareness and address stigma has also been highlighted. Other initiatives include enhanced social protection for homeless and other disadvantaged populations, continued involvement of civil society organizations in community-based TB services to reduce loss to follow-up and engagement of universities and technical partners to carry out operational research.

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PART II

Vision, goal, indicators, targets and milestones

KEY MESSAGES

- The End TB Strategy includes a vision, a goal, and three high-level indicators with corresponding targets for 2030 and 2035 and milestones for 2020 and 2025.
- The 2035 targets are to reduce the TB incidence rate by 90% to ≤10 cases per 100,000 population per year and to reduce the absolute number of TB deaths by 95% compared with a baseline of 2015. They correspond to the overall goal of ending the global TB epidemic by 2035. The 2030 targets (reductions of 80% and 90% respectively compared with 2015) correspond to the end date of the post-2015 UN SDGs. The third high-level target is the elimination of catastrophic costs faced by TB-affected families. This target is set to be achieved by 2020.
- Strategy targets and milestones were defined based on projections of what could be achieved in two phases: 2016-2025 and 2026-2035. Key elements of the first phase include optimum use of existing interventions, achievement of UHC for essential prevention, treatment and care interventions as well as efforts to address the social determinants and consequences of TB. The second phase requires, in addition, the availability and wide use of new tools, including pre- and post-exposure vaccines; point-of-care diagnostic tests for infection and disease and shorter treatment regimens for TB disease and LTBI.
- Countries can adapt the global targets and milestones to their own settings using guidance provided in this chapter. Particular attention is given to how to set targets for 2020 and 2025, since these years are especially relevant for nearer-term strategy and planning.
- Reliable measurement of progress in reducing TB incidence, TB deaths and catastrophic costs is essential. High-performance TB surveillance within national health information systems and national vital registration systems must be in place to monitor TB incidence and TB mortality, while special surveys are the most appropriate way to measure catastrophic costs.
- A top ten list of priority indicators relevant to global and national monitoring of progress in implementing all components of the End TB Strategy is provided, along with recommended target levels. As a minimum, countries will need to define the year(s) by which these targets can be met and ensure that monitoring systems are in place to allow for reliable measurement of progress. It is recommended that the target date for these ten indicators should not be later than 2025.

FIGURE 2.1 PROJECTED GLOBAL TRAJECTORY OF TB INCIDENCE RATE 2015-2035 REQUIRED TO REACH 2035 TARGETS (LOG SCALE)

Desired decline in global TB incidence rates to reach the 2035 targets

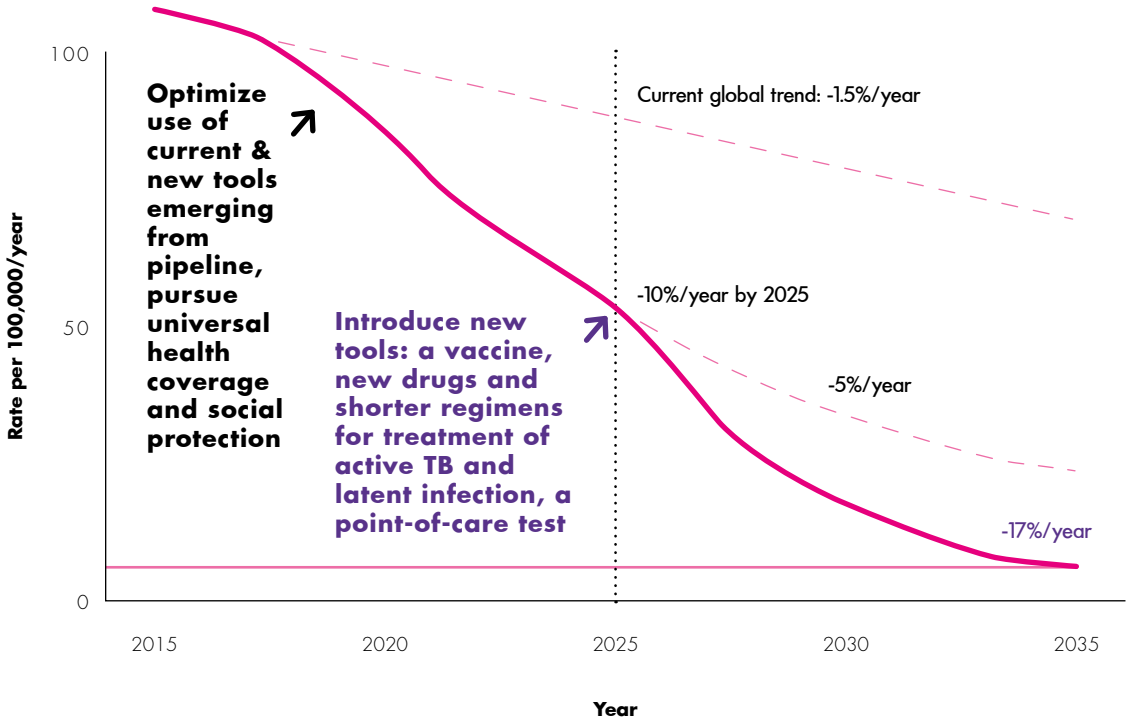
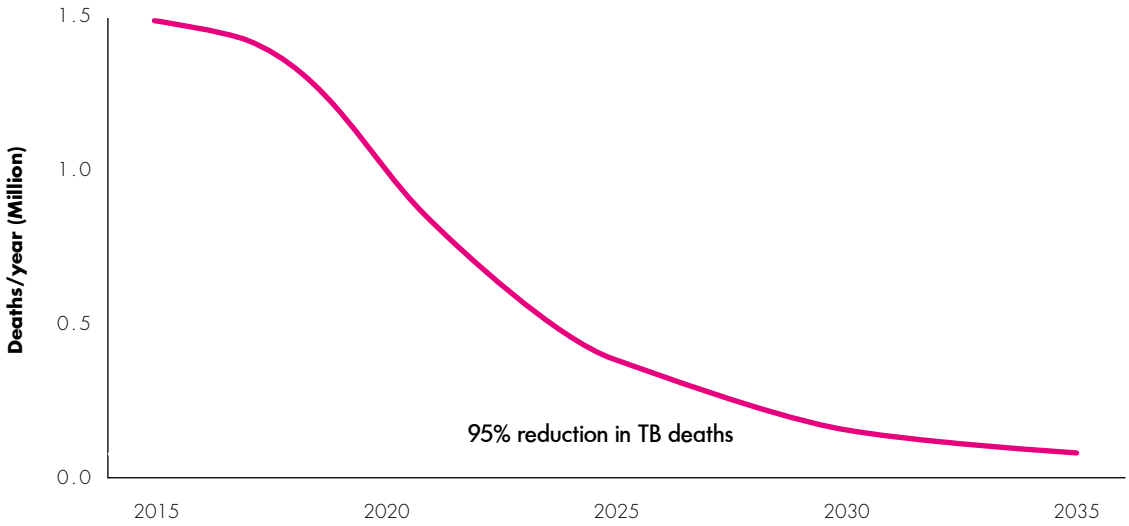


FIGURE 2.2 PROJECTED GLOBAL TRAJECTORY OF TB DEATHS 2015-2035 REQUIRED TO REACH 2035 TARGET



Introduction

Part II presents the aspirational vision and the ambitious goal of the End TB Strategy. It sets out the milestones and targets to be met along the way to achieving the goal of ending the global TB epidemic. The definitions of and the rationale for the three, high-level, overarching indicators of the Strategy, and the corresponding global targets and milestones, are explained. The global trajectory of TB incidence 2015-2035 is depicted and the key interventions required during the first decade and the second decade to reach the 2030 and 2035 targets are described. Guidance on how the global targets can be adapted to national settings is then provided. The final section presents the top ten priority indicators for monitoring implementation of the End TB Strategy at global and national levels, giving recommended target levels that apply to all countries.

2.1 Vision and goal

The vision of the End TB Strategy is "a world free of TB", also expressed as "zero deaths, disease and suffering due to TB". All countries could use this vision in national strategies and plans, without need for adaptation.

As its name implies, the goal of the End TB Strategy is to "end the global TB epidemic". This is defined as ten new (incident) cases per 100 000 population per year, a level achieved in countries considered to have a low burden of TB disease. Many countries have higher TB incidence rates, and globally in 2014 there were an estimated 133 new cases per 100 000 population (1).

Countries with an incidence rate of >10 per 100 000 population per year could adapt the goal nationally by using wording such as "End the national TB epidemic". Countries that already have an incidence rate of 10 cases per 100 000 population per year should adapt the global goal by focusing on TB elimination (<1 case per million population) as well as ending the TB epidemic in specific subpopulations or subnational areas with incidence rates of >10 per 100 000 population per year.

2.2 Global indicators, targets and milestones: definition and rationale

The End TB Strategy approved by the WHA includes three high-level, overarching indicators, with corresponding global targets and milestones (Table 2.1). The 2035 global targets for reductions in TB deaths and cases correspond to the goal of ending the TB epidemic, while the 2030 targets for these two indicators correspond to the end date of the United Nations' post-2015 SDG framework. SDG3 is specifically related to health and one of the targets under this goal is: "By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases". A monitoring framework for all SDGs is well advanced, and TB incidence is one of the indicators that has already been approved for SDG3[a].

The trajectories of global reductions in TB mortality and incidence required to reach the 2035 and 2030 targets are shown in Figure 2.1 and Figure 2.2.

a. For further details, see https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals.

The third high-level indicator, the percentage of TB patients and their households experiencing catastrophic costs as a result of TB[b], was chosen because of its direct link to progress towards UHC and universal social protection[c]. Major global progress towards UHC and social protection by 2025 are fundamental requirements for achievement of the global targets for reductions in TB cases and deaths.

Milestones are defined for 2020 and 2025, since these are required for nearer-term strategy and planning and for monitoring and evaluation of progress.

During the period 2015-2025, the decline in the TB incidence rate must accelerate from 2% per year in 2015 (1) to 10% per year by 2025. In the period 2025–2035, this rate of decline needs to increase to an average of 17% per year.

The global targets and milestones were based on an assessment of what could be achieved during two phases: 2016-2025 and 2026-2035 (Figure 2.1) (2).

TABLE 2.1 THE END TB STRATEGY'S THREE HIGH-LEVEL GLOBAL INDICATORS AND ASSOCIATED TARGETS AND MILESTONES*

	MILESTONE		TARGETS	
	2020	2025	SDG 2030	END TB 2035
Reduction in number of TB deaths *compared with 2015 (%)*	35%	75%	**90%**	**95%**
Reduction in TB incidence rate *compared with 2015 (%)*	20%	50%	**80%**	**90%**
Percentage of TB patients and their households experiencing catastrophic costs due to TB	0%	0%	**0%**	**0%**

*The targets are for 2030, marking the end of the SDGs, and for 2035, marking the end of the period covered by the Strategy. The milestones are for 2020 and 2025.

b. The operational definition of "catastrophic costs as a result of TB" refers to medical and non-medical out-of-pocket payments and indirect costs exceeding a given threshold (e.g. 20%) of the household's income. Medical costs refer to the sum of out-pocket payments for TB diagnosis and treatment made by TB patients in a given household. Non-medical out-of-pocket costs are payments related to the use of TB health services, such as payments for transportation, accommodation or food. Both costs are net of any reimbursements to the individual who made the payments. Indirect costs refer to patient or guardian lost time, lost wages (net of welfare payments) and lost income due to TB health-care seeking and hospitalization during the TB episode.

c. UHC is defined as "all people who need health services (promotion, prevention, treatment, rehabilitation and palliation) receive them, without undue financial hardship... It has two interrelated components: the full spectrum of good-quality essential health services according to need, and protection from financial hardship, including possible impoverishment, due to out-of-pocket payments for health services." For further details, see: Monitoring progress towards universal health coverage at country and global levels: Framework, measures and targets. WHO and World Bank Group, 2014. WHO/HIS/HIA/14.1. Social protection includes replacement of income when this is lost due to ill-health.

Getting to 2020 and 2025 milestones

Achieving the 2020 and 2025 global milestones for reductions in TB cases and deaths requires:

1. Globally, the annual decline in the TB incidence rate needs to accelerate from 2% per year around 2015 to 6% per year by 2020 and 10% per year by 2025. A fall of 10% per year is the fastest rate that has been achieved historically, at national level. Similar rates were achieved in parts of Western Europe in the late 1940s and 1950s, at a time of substantial progress towards UHC and social protection, and wider socioeconomic development. Within the End TB Strategy, the elimination by 2020 of catastrophic costs for TB patients and their households is a marker for progress towards UHC and social protection;
2. A reduction in the proportion of people with TB who die from the disease (case fatality ratio) from around 16% globally in 2015 to 10% in 2020 and 6% in 2025. A level of 6% corresponds to the average achieved in recent years in high-income countries.

Getting to 2030 and 2035 targets

Achieving the 2030 and 2035 targets requires:

1. Achievement of all the 2025 milestones;
2. Around 2025, new tools that can substantially reduce the risk of developing TB disease among people who have LTBI (people who have already been infected with "M. tuberculosis") must be available, and then scaled up such that globally the TB incidence rate falls at an average rate of 17% per year (Figure 2.1). The new tools that are of particular importance are an effective post-exposure vaccine (one that prevents TB disease from developing in people already infected with "M. tuberculosis"), a safer and more effective treatment for LTBI, and better tests for diagnosis of LTBI;
3. Immediate and greatly expanded investment in research and development throughout the period 2016-2025.

2.3 Country adaptation of targets and measurement of progress, 2016-2025

The three high-level indicators of the End TB Strategy – reductions in TB deaths, reductions in the TB incidence rate and elimination of catastrophic costs – are relevant to all countries. However, targets and milestones for these indicators can be adapted by countries to reflect such factors as different starting points, the main drivers of local epidemics, national policy and strategy related to UHC and social protection and planned interventions. Countries need to set their own national targets guided by the global level of ambition but taking into account national circumstances.

Since NSPs are generally developed for 5-10 years, this section focuses on national target-setting for the three high-level indicators of the End TB Strategy during the ten year period 2016-2025.

BOX 2.1 SETTING NATIONAL TARGETS FOR REDUCTIONS IN TB DEATHS AND TB INCIDENCE, 2016-2025: AN EXAMPLE

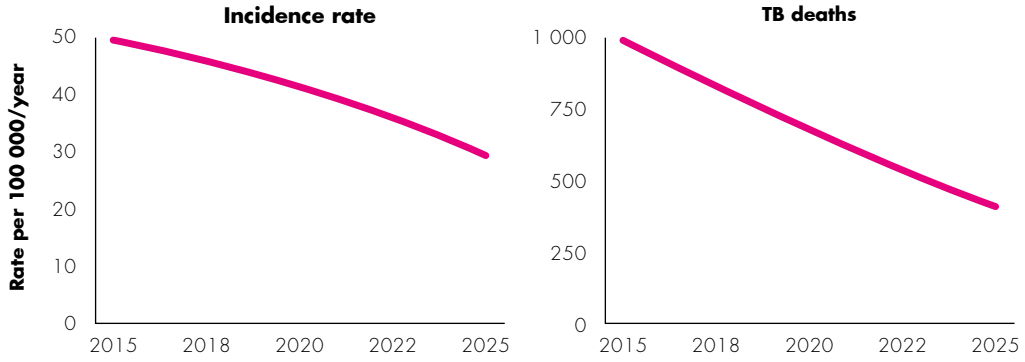
In the baseline year of 2015, the TB incidence rate is estimated at 50 per 100 000 population per year, and is falling at 2.5% per year. There is a plan to achieve UHC with social protection by 2025, and on this basis it is expected that the rate of decline in the TB incidence rate will progressively accelerate to 10% per year by 2025. The case fatality ratio (CFR) is expected to decline from a baseline of 10% in 2015 to 6% in 2025. The population is growing at 1% per year.

Projections according to these assumptions are shown in Table B2.2.1a. Based on these projections, examples of targets for 2025 include a 63% reduction in the annual number of TB deaths compared with 2015 (371 in 2025 compared with 1000 in 2015) and a 44% reduction in the TB incidence rate compared with 2015 (28 per 100 000 population compared with 50 per 100 000 population in 2015).

Example of country-specific projections for reductions in TB incidence and mortality and associated targets for 2025

Year	Population (millions)	Incidence rate per year, per 100 000 population	Mortality rate per year, per 100 000 population	Annual change in incidence (%)	CFR (%)	TB deaths	TB cases
2015	20	50	5.0	2.5	10	1 000	10 000
2016	20.2	48.6	4.63	2.87	9.5	932	9 814
2017	20.4	47.0	4.24	3.30	9.03	866	9 591
2018	20.6	45.3	3.88	3.79	8.58	800	9 326
2019	20.8	43.3	3.53	4.35	8.15	735	9 018
2020	21.0	41.2	3.19	5.0	7.75	671	8 664
2021	21.2	38.9	2.86	5.74	7.36	608	8 262
2022	21.4	36.4	2.55	6.60	6.99	546	7 812
2023	21.7	33.8	2.24	7.58	6.65	486	7 315
2024	21.9	31	1.96	8.71	6.31	428	6 772
2025	22.1	28	1.68	10.0	6.0	371	6 189

Projected trends in the TB incidence rate (left) and the number of TB deaths (right), 2016-2025



a. For details about the methods used, see Annex 1. Dynamic models that allow robust projections for different scenarios for the scale-up of interventions recommended in the End TB Strategy are under development.

2.3.1 National targets for reductions in TB deaths and the TB incidence rate, 2016-2025

The process of setting country-specific targets for reductions in TB deaths and the TB incidence rate should start with a comprehensive analysis of the baseline situation. This should include a thorough epidemiological analysis (for example, analyses of recent trends in TB incidence and mortality and the major determinants of the TB epidemic (3)) and an assessment of planned actions to improve TB prevention, diagnosis and treatment according to the three pillars of the End TB strategy (Part I) and their likely impact on the epidemic.

In many countries, particular attention should be paid to the current status of progress towards UHC and social protection. If UHC is not yet in place for an essential set of health-care interventions including TB diagnosis and treatment, the national strategy for achieving it must be considered. This will have a major influence on whether the annual reduction in the TB incidence rate can be pushed up to 10% per year and the case fatality ratio down to 6% by 2025, the levels required to achieve the End TB Strategy's 2025 global milestone (see Figure 2.1 and section 2.2 above).

In the context of the baseline situation and national strategies for UHC and social protection, national sub-targets can be set for both the rate at which TB incidence should be falling by 2025 and the case fatality ratio in 2025. A case fatality ratio of around 6-7% can be targeted in the year in which UHC and social protection are expected to be achieved[d].

The 2025 national sub-targets for the case fatality ratio and the rate at which incidence is falling can then be used, along with estimates of the baseline level of TB incidence and TB deaths, to produce projections of TB incidence and TB deaths for 2016-2025, with the assumption that there will be a progressive acceleration in the rate of progress towards these two sub-targets[e]. Based on these projections, targets can be set for 2025 and earlier years. A practical example of this approach is provided in Box 2.1.

The example in Box 2.1 illustrates that targets can be expressed in one of three ways:

- in terms of absolute numbers – the annual number of deaths and incident cases per year;
- in terms of rates – the number of deaths and incident cases per 100 000 population per year;
- in terms of relative reductions by the target year compared with a 2015 baseline, such as a 35% reduction in TB deaths by 2020 compared with 2015.

An important advantage of targets based on relative reductions is that they are much less sensitive to uncertainty about the baseline level of TB burden (which may later be updated as new data become available) than targets based on absolute numbers.

If national targets for reductions in TB deaths and the TB incidence rate are set for 2020, then it must be possible to accurately measure both indicators by this target date (Box 2.2).

Besides setting targets for reductions in disease burden for the indicators of TB deaths and the TB incidence rate, country adaptation of the End TB Strategy could also include setting a national target for reducing TB prevalence (Box 2.3). This is especially relevant for the countries that conducted a national TB prevalence survey between 2009 and 2015-2016[f].

d. Ambitious targets for reductions in the case fatality ratio can be set even in countries with a high prevalence of HIV among TB patients, provided that timely access to antiretroviral therapy is widely available. They can also be set in countries with a high prevalence of MDR-TB if the performance of care is improved, for example through better diagnosis and care and shorter and more effective treatment regimens.

e. Tools to assist countries to develop projections will be developed by WHO and partners.

f. Between 2009 and September 2015, 18 countries completed a national TB prevalence survey. As of September 2015, a few more countries were scheduled to complete a survey by the end of 2016.

BOX 2.2 **REDUCTIONS IN TB DEATHS AND TB INCIDENCE: THE ROLE OF NATIONAL TARGETS FOR 2020**

It is highly desirable to measure progress towards a target in advance of the target year. This allows for corrective action if progress is not on track, or reassurance that progress is on track. Progress must be measurable with reasonable precision, so that resulting decisions can be made using reliable data.

Accurate measurement of the level and trends in TB deaths requires a national vital registration system (or sample system that represents the country), with high-quality cause-of-death data according to the ICD-10 coding system.[a]

Accurate measurement of the level of and trends in TB incidence requires that TB notification data provide a good proxy for TB incidence. Among other things, this means that there must be limited or negligible under-reporting of diagnosed cases, and limited or negligible under-diagnosis or over-diagnosis of cases. Otherwise, the gap between the annual number of notified cases and the actual number of new and relapse cases that arose in the same year will be difficult to estimate.

The WHO Checklist of standards and benchmarks for TB surveillance and vital registration systems (3) can be used to assess whether the surveillance standards required to directly measure TB incidence and mortality using notification and vital registration data have been met, and to identify actions required to close any gaps that are identified.

If the standards required for direct measurement of TB mortality and TB incidence by 2020 can be met, targets for reductions in the number of TB deaths and the TB incidence rate by 2020 can be set. If these standards cannot be met by 2020, an accurate assessment of whether targets are met or on track will not be possible. In this case, population-based prevalence surveys may still be required to document the burden of TB, and 2020 targets should be set for other indicators such as those shown in Table 2.2.

a. TB mortality cannot be measured using routine analysis of TB treatment outcomes. This is because deaths that occur during treatment are not necessarily due to TB, and TB deaths can occur among cases for whom treatment outcomes were not recorded.

2.3.2 National targets for the percentage of TB patients and their households that experience catastrophic costs, 2016-2025

If sufficient political commitment exists, the costs incurred by TB patients and their households as a result of TB disease could be rapidly reduced by decreasing out-of-pocket expenditures and mitigating or compensating income loss and other indirect costs. The global milestone to eliminate catastrophic costs by 2020 could be used as a national target in all countries (and would apply to later years as well) (8-9). Middle- and high-income countries that have not yet eliminated these costs could be more ambitious, with a target year before 2020.

2.3.3 Measurement of progress: TB incidence and TB deaths

TB incidence

Ideally, national TB notifications should be a close proxy for TB incidence. This requires the existence of both a high-performance surveillance system and a health-care system that ensures universal

access to good-quality essential health services according to need, with protection from financial hardship. In other words, TB notification data should be of high quality with limited or negligible under-reporting of cases, and UHC and social protection should be in place[g]. WHO has developed a checklist of standards and benchmarks for TB surveillance and vital registration systems (3) to assess whether TB notifications are a good proxy for TB incidence.

In most TB endemic countries, TB notifications are not yet a good proxy for TB incidence. As a result, TB incidence can only be estimated indirectly with considerable uncertainty. Until this situation improves, setting national targets for reductions in TB incidence will be problematic (see also Box 2.2). Long-term targets could be set, as explained in section 2.3.1 since a ten year timeframe allows for substantial strengthening of surveillance and broader health-care systems. However, short-term targets (for example, for 2020) are not advisable unless surveillance and broader health system improvements can allow TB notifications to become a good proxy of TB incidence by that target date.

An assessment of TB surveillance should be undertaken using the WHO Checklist to identify current strengths and gaps and to budget the investments needed to close any gaps.

TB deaths

The number of TB deaths per year can be reliably measured if there is a national vital registration (VR) system (or sample system) that provides high-quality annual cause-of-death data (using the ICD-10 coding system) (10-11). Such systems are not yet in place in many TB endemic countries. They can however be put in place, or existing systems improved, for an estimated cost of US$ 0.5-1 per capita in the areas covered by the system.

Until strong vital registration is in place, estimates of TB mortality will remain uncertain. As is the case with TB incidence mentioned above, long-term targets can still be set since national or sample VR systems can be established or strengthened over ten years. Again, short-term targets such as those for 2020 are not advisable unless there are plans for a VR system of high quality and coverage by the target year.

Standard indicators and guidance from WHO are available to evaluate the coverage and quality of cause-of-death VR data (10-11). The WHO Checklist (3) includes one standard for assessment of VR data. A systematic approach for reviewing the status of VR and making associated improvements to national VR systems is also available.

2.3.4 Measurement of progress: Percentage of TB patients and their households experiencing catastrophic costs

The percentage of TB patients (and their households) facing catastrophic costs can be estimated through health facility-based surveys in which a random sample of TB patients are interviewed about costs of health care for TB diagnosis and treatment. A standard questionnaire (8) can be used to collect information about direct medical costs (purchase of medicines, payments for diagnostic tests, net of reimbursements), payments for transport, lodging and food expenses as well as income losses from illness and care seeking (net of transfers, such as income replacement) faced by the patient and their household. The same questionnaire can be used to collect information related to household income (either self-reported or derived from asset scores)[h].

g. Surveys to assess whether TB patients and their households experience catastrophic costs (see also section 2.3.4), along with data on overall levels of public health spending per capita and the percentage of all health expenditures accounted for by out-of-pocket expenditures, can provide an indication of whether UHC and social protection are in place. For example, along with adequate public health spending per capita, it has been suggested that out-of-pocket expenditures need to be ≤15% of total health expenditures for UHC to be considered in place.

h. Asset scores allow definition of the income quintile to which the household belongs, from which estimates of income can be derived using data on income quintiles available from national household demographic and expenditure surveys.

Using these data, the total cost (direct and indirect combined) of TB to the household can be calculated as a percentage of annual household income. If the total cost exceeds 20% of annual household income, the cost is considered catastrophic. This threshold is based on expert opinion rather than empirical evidence, which is limited[i]; it may be adjusted after further research. Additional research will also determine if major "dissaving" (such as taking a loan or selling property or livestock) can be used as a good proxy indicator for catastrophic costs. A generic protocol and associated questionnaire for surveys of costs incurred by TB patients and their households is available (8).

BOX 2.3 **COUNTRY ADAPTATION: USING TB PREVALENCE AS AN ADDITIONAL INDICATOR OF DISEASE BURDEN FOR WHICH A TARGET COULD BE SET FOR 2020 OR 2025**

The End TB Strategy's three high-level targets do not include a target for the prevalence of TB disease. This is because only a relatively small number of countries will undertake a national TB prevalence survey in the period 2016 2035. As the burden of TB disease falls below about 100 prevalent cases per 100 000 population, the sample sizes required for such surveys to be reliable become prohibitive in terms of costs and logistics (4). In addition, most countries lack a national survey that could provide a suitable baseline, and as countries become wealthier and more urbanized it may not be possible to achieve the necessary survey participation rates.

Nonetheless, there are 18 countries with a high TB burden that completed a national TB prevalence survey between 2009 and 2015 (1), with a few more scheduled to do so by the end of 2016. In these countries, a target for a reduction in TB prevalence around ten years after the last survey (since intervals of 7-10 years are needed between surveys to identify statistically significant changes) could be highly relevant. Whether the target is achieved could be assessed in a repeat survey during the target year. Experience in countries such as Cambodia and China suggests that reductions of around 50% within ten years can be targeted.

Comprehensive guidance on survey design, implementation, analysis and reporting is provided in a WHO handbook (National TB prevalence surveys: a handbook, published in 2010 (4)) and supplementary guidance (5-7) is available on the website of the WHO Global Task Force on TB Impact Measurement (www.who.int/tb/advisory_bodies/impact_measurement_taskforce/en/).

i. Wingfield T et al. *Defining catastrophic costs and comparing their importance for adverse tuberculosis outcome with multi-drug resistance: a prospective cohort study*. Peru, 2014.

2.4 Indicators for monitoring global and national progress in implementing the main components of the End TB Strategy, and recommended target levels

In addition to the three high-level indicators discussed in section 2.2 and section 2.3, operational indicators and associated targets are required to monitor implementation of the ten components of the End TB Strategy. These indicators and targets should allow reliable monitoring of progress within a national planning cycle, typically 3-5 years. Ideally, these indicators should be measured annually to help foster accountability for achievement of targets, prompt changes to policy, strategy and interventions when targets are not on track to be met, and allow regular and accurate assessments of progress. Measurement at a disaggregated level, for example for specific subpopulations or geographical areas, is also desirable to allow for better adaptation of the country response.

Indicators of uncertain value and based on mathematical modelling are best reserved for targets set for more than five years into the future.

A top-ten list of operational indicators relevant to both global and national monitoring of progress in implementing the End TB Strategy is provided in Table 2.2. This table also defines the recommended target level for each indicator and explains the rationale for its inclusion in the "top-ten".

A common target year for all countries is not recommended; instead, when adapting the End TB Strategy at national level, the year in which the target level is expected to be achieved should be clearly defined for each indicator. Some countries will have already achieved the recommended target level, with targets set to sustain or improve upon the current level. In other countries, the target year will need to be defined in relation to the baseline situation and the anticipated speed and scale at which the necessary improvements can be made. It is suggested that all countries aim to reach the target level at the latest by 2025 to enable achievement of the 2025 global milestones of the End TB Strategy (Table 2.1).

For each indicator, routine TB information systems should be adapted or appropriate surveys planned to ensure reliable measurement over time. In some countries, TB recording and reporting systems may need to be updated.

Fuller sets of indicators to monitor the End TB Strategy's three pillars, as well as measurement requirements, are provided at the end of each pillar in Part III.

TABLE 2.2 TOP-TEN 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.

The target level is for 2025 at the latest.

	INDICATOR	RECOM-MENDED TARGET LEVEL	MAIN RATIONALE FOR INCLUSION IN TOP-TEN	CHANGES REQUIRED TO DATA COLLECTION SYSTEMS*
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 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 two indicators will be used as tracer indicators for monitoring progress towards UHC within the SDGs.	**No change required**
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%		**No change required**
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.	**No change recommended, but periodic surveys are required** ***Country level:*** Periodic surveys (e.g. every 2–3 years) of a random sample of TB patients are required, to measure the costs faced by TB patients and their households as a result of TB disease. WHO is providing guidance on the conduct of these surveys; a generic protocol and questionnaire are already available. ***Global level:*** WHO will request data on this indicator from countries in annual rounds of global data collection from 2017 onwards, if they state that such data are available.
4	**PERCENTAGE OF NEW AND RELAPSE TB PATIENTS TESTED USING A WHO-RECOMMENDED RAPID TESTS AT THE TIME OF DIAGNOSIS** patients tested using a WHO-recommended rapid test at the time of diagnosis, divided by the total number of new and relapse TB patients, expressed as a percentage.	≥ 90%	Accurate diagnosis is a fundamental component of TB care. Rapid molecular diagnostic tests help to ensure early detection and prompt treatment.	**No change recommended, but if data are not already captured, surveys are required** ***Country level:*** The indicator can be measured using a survey of a random sample of medical records or patient cards of TB patients, which should capture information on diagnostic tests used. ***Global level:*** WHO will request data on this indicator from countries in annual rounds of global data collection, starting in 2016, if they state that such data are available (from either case-based reporting or a survey).

* WHO does NOT anticipate updating the 2013 revision of the paper-based reporting forms and recommends periodic surveys to capture data on new variables.
**costs faced are above 20% of annual household income.

	INDICATOR	RECOM-MENDED TARGET LEVEL	MAIN RATIONALE FOR INCLUSION IN TOP-TEN	CHANGES REQUIRED TO DATA COLLECTION SYSTEMS*
5	**LTBI TREATMENT COVERAGE** Number of people living with HIV newly enrolled in HIV care and the number of children aged <5 years who are household 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%	Treatment of LTBI is the main treatment intervention available to prevent development of active TB disease in those already infected with *M. tuberculosis*.	**No change recommended, but if data are not already captured, surveys are required** ***Country level:*** The numerator for this indicator i.e. the number of child household contacts <5 started on LTBI treatment can be measured using a survey of a random sample of medical records or patients cards of TB patients, which should capture information on treatment for LTBI provided to contacts aged < 5 years. Alternatively, a survey is not required if the variable is already included in a case-based reporting system. The denominator can be estimated based on the reported number of bacteriologically-confirmed cases (routinely compiled in almost all countries), demographic data, and data on household size. ***Global level:*** For people living with HIV, WHO will continue to use data compiled by UNAIDS and the WHO HIV department. For children<5, data on the number of children started on LTBI treatment will be requested in annual rounds of data collection, starting in 2016, if countries state that such data are available (from either case-based reporting or a survey).
6	**CONTACT INVESTIGATION COVERAGE** Number of contacts of people with bacteriologically-confirmed TB 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.	**No change recommended, but if data are not already captured, surveys are required** ***Country level:*** The numerator for this indicator i.e. the number of contacts investigated can be measured using a survey of a random sample of medical records or patient cards from of TB patients with bacteriologically-confirmed TB, which should capture information on contact investigations. Alternatively, a survey is not required if the variable is already included in a case-based reporting system. The denominator for this indicator (the number of eligible contacts) can be estimated as described for indicator 5. ***Global level:*** WHO will request data on this indicator from countries in annual rounds of global data collection, starting in 2016, if they state that such data are available (from either case-based reporting or a survey).

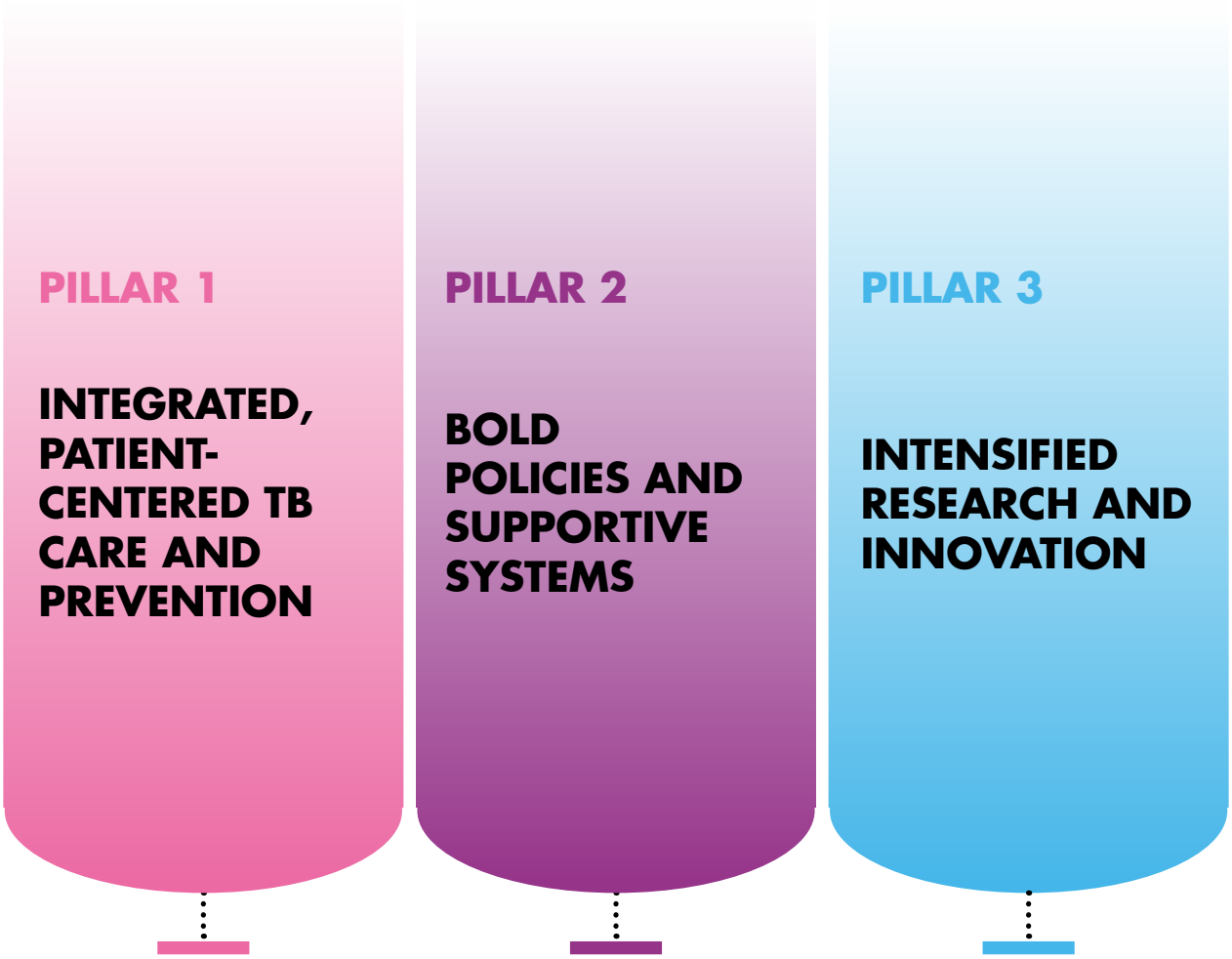
	INDICATOR	RECOM-MENDED TARGET LEVEL	MAIN RATIONALE FOR INCLUSION IN TOP-TEN	CHANGES REQUIRED TO DATA COLLECTION SYSTEMS*
7	**DRUG SUSCEPTIBILITY TESTING (DST) COVERAGE FOR TB PATIENTS** Number of TB patients with DST results for at least rifampicin divided by the total number of notified (new and retreatment) 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.	**No change recommended, but if data are not already captured, surveys are required** ***Country level:*** This indicator can be measured using a survey of TB registers, medical records or treatment cards of TB patients. Alternatively, a survey is not required if test results on susceptibility to rifampicin are already included in a case-based reporting system. It is important to highlight that these data should not be collected from laboratory registers because laboratory registers are organised by sample, not by patient. ***Global level:*** WHO will continue to request data on this indicator from countries in annual rounds of global data collection, if they state that such data are available (from either case-based reporting or a survey). WHO will use the number of TB patients *tested for rifampicin resistance* to assess DST coverage.
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.*	**No change recommended, but if data are not already captured, surveys are required** ***Country level:*** Treatment coverage with new TB drugs is an indicator that is not captured in the WHO-recommended reporting forms for paper-based systems (2013 revision). The indicator can be measured using a survey of medical records or treatment cards of TB patients that meet the eligibility criteria for a new TB drug, to identify what proportion receive it. Alternatively, a survey is not required if the treatment regimen is already included in a case-based reporting system. In 2016, the only new TB drugs for which it is relevant to collect data are bedaquiline and delamanid (approved by WHO in 2013 and 2014, respectively). Their use is recommended for very specific groups of patients with drug-resistant TB. ***Global level:*** WHO started to request data on use of bedaquiline for TB patients with MDR-TB in 2014. In 2016, data will also be requested on use of delamanid.

	INDICATOR	RECOM-MENDED TARGET LEVEL	MAIN RATIONALE FOR INCLUSION IN TOP-TEN	CHANGES REQUIRED TO DATA COLLECTION SYSTEMS*
9	**DOCUMENTATION OF HIV STATUS AMONG TB PATIENTS** Number of new and relapse TB patients offered HIV test 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.	**No change required**
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.	**No change required**

Ethiopia's health ministry has invested in organizing thousands of community volunteers across the country for health. These people work on the frontlines in the communities to identify villagers who may have TB. Hirpessa Geleta (left) and Angasu Dhuguma (middle) are community volunteers in Wolisso, Ethiopia.

PART III

The three pillars



PILLAR 1

INTEGRATED, PATIENT-CENTERED TB CARE AND PREVENTION

A. Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high risk groups

B. Treatment of all people with TB including drug-resistant TB, and patient support

C. Collaborative TB/HIV activities, and management of co-morbidities

D. Preventive treatment of persons at high risk, and vaccination against TB

PILLAR 2

BOLD POLICIES AND SUPPORTIVE SYSTEMS

A. Political commitment with adequate resources for TB care and prevention

B. Engagement of communities, civil society organizations, and public and private care providers

C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

D. Social protection, poverty alleviation and actions on other determinants of TB

PILLAR 3

INTENSIFIED RESEARCH AND INNOVATION

A. Discovery, development and rapid uptake of new tools, interventions and strategies

B. Research to optimize implementation and impact, and promote innovations

PILLAR 1 : KEY COMPONENTS

A. Early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups

B. Treatment of all people with TB including drug-resistant TB, and patient support

D. Preventive treatment of persons at high risk; and vaccination against TB

C. Collaborative TB/HIV activities; and management of comorbidities

PART III - PILLAR 1

Integrated, patient-centred care and prevention

KEY MESSAGES

- Pillar 1 of the End TB Strategy builds on the DOTS strategy (1994-2005) and the Stop TB Strategy (2006-2015) and encompasses all core functions of health services essential for TB care and prevention. Their implementation requires close collaboration with all stakeholders including the social sector, civil society and communities.
- The human and financial resources required for implementation should be commensurate with the enhanced scope of core functions that are integrated effectively within delivery of general health services.
- Early diagnosis and prompt treatment of all persons of all ages with any form of drug-susceptible or drug-resistant TB is fundamental. WHO-endorsed rapid TB diagnostics and DST should be available to all who need it and prioritized for persons at risk of MDR-TB and HIV-associated TB. DST for anti-TB medicines other than rifampicin should be offered.
- Appropriate treatment of drug-susceptible and drug-resistant TB should be available and accessible to all who need it. Proper drug safety monitoring and management should be pursued. All relevant care providers should be engaged in the delivery of TB care. Palliative and end-of-life care should also be available when all curative treatment options are exhausted.
- Joint TB and HIV programming should be pursued for integrated and decentralized delivery of services for TB and HIV; the latest WHO recommendations on collaborative TB/HIV activities and on management of LTBI should be followed.
- As part of patient-centred care and depending on needs, all patients should receive educational, emotional and economic support to enable them to complete the diagnostic process and full course of required treatment.
- Close contacts of people with TB, PLHIV and workers exposed to silica dust should be systematically screened for TB and considered for preventive therapy.
- All persons with TB need to be assessed for nutritional status and receive nutritional counselling and care according to need. All persons with TB should also be screened for diabetes. Further, depending on local epidemiology, all persons with TB should be assessed for other co-morbidities and related risk factors such as smoking and alcohol or drug abuse.
- TB infection control measures should be applied in all settings.
- Proven digital health tools need to be progressively introduced to improve efficiency of implementation, monitoring and evaluation.

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Introduction

The first pillar of the End TB Strategy encompasses integrated patient-centred TB care and prevention. It builds on and expands the DOTS strategy (1994-2005) and the Stop TB Strategy (2006-2015). The focus is on providing universal access to TB care and prevention with greater attention to vulnerable and hard-to-reach populations. Early diagnosis of all cases, critical to reducing disease transmission, is underscored. This requires ensuring access to WHO-recommended rapid diagnostics and DST for all who need it. Appropriate treatment for all people with any form of TB is emphasized. Systematic screening of contacts and selected high-risk groups as well as preventive treatment of selected groups are now an integral part of patient care and prevention. The importance of infection control measures is highlighted. Furthermore, attention is drawn to providing care through an integrated approach in collaboration with other public health programmes such as HIV, maternal and child health, nutritional care, diabetes care, lung health, and mental health services. Progressive application of proven digital health tools is recommended to enhance the effectiveness of every aspect of implementation.

Patient-centredness at the core of care and support

Patient-centred care involves systematically assessing and addressing the needs and expectations of patients. The objective is to provide high-quality TB diagnosis and treatment to all patients – men, women and children – without their having to incur catastrophic costs. Depending on patients' needs, educational, emotional and economic support should be provided to enable them to complete the diagnostic process and the full course of prescribed treatment. To ensure systematic implementation of a patient-centred approach, NTPs need to establish clear policies and strategies that incorporate social support into clinical care. This calls for orientation and training of all health-care providers. Implementing patient-centred care in an integrated manner will also require collaborating with all relevant government and nongovernmental agencies, civil society and communities as well as the private sector. The paragraphs below describe the essentials of implementing the components of Pillar 1 of the End TB Strategy.

Component 1A. Early diagnosis of TB including universal drug susceptibility testing, and systematic screening of contacts and high-risk groups

WHO has produced a number of guidelines and additional resources to help implement this component (1-15). The WHO policy framework for implementing TB diagnostics provides an overview of approved diagnostics and outlines their use for different risk groups and settings (16-26). The WHO guide on early detection of tuberculosis gives an overview of approaches, guidelines and tools to improve access and early diagnosis (27). WHO guidelines on systematic screening for active TB comes with a companion operational tool: (15, 28, 29), as do guidelines on contact investigations in low- and middle-income countries (8, 30).

1A-1 Early diagnosis of TB including universal drug susceptibility testing

Policies and strategies

Early diagnosis of TB calls for a combination of interventions based on in-depth knowledge of people's health-seeking behaviour. A good understanding of the health-care providers initially approached by people with TB, the tests used for diagnosing TB, and the delays people encounter in receiving diagnoses are essential to the design and implementation of interventions. Engaging all care providers in TB care and prevention is discussed in Pillar 2.

An estimate should be made of diagnostic service needs including infrastructure for adequate coverage of laboratory networks and radiography, technology requirements and human resources. This should be based on the size of the population to be served, the epidemiological situation, the diagnostic algorithm to be used for different risk groups for TB, TB/HIV or DR-TB, and the current laboratory capacity including capacity for DST and patient monitoring. Assumptions related to diagnostic needs for different risk groups are described in the WHO planning and budgeting tool (13).

National TB guidelines need to be updated to incorporate country-specific diagnostic algorithms that promote progressive expansion of WHO-endorsed technologies. In addition, a formal collaboration agreement should be signed with a WHO TB Supranational Reference Laboratory to support quality assurance of phenotypic and genotypic DST methods (14).

Taking the national guidelines and needs assessments into consideration, a NSP for TB laboratory services should be developed or updated, preferably as part of the NSP. This plan should also include funding requirements and guide overall strengthening of diagnostic services.

Key actors to engage

Depending on the setting, a number of key actors need to be engaged by the NTPs to effectively implement this sub-component. These actors include national TB reference laboratories and national public health laboratory services; specialized government agencies that deliver TB diagnostic and clinical care such as health services of the penitentiary, military, police, railroad or education departments; and private non-profit and for-profit health-care providers and laboratories.

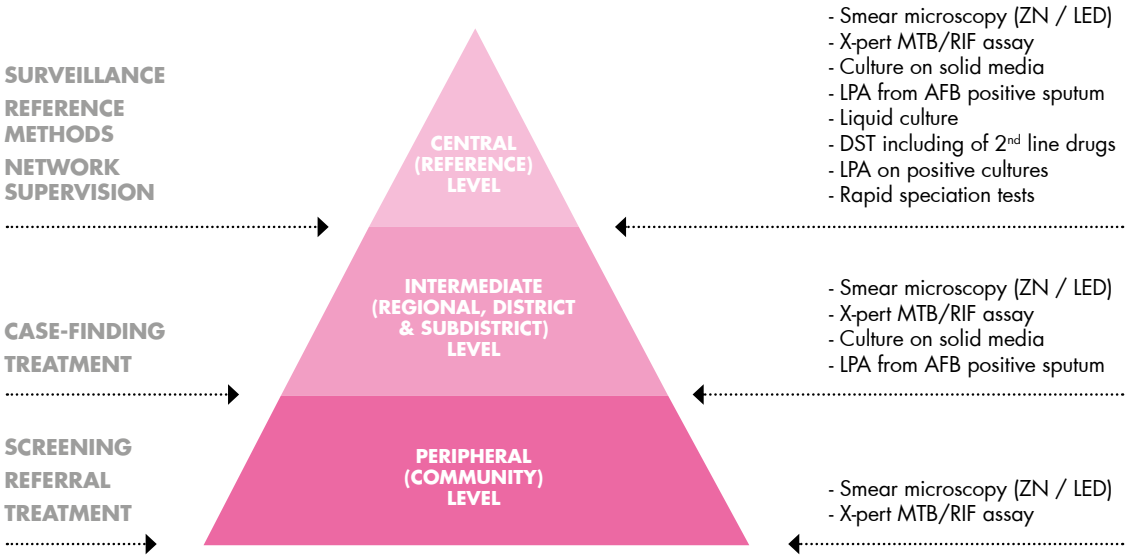
Health system requirements

The efficiency of the TB diagnostic network depends on the functioning of overall diagnostic services within the general health system. To improve access to rapid TB diagnosis and DST, a quality-assured network of diagnostic services using WHO-recommended TB tests must be strengthened and expanded. As diagnostic technologies have different infrastructure and biosafety requirements, only certain tests – microscopy and Xpert MTB/RIF currently – can be positioned within the peripheral health-care services. Radiography is an essential and basic technology that should be available as a part of primary health care (Figure 1A.1). Health systems must ensure timely specimen collection and transport, stronger referral mechanisms among the different levels of health services, and progressive use of modern digital health tools to accelerate the reporting of results and improve overall performance.

Rapid rifampicin resistance testing should to be prioritized for high-risk groups. Early diagnosis of MDR-TB requires expanding access to DST. Strengthening DST capacity and expanding treatment services for DR-TB need to be undertaken in parallel. Allocation of appropriate human resources, together with regular training and adequate mentoring, monitoring and supervision at all levels of health-care services are essential.

Early detection of all people with TB requires clear and simple protocols for identification of persons with suspected TB by community health workers and volunteers, mechanisms for timely referral for diagnosis and follow-up, and recording and reporting systems for monitoring and evaluation.

FIGURE 1A.1 THE THREE TIERS OF THE NETWORK OF TB LABORATORIES AND THE TESTS OFFERED AT EACH LEVEL



BOX 1A.1 INDIA: ENABLING ACCESS TO MODERN DIAGNOSTICS

Each year, India's Revised National TB Control Programme (RNCTP) screens roughly eight million people with symptoms for TB primarily using sputum smear microscopy. Between 2008 and 2014, the RNCTP diagnosed and treated a growing number of TB patients with MDR-TB. As of 2014, 325 000 patients had been tested for DR-TB and 41 000 patients had initiated MDR-TB treatment.

Between 2009 and 2014, the RNTCP succeeded in establishing 54 quality-assured culture and DST laboratories throughout India, including: 36 laboratories performing culture and DST using solid culture media, 41 using line probe assays for the rapid detection of rifampicin resistance conferring mutations, and 12 laboratories using the current gold standard method of culture in commercial liquid medium. These newly established services have been central to supporting scale-up of services for the programmatic management of drug-resistant TB (PMDT).

The RNTCP is implementing a feasibility project on the use of Xpert MTB/RIF. As of 2015, the programme had placed 80 GeneXpert machines across the country for rapid detection of TB and simultaneous detection of rifampicin resistance, with an ambitious plan for an additional 950 GeneXpert instruments between 2015 and 2020.

Key implementation steps

The following sequential steps should be considered:

- Ensure all health facilities identify all persons who should be evaluated for TB

  A meticulous and systematic identification of people requiring TB evaluation should start with all those visiting health-care facilities. People with TB symptoms should be rigorously identified. All patients, including children, with unexplained findings suggestive of TB on chest x-rays should be evaluated for TB disease, preferably using rapid diagnostic tests (10, 11). For persons with suspected drug-resistant TB or HIV-associated TB, rapid tests that simultaneously detect TB and drug resistance (to rifampicin at least) should be used as the initial diagnostic test. TB diagnosis and treatment should be an integral part of management of respiratory conditions. The WHO-recommended Practical Approach to Lung Health should be applied especially in settings where respiratory patients are managed in specialized clinics (31).

- Expand networks of diagnostic facilities with access to WHO-recommended TB rapid diagnostic tests

  Early and accurate diagnosis of TB and drug resistance will require scaling up use of WHO-recommended rapid diagnostic tests. Their introduction and strategic placement in HIV care settings is also essential. This will facilitate early and prompt treatment and help decrease disease transmission, prevent unfavourable outcomes and reduce case fatality.

  Sound laboratory management including quality-assurance helps maintain high standards of diagnostic services. The expertise essential at different levels of health services will depend on the diagnostic methods and tools offered at each level. Problems with transporting specimens often contribute to delays in diagnosis. Proper coordination of specimen referral mechanisms is therefore critical to reduce delays. Further, to expand the network of TB diagnostic services, links should also be established with diagnostic facilities outside the TB programme such as maternal and child health services and the private sector.

- Aim to provide universal access to DST

  DST by phenotypic or genotypic methods should be done for all persons with bacteriologically confirmed TB. Placing diagnostics that allow rapid detection of drug-resistant TB at lower levels of health-care services will be essential to achieving universal access to DST.

  High-burden countries should develop national capacity to perform quality-assured DST for first-line drugs using phenotypic and genotypic methods. DST for fluoroquinolones and injectable second-line drugs is necessary for all patients detected with rifampicin-resistant TB or MDR-TB. Building capacity for second-line DST currently requires sophisticated laboratory containment, high-risk biosafety precautions, properly maintained equipment, standard operating procedures and specialized quality assurance programmes.

  National laboratory networks should participate in regular external quality assurance programmes such as those provided by the WHO Supranational Reference Laboratory Network (SRLN). They should also ensure the reliability of test results with a quality management system that meets the requirements of international standards for laboratory accreditation.

1A-2 Systematic screening of selected high-risk groups

Many people with active tuberculosis do not experience typical symptoms in the initial stages of the disease. They may not seek care early enough and may not be tested for TB. Other groups may be unable to access health care due to financial, geographical or other barriers. Mapping

of high-risk groups and carefully planning systematic screening, within or outside health services, can help improve early TB detection.

WHO has developed guidelines on systematic screening for active TB along with a companion operational tool to help implement activities. The guidelines recommend that contacts of people with TB, PLHIV and workers exposed to silica dust should always be systematically screened for active TB. For other risk groups, possible systematic screening should be based on national or local TB epidemiology, health system capacity, resource availability and the feasibility of reaching those groups (28, 29).

Mass screening should be avoided since costs can be very high and impact is uncertain. Even targeted screening, especially if done as an outreach activity, can be very resource-intensive. When screening is poorly planned, targeted or conducted, or where suboptimal screening and diagnostic tools are used, resources can be wasted and individuals may be harmed by false positive diagnosis, financial burden, or increased stigma and discrimination.

Policies and strategies

A strategy for systematic screening in selected high-risk groups should be developed as part of the TB NSP. This should be based on a careful assessment of the TB epidemiology and capacity of the health system.

The strategy should include clear screening objectives; risk groups to screen; preferred screening and diagnostic algorithms; a plan for reaching out to and ensuring high-quality care for especially vulnerable and hard-to-reach groups; principles for ensuring ethical screening and protection of human rights; and a monitoring and evaluation plan to guide future modifications of the strategy or possible discontinuation of screening.

Key actors to engage

The development of guidance on systematic screening for active TB is the responsibility of the NTP or its equivalent. However, planning and managing the required financial and human resources should involve all possible stakeholders.

Where possible, TB screening should be integrated into other screening and outreach activities to improve both the efficiency of screening and its relevance for users. Identifying appropriate entry points for screening is critical and requires mapping the health-care, social service and nongovernmental providers for relevant groups, especially for vulnerable and hard-to-reach groups. The following are examples of stakeholders to consider:

- Health-care providers offering services for people with clinical conditions that constitute TB risk factors, such as endocrinology departments caring for people with diabetes;
- The penitentiary sector, essential to screening initiatives in prisons;
- Employers and departments of occupational health, for TB screening in relevant workplaces, such as workers exposed to silica dust in the mining industry;
- Social services and nongovernmental organizations providing social support for vulnerable groups, which can be engaged in community outreach TB screening and;
- Migration authorities, for screening of immigrants from high-burden countries or settings.

Health system requirements

TB screening is ineffective without linkages to high-quality treatment, care and support services. It is therefore essential to review and optimize referral chains and plan for tailored treatment, care and support services for targeted groups. Successful screening will expand the number of people started on treatment. The increased demand for resources for all these needs should be considered from the outset, including possible contributions from key actors above.

A guiding principle is that access to quality diagnostic and treatment services should be sufficient before systematic screening is implemented and scaled up.

Key implementation steps

Several steps should be taken before embarking upon systematic screening.

- A careful situation assessment of the potential benefits, risks, and costs should first take place. This will help:
  - » to define goals and specific objectives of screening;
  - » to identify risk groups to be screened;
  - » to design appropriate screening and diagnostic algorithms and;
  - » to plan for linkages to high-quality treatment, care and support.
- Ethical principles for screening should be established ; these should follow general principles for infectious disease screening;
- A detailed plan and budget need to be developed as part of the NSP and should outline the roles and responsibilities of stakeholders;
- A screening strategy should be monitored and assessed continuously to inform re-prioritization of risk groups, re-adaptation of screening approaches, and discontinuation of screening if indicated.

Component 1B. Treatment of all people with TB including drug-resistant TB, and patient support

To cure TB and reduce disease transmission, patients should be placed on effective treatment soon after diagnosis. 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. In most circumstances, community-based treatment adherence support may lead to more favourable treatment outcomes. Ensuring all TB patients have access to free-of-charge life-saving treatment is fundamental to minimizing disease and deaths due to TB. Resistance to anti-TB medicines poses a major threat to global progress and needs to be promptly and adequately addressed.

WHO guidelines on the scope of work of this component are available in a number of publications including guidance on the treatment of drug-susceptible and drug-resistant TB, and management of TB in children (32-45).

1B-1 Treatment of TB including drug-resistant TB among adults

Policies and strategies

National TB treatment policies and guidelines should ensure all people with TB are enrolled on effective treatment. This requires explicit national policies, strategies, and guidelines that support:

- Patient-centred care that delivers educational, emotional and economic support that enables patients to adhere to and to complete treatment;
- Algorithms for diagnosis of TB, as outlined in section 1A, and enrolment of patients on proper treatment regimens (Box 1B.1);
- Availability of TB treatment services in decentralized settings, meeting the needs of most of patients without compromising the quality of care and;
- Engagement of all health-care providers in the treatment of DR-TB through collaborative and regulatory measures (44);

TABLE 1B.1 WHO-RECOMMENDED REGIMENS FOR THE TREATMENT OF TB AND MDR-TB

TYPE OF TB	INTENSIVE PHASE TREATMENT	CONTINUATION PHASE
Presumed or known to have drug-susceptible TB	2 months of HRZE	4 months of HR
Confirmed or high likelihood of MDR-TB	8 months, for most patients, with four second-line anti-TB drugs likely to be effective (including a parenteral agent), as well as pyrazinamide	Completion of 20 months of total treatment duration with at least three anti-TB drugs likely to be effective as well as pyrazinamide
Confirmed MDR-TB (susceptible to fluoroquinolones and second-line injectable agents)	4-6 months of seven second-line anti-TB drugs of the recommended standardized shorter MDR-TB regimen	Upto 5 months of four second-line anti-TB drugs of the recommended standardized shorter MDR-TB regimen

BOX 1B.1 TB DRUG MANAGEMENT SYSTEM

For successful treatment, it is essential to have an effective drug management system that ensures uninterrupted supply of quality-assured medicines needed for treatment of drug-susceptible and drug-resistant TB by:

- Updating the national essential medicines list to include all products and formulations needed for TB treatment, including paediatric formulations;
- Establishing reliable mechanisms for drug forecasting and prevention of stock-out;
- Implementing and maintaining good storage practices in all health-care facilities and;
- Developing frameworks for compassionate use and expanded access to drugs under development recommended for MDR-TB patients with limited treatment options.

- Enhanced coverage and quality of TB services through digital tools and communication technologies (46);
- Access to care for co-morbidities (such as HIV infection and diabetes) and health risks (such as tobacco smoking and alcohol abuse) which have an influence on TB treatment as well as broader public health impact;
- Active TB drug-safety monitoring and management (aDSM) for patients on treatment using new TB drugs, on XDR-TB treatment, or on novel regimens (47);
- Prevention of drug resistance through regulated access to anti-TB medicines and;
- Prevention of TB transmission in health-care facilities, congregate settings, community and household level through TB infection control measures and rapid enrolment on effective treatment.

Key actors to engage

Formulating policies, planning and implementing strategies for TB treatment and care should be led by the ministry of health in cooperation with a variety of actors, including:

- Health-care providers within the health and community systems in both public and private sectors, such as those covering HIV, diabetes, chronic pulmonary diseases, mother and child health, mental health, patient education, nutrition, tobacco cessation, palliative and end-of-life care, and substance use;
- Professional societies representing the key health-care providers for integrated TB care;
- Drug regulatory authorities, including those responsible for pharmacovigilance;
- Developers of digital health regulatory frameworks, products and supporting systems (such as mobile network providers);
- Ministries and departments of occupational health and social welfare;
- NGOs and CSOs and;
- Bilateral and multilateral donors.

Responsibility for proper coordination among these actors at all levels of the health system lies with the NTP. Ensuring clear lines of communication, responsibility and accountability promotes effective contributions by all.

Health system requirements

Treatment and care of TB patients require several functional units of the health system to work in harmony, including:

- A robust network of facilities that provides universal access to treatment for people with TB;
- Mechanisms for effective integration and coordination with other health and community stakeholders, such as child health services, services for HIV, diabetes, chronic pulmonary diseases, mother and child health, mental health, nutrition, tobacco cessation, palliative and end-of-life care, and substance use; and public health services such as antimicrobial resistance surveillance, pharmacovigilance, infection control, nutrition surveillance, and drug management;
- Assignment of sufficient, competent and motivated staff who receive continued training and education on national policies to enable them to align their practices with international standards and collaborate with services for children, the elderly, migrants, miners, homeless people, prisoners, PLHIV and co-morbidities, and persons who use alcohol and other substances;
- Development, maintenance and improvement of effective management systems that ensure uninterrupted supply of TB quality-assured commodities for monitoring microbiological response to TB treatment, TB medicines (Box 1B.1), medicines to manage adverse TB drug reactions, and infection control and;
- A system for early detection and proper management of all adverse events, and timely reporting of at least all serious adverse events, especially in patients taking new anti-TB medicines (Box 1B.3);

BOX 1B.2 **BANGLADESH: F-A-S-T TB TRANSMISSION CONTROL STRATEGY**

Although evidence suggests that most nosocomial TB transmission occurs from persons with unsuspected TB or unknown drug resistance on inadequate treatment, ironically most infection control activities focus on known patients already on effective treatment and thereby rendered rapidly non-infectious. The F-A-S-T Strategy refocuses efforts on Finding cases Actively, and Separation until effective Treatment is started. Emphasizing cough surveillance and rapid molecular testing, FAST aims to shorten the time between a symptomatic patient's entry into a congregate setting until the start of effective treatment. In TB and chest hospitals and clinics, where cough is common, focus is on rapid molecular testing to identify drug resistance. The concept is that if there are no symptomatic patients with unsuspected TB or drug resistance, transmission should cease.

FAST was recently implemented in a 680-bed chest hospital in Dhaka, Bangladesh. Over the first 21 weeks of implementation, 1891 sputum samples from discrete patients admitted to the hospital were tested. Of these 1891 samples, approximately 11% of TB and 1% of DR-TB unsuspected cases were identified. Of the 1453 patients admitted to the facility as non-TB patients with other respiratory diseases, about 9% actually had TB and had been misclassified upon admission. The unsuspected TB rate was more than twice as high among patients with a previous history of TB. Furthermore, of the 60 TB patients on treatment admitted to the facility, approximately 8% were identified as unsuspected, Xpert-confirmed DR-TB cases. All 1891 samples were processed the same day of collection. Diagnoses were available for treatment initiation within 1-2 days of collection. A reporting delay of one day may have occurred if samples were processed at the end of the day. Treatment was initiated within one day of confirmed diagnosis. Implementing the FAST strategy at the hospital has resulted in a sharp increase in the number of unsuspected TB and DR-TB cases identified and effectively treated compared to routine practice.

The evidence base for rapid impact of effective treatment on transmission and a more complete description of FAST has been published (48, 49). The idea of a simple, easy-to-remember strategy is based on the successful 3Is strategy, focused on HIV settings, and shares the elements of active case finding and transmission control.

- Proper respiratory infection control measures in all health-care facilities. All health-care providers, including those in the community, should operate under conditions that protect them from infection. Strategies like FAST (Box 1B.2) that promote early identification of presumptive cases for quick enrolment on effective treatment should be actively pursued in all congregate settings;
- Enhanced digital technologies for more efficient delivery, monitoring and evaluation of TB patient diagnosis, treatment and care. Digital health tools play a role in TB management (for example in video-observed therapy, calls for appointments, surveillance, reporting of adverse drug reactions, transmission of laboratory results, training of health professionals, patient information and education) and have been proven feasible and effective (Box 1B.3) and;
- A network of institutional and community-based palliative and end-of-life care services that prioritize MDR-TB patients for whom all other available effective treatment options have been exhausted.

BOX 1B.3 **EXAMPLES OF TB CARE INNOVATIONS**

Harnessing digital health for TB care in Swaziland

The NTP in Swaziland, with the support of WHO and other partners, has successfully implemented an extensive patient database at its main hospital. By investing in novel methods of data capture using mobile handheld devices, GPS coordinates of a patient's residence are captured before patients are discharged from hospital or during their visits home. Juxtaposing these data with maps of the spatial distribution of health centres and community health workers, a health manager can visualize how services match the location of patients.

Engaging the private sector in management of MDR-TB patients in Pakistan

The NTP of Pakistan has developed models of public-private mix (PPM) for TB that centre around engagement of different actors such as NGOs (for example Green Star, Bridge Consultants, Mercy Corps, Association of Social Development), public and private hospitals, independent private practitioners, public and private laboratories and private pharmacies. The NTP and its partners have also established a successful PPM model for management of drug-resistant TB based in public and private tertiary hospitals (16 PMDT functional sites in 13 public and 3 private hospitals by end 2013). Good outcomes have been demonstrated by several PPM providers in quality of diagnosis, treatment and patient support for patients with drug-resistant TB. For example, Indus Hospital and Gulab Devi Chest Hospital are very capable in MDR-TB management. Standardized algorithms for diagnosis and management of drug-resistant TB, ambulatory care models and electronic data management have been implemented across PPM sites which manage drug-resistant TB(44).

TB active drug-safety management in Belarus

In Belarus, active drug-safety management for TB/HIV patients on treatment for both conditions has been implemented since 2013 through successful collaboration between the TB programme and the pharmacovigilance centre of the Ministry of Health. In 2014 the two centres started another project to capture data on patient safety and effectiveness of Linezolid-containing regimens in accordance with WHO recommendations for MDR-TB patients. This model is now being applied by the Belarus Ministry of Health to monitor patients who have started on Bedaquiline since June 2015. Clinical staff are collecting data at the start, during treatment and at follow-up. Active drug-safety management adds value to other monitoring activities geared to improving TB patient outcomes, especially for new therapeutic interventions.

Key implementation steps

Delivery of treatment and care to patients with drug-susceptible TB is a relatively standardized procedure, unlike the treatment and care of patients with MDR-TB, which can be a complex intervention (40). Several crucial steps are common to both treatment of drug-susceptible and drug-resistant TB:

- Implementing patient-centred care based on the patient's values and needs, followed by counselling and social support to ensure adherence, through directly observed treatment when necessary; improving treatment outcomes; preventing development of drug resistance; and preventing and relieving stigma and discrimination;
- Ensuring that all health-care providers receive support and incentives to treat TB patient according to national strategies and guidelines;
- Establishing new or stronger mechanisms to ensure access to first-, second-line or new anti-TB drugs;
- Providing early treatment to patients with HIV and other co-morbidities to avoid unfavourable outcomes and to reduce transmission;
- Building stronger systems to ensure safety, monitoring and management of patients, and TB drug safety (Box 1B.3) and;
- Digital recording and reporting for management of TB patients including monitoring of treatment outcomes and adverse events (46).

1B-2 TB among children and working with maternal and child health services

WHO has produced detailed guidelines on management of TB in children (39, 41). An online training course for health workers is also available (45). TB in children is often overlooked due to non-specific symptoms and difficulties in diagnosis. Children most at risk for falling ill or dying from TB include those with vulnerable immune systems, such as the very young, HIV-infected or severely malnourished children, or those with a household or other close contact with a case of pulmonary TB.

In countries with a high prevalence of tuberculosis, 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 tuberculosis associated with HIV is a risk factor for transmission of tuberculosis 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 (50, 51). An integrated family-based approach to tuberculosis care would help remove access barriers, reduce delays in diagnosis and improve management of TB in women and children (and enable adherence to treatment) (Box 1B.4).

Decentralizing TB care for children is also likely to be highly cost-effective because it will improve access to diagnosis and early initiation of treatment without a significant increase in costs. Resources on the management of childhood TB are available in the annex.

BOX 1B.4 KENYA: INTEGRATED SERVICE DELIVERY

An intervention in Kenya is showing the benefits of working with MCH and PMTCT programmes to promote the childhood TB agenda. This intervention to strengthen TB case detection was part of the Focused Ante Natal Care (FANC) and PMTCT programme in Kenya was piloted. A situation analysis was conducted in 2005 in six hospitals in Kenya's Western Province, and the intervention was evaluated in 2007. The project also developed a training module for TB screening in pregnancy along with job aid for use by health workers to facilitate screening. It was observed that overall TB screening activities improved. The proportion of providers advising routine TB screening for pregnant women increased significantly from less than one-tenth at the baseline to about two-thirds at the end. The intervention has received broad acceptance, as demonstrated through its widespread use and the integration of TB screening into routine activities for a majority of nurses. The effectiveness of integrating TB into FANC was also demonstrated by the increased number of pregnant women detected to have TB and started on treatment. The simplicity of this approach further helped with screening on multiple occasions during antenatal care as well as postnatal or other reproductive-health related visits.

Policies and strategies

- A number of policies and strategies should be in place to manage TB among children and to work with maternal and child health services.
- National TB control programmes should include childhood TB in their NSP in line with global policy documents and guidelines.
- National policies and guidelines should be based on global recommendations and include guidance that is specific to infants, children and adolescents. Guidelines should be evidence-based and relevant to each country's specific priorities and possibilities.
- In high-TB and HIV prevalence settings, national policies are needed to promote the inclusion of TB prevention, screening, diagnosis and treatment services as a part of the integrated management of pregnancy and child health services and ensure early detection and treatment of TB. Intensified TB screening should be integrated into prevention of mother-to-child transmission programmes to ensure early detection and treatment of TB and HIV-associated TB.
- Policies can also facilitate the integration of TB and TB/HIV interventions into the training curriculum of health-care workers involved in RMNCAH services, community health workers and birth attendants.

Key actors to engage

The NTPs need to engage all relevant stakeholders including RMNCAH services, HIV programmes, health education institutions, the private health-care sector, national paediatric associations, representatives of medical and nursing schools, community-based and nongovernmental organizations, community leaders and community health workers.

Health system requirements

- Training on childhood TB is essential and needs to be combined with regular supervision. The NTP could also consider joint reviews and planning with RMNCAH programmes. Job aids and simple algorithms for use by peripheral health staff could facilitate their work.
- Where services for diagnosis, prevention and treatment of TB are difficult to implement, the NTP should consider developing a robust referral and feedback mechanism to help limit disruption of services to patients and ensure a seamless continuum of care.

- The NTP has to ensure that child-friendly formulations for children with appropriate dosing (ideally FDCs, as well as single dose INH and other single medications as required) are available at no cost from all services diagnosing and treating children with TB, without interruption or shortages.
- The NTP needs to ensure implementation of services, including timely referral and feedback, and ongoing monitoring and evaluation.
- Integrated and interoperable age- (0-4 years and 5-14 years) and sex-disaggregated recording and reporting systems should be set up. These systems can be further improved to allow disaggregation of data on TB and HIV-associated TB by sex and age to facilitate assessment of the need and access to TB, HIV and RMNCAH care for women and children.

Key implementation steps

NTPs are advised to begin by identifying a dedicated focal point and establishing a childhood TB working group. The group should include representatives from MCH/RMNCAH and other public or private health services managing sick children, paediatricians working with the NTP, a representative from the national paediatric association, representatives of medical and nursing schools and community health workers.

Mechanisms for collaboration in planning and implementation are needed among all stakeholders at national, regional and district levels, including patient groups and civil society.

Other key steps for improving childhood TB activities within NTPs include the following:

- Undertaking epidemiological and health system assessments to understand the TB burden and challenges in providing TB services to children;
- Ensuring that policies are evidence-based and relevant;
- Identifying priorities and gaps;
- Engaging in continuing surveillance;
- Training health workers and implementing care strategies for children with TB;
- Conducting operational research;
- Assessing funding needs;
- Assigning responsibility and ensuring accountability;
- Exercising leadership and working in partnership with all stakeholders and;
- Collaborating and communicating across the entire health-care sector, especially with MCH/RMNCAH counterparts.

Component 1C. Collaborative TB/HIV activities and management of co-morbidities

1C-1 Collaborative TB/HIV activities

HIV is one of the highest risk factors for TB, and TB is the leading cause of death among PLHIV, including among those taking antiretroviral therapy (ART). HIV-associated TB accounts for about one quarter of all TB deaths and 30% of all AIDS-related deaths (52). Post-mortem studies in resource-limited settings found that TB accounted for approximately 40% of facility-

based AIDS-related adult deaths. Almost half of these TB cases were undiagnosed prior to death (54).

However, TB among PLHIV is preventable and even curable. 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 WHO policy package on collaborative TB/HIV activities (Table 1C.1) (53). Experience from countries has shown that high coverage of the comprehensive package of collaborative TB/HIV activities can significantly reduce mortality. Other key policy documents include the latest WHO guidance on use of rapid diagnostics for HIV-associated TB (55); prevention, testing and treatment of HIV (56, 60-62); management of LTBI (57, 63); and guidance on monitoring and evaluation (58).

Policies and strategies

National policies and efforts to address HIV-associated TB should be adapted from the WHO policy on collaborative TB/HIV activities. Adoption of the latest ART policies for the prevention and treatment of HIV will also have a significant impact on the prevention of HIV-associated TB (53) (Box 1C.1).

Countries also need to ensure that clear policies are in place to implement treatment of LTBI with WHO-recommended regimens for all eligible PLHIV. This has a proven role in reducing the incidence of TB regardless of CD4 cell count, even if PLHIV are taking ART. (57) Randomized control trials show that the protective effect of isoniazid preventive therapy is additional to that of ART in preventing progression of LTBI to active TB, even among PLHIV whose CD4 cell counts are higher than 500 cells/mm^3 (59).

To increase case detection among PLHIV, countries should consider policies to expand TB screening by integrating screening into all HIV prevention and care services including HIV pretest counselling services (56).

BOX 1C.1 SUMMARY OF WHO GUIDELINES ON PREVENTION AND TREATMENT OF HIV

In order to prevent HIV-associated TB, countries will need to ensure that services for HIV testing, treatment and prevention are readily available. Below is a summary of the latest WHO HIV-related guidance.

1. Consolidated guidelines on HIV testing services, 2015;
2. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV, 2015;
3. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, 2013 (the update of these guidelines is due to be released in early 2016) and;
4. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations, 2014.

TABLE 1C.1 **WHO POLICY PACKAGE ON COLLABORATIVE TB/HIV ACTIVITIES**

A. ESTABLISH AND STRENGTHEN THE MECHANISMS FOR DELIVERING INTEGRATED TB AND HIV SERVICES
A.1. Set up and strengthen a coordinating body for collaborative TB/HIV activities functional at all levels
A.2. Determine HIV prevalence among TB patients and TB prevalence among people living with HIV
A.3. Carry out joint TB/HIV planning to integrate the delivery of TB and HIV services
A.4. Monitor and evaluate collaborative TB/HIV activities
B. REDUCE THE BURDEN OF TB IN PEOPLE LIVING WITH HIV AND INITIATE EARLY ANTIRETROVIRAL THERAPY
B.1. Intensify TB case-finding and ensure high-quality antituberculosis treatment
B.2. Initiate TB prevention with isoniazid preventive therapy and early antiretroviral therapy
B.3. Ensure control of TB infection in health-care facilities and congregate settings
C. REDUCE THE BURDEN OF HIV IN PATIENTS WITH PRESUMPTIVE AND DIAGNOSED TB
C.1. Provide HIV testing and counselling to patients with presumptive and diagnosed TB
C.2. Provide HIV prevention interventions for patients with presumptive and diagnosed TB
C.3. Provide cotrimoxazole preventive therapy for TB patients living with HIV
C.4. Ensure HIV prevention interventions, treatment and care for TB patients living with HIV
C.5. Provide antiretroviral therapy for TB patients living with HIV

To further reduce diagnostic delays and facilitate early access to life-saving treatment, national policies are needed that ensure ease of access to WHO-recommended rapid diagnostics (such as Xpert MTB/RIF) as the first TB diagnostic test for all PLHIV (52). For PLHIV with bacteriologically-negative or extrapulmonary TB, diagnostic algorithms should be in place to ensure early identification and timely treatment of diagnosed or presumed TB.

Integration of TB and HIV services into existing platforms such as services for the prevention of mother-to-child transmission of HIV, maternal and child health services, and community-based interventions for HIV is also critical for coverage of services (50). National programme policies to complement these integration efforts should also be in place.

Ending TB deaths among PLHIV will not be possible without enabling policies to ensure populations most at risk of both TB and HIV, such as people who use drugs, prisoners and miners, have equitable access to services (60). For people who use drugs and for prisoners, policies should ensure a comprehensive package of services that includes the screening, diagnosis, prevention and care of HIV, TB, viral hepatitis, STIs as well as the provision of opioid substitution, condoms, needle and syringe programmes and psychosocial support as necessary.

In most settings with a concentrated HIV epidemic[1], the burden of HIV-related TB is often exacerbated and access to health care hampered by vertical systems, high incarceration rates, stigma and discrimination. To encourage continued access and adherence, policies should provide these populations with comprehensive, patient-centred services, free from stigma and discrimination.

Key actors to engage

To respond adequately to HIV-associated TB and enhance access to patient-centred and integrated service delivery, TB and HIV programmes need to work closely with one another at every level, as well as with:

- Other health services such as those focusing on prevention of mother-to-child transmission of HIV, maternal and child health, general health, drug dependence and social services;
- Line ministries such as those responsible for prisons, mining, labour, food and agriculture, and immigration, in order to harmonize approaches and improve access to an uninterrupted, patient-centred continuum of care;
- Communities, nongovernmental and civil society organizations and individuals, who should all be involved in planning, implementing and monitoring TB/HIV activities at all levels. Pillar 2 goes into greater detail on the nature of this collaboration.

Health system requirements

Integrating TB and HIV service delivery has been shown to increase ART uptake and timeliness of ART initiation, and reduce mortality from HIV-associated TB by up to 40% (58). Combining these efforts can avoid both duplication and additional travel costs and time spent visiting separate locations. Several key requirements are needed for integration and nationwide implementation of collaborative TB/HIV activities.

- Close coordination between TB and HIV programmes is fundamental. This may be facilitated by establishing functional coordinating bodies that operate at all levels with participation of relevant stakeholders. These bodies should ensure broad commitment and ownership. A national coordinating body should address governance issues, including division of labour and resources, to implement joint plans and ensure accountability.
- Depending on the maturity and magnitude of the HIV-associated TB epidemic and the local context, crucial elements for joint planning include cross-cutting areas such as health information systems and monitoring and evaluation, laboratory and diagnostic services, human resource planning and capacity building, procurement and supply chain management, and resource mobilization.
- Whatever the model of service delivery, a system-wide effort to minimize airborne transmission of TB in health-care facilities visited by PLHIV, including in TB and HIV facilities, is vital to keep the nosocomial transmission of both drug-sensitive and drug-resistant TB infection to a minimum. This should be considered a priority in health systems strengthening efforts. (See Box 1B.2 on FAST strategy and Pillar 2 for more on infection control).
- Accountability mechanisms between line ministries need to be in place to ensure smooth continuum of care for prisoners, migrants, miners and other more at risk or vulnerable groups.

Key implementation steps

The majority of countries are already implementing most collaborative TB/HIV activities and have mechanisms in place to do so, including for joint planning, implementation, and accountability, an essential component. However, in many countries, further measures still need to be taken; these are outlined below.

1. Concentrated epidemic state: HIV prevalence is consistently >5% in at least one defined subpopulation and is <1% in pregnant women in urban areas.

Joint TB and HIV programming is needed to identify opportunities to align plans, optimize support systems and gain efficiencies that will deliver high-quality and sustainable integrated TB and HIV services, including community-based activities. In countries with a low burden of HIV, joint TB and HIV programming should strengthen mechanisms for collaboration between TB and HIV programmes and with other key stakeholders who provide services to groups at high risk for HIV. Joint planning and financing for logistics also help ensure uninterrupted laboratory supplies, test kits and drugs.

Barriers and enablers for collaborative TB/HIV activities should be assessed. Furthermore, policy adoption and implementation should be ensured, particularly for:

- Scale-up of HIV testing among presumptive TB cases, and of all TB patients in concentrated epidemic settings;
- Routine implementation of intensified TB screening of all people attending HIV care;
- Access to rapid diagnostics;
- Access to ART (within eight weeks of TB treatment start);
- Scale-up of management of LTBI and;
- Rigorous implementation of recommended TB infection control policies.

Increased access to all TB/HIV services should be provided to best meet the needs of affected populations and high-risk groups through integration and decentralization of services, including:

- Rolling out WHO-recommended rapid diagnostics within HIV facilities, taking advantage of multiple analytic platforms for TB diagnosis and, for example, viral load testing provided by GeneXpert;
- Expanding HIV testing services to peripheral health facilities, TB services and community settings to ensure coverage of all presumptive and diagnosed TB patients;
- Ensuring that basic TB screening is carried out among all PLHIV at every health visit;
- Decentralizing ART services, including to those providing TB services, as well as through task shifting, to ensure expanded access to timely ART;
- Reinforcing capacity of the workforce at all levels to strengthen implementation and related supervisory activities and;
- Introducing electronic reporting and web-based systems with unique identifiers that respect patient confidentiality, to be used by both programmes for enhanced patient follow-up.

1C-2 Management of other co-morbidities

In addition to HIV/AIDS, other 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 (COPD) and other non-communicable diseases including mental health problems. These conditions constitute risk factors for TB and can complicate clinical management. Moreover, some need to be considered as differential diagnoses. Relevant co-morbidities and health behaviours should be routinely assessed and managed for improved TB treatment and general health outcomes.

Policies and strategies

Undernutrition

Undernutrition is both an important risk factor for and a common consequence of TB. It is a common condition for people with active TB and is associated with increased risk of mortality and poor treatment outcomes. All individuals with active TB should be assessed and counselled

on their nutritional status at diagnosis and throughout treatment. Persons with severe malnutrition should receive nutritional therapy in line with WHO recommendations for treatment of severe malnutrition in children, adolescents and adults. Nutritional care of persons with moderate malnutrition includes identifying and treating its underlying causes; improving nutrient intake through education, counselling, food support and other activities as required; and monitoring weight changes (64).

Diabetes

In all settings, TB patients should be screened for diabetes and managed according to guidelines for diabetes care. When diabetes is newly diagnosed in a person with TB, regular health-care contacts can be used for intensive health education and integrated management of both diseases simultaneously, in collaboration with specialist endocrinology services if required. Advice on diabetes screening and management in people with TB is provided in the collaborative framework for care and control of tuberculosis and diabetes (65).

Chronic respiratory conditions

Tobacco smoking is an important and common TB risk factor and causes other respiratory diseases such as COPD and chronic bronchitis. Silicosis is much less frequent but a very strong risk factor for TB and a common cause of TB co-morbidity in certain groups, such as miners and people working in other occupations that expose them to silica. These respiratory conditions are important differential diagnoses for TB, as well as co-morbidities that need to be identified and managed. People diagnosed with TB should always be asked and counselled about smoking. Guidelines on WHO's Practical Approach to Lung Health provides advice on TB care as an integral part of management of respiratory illnesses (31, 66). Recommended actions on smoking and tobacco control in the context of TB care and prevention are provided in the WHO/The Union monograph on TB and tobacco control (67).

Alcohol and drug use

Screening for alcohol and drug use disorders, as well as mental health problems, is relevant in many settings and may require tailoring of TB care delivery models to special needs and referral to specialist services such as psychiatric and drug addiction services. The consideration of other co-morbidities, including several immune-compromising disorders, will depend on the national situation.

Key actors to engage

It is essential to plan programmatic activities in collaboration with relevant counterparts responsible for clinical services and public health initiatives that address these co-morbidities. The following actors should be considered:

- Nutrition programmes and nutritional care services;
- NCD programmes or equivalent;
- Endocrinology departments or special units for diabetes care;
- Respiratory care services, if different from TB services;
- Tobacco cessation programmes;
- Psychiatric and addiction services;
- Professional associations;
- Private sector providers and;
- NGOs, patient organizations and community groups.

Key implementation steps

While nutritional assessment, screening for diabetes and interviews about smoking habits should be undertaken in all settings, other co-morbidities requiring evaluation will be determined by local conditions. This requires mapping of common and important co-morbidities. If routine data are unavailable, a brief survey may help guide policy by documenting the co-morbidity profile of patients.

Planning and implementation should take place jointly with the relevant stakeholders, who need to agree human resources and financial and logistical arrangements for testing and treating co-morbidities. Costs, for example for diabetes tests, should not normally be covered by the national TB programme budget.

When screenings for co-morbidities are planned, bi-directional screening for TB in these risk groups may also be considered. For example, people with diabetes managed in an endocrinology department may be systematically screened for TB. Reciprocal screening and management needs careful planning with relevant clinical services.

Piloting is recommended, especially for newly introduced practices, and should be followed by monitoring and periodical assessment against clear objectives. A set of locally adapted operational indicators should be developed, for example to determine how many patients are moderately or severely undernourished, diabetes prevalence among newly diagnosed TB patients, and the proportion of patients receiving care for co-morbidities.

Component 1D. Preventive treatment of persons at high risk, and vaccination against TB

1D-1 Preventive treatment

One third of the world's population is estimated to have LTBI; in other words, they do not have active TB disease but may develop it through a process of reactivation of dormant bacilli that start multiplying and produce active TB. The lifetime risk of reactivation for a person with documented LTBI is estimated to be 5-10%, with the majority developing TB disease within 18 months of initial infection. However, the risk is considerably higher in the presence of predisposing factors. The management of LTBI is an innovative element of the "prevention package" of the End TB Strategy. The potential impact could be large: the infection reservoir constitutes the pool from which many new cases arise, depending on the extent of the epidemic.

Currently, treatment options can reduce the risk of developing active TB by 60-90%. LTBI management is particularly important in countries with lower TB incidence (<100 cases per 100 000 population) where a large proportion of cases is due to reactivation of latent infection.

WHO recommendations for LTBI management differ between low- and lower-middle income countries with a high TB burden and high- and upper-middle income countries with a lower burden (57, 68, 69).

Policies and strategies

Policies required to implement this component of Pillar 1 vary according to TB incidence and resource availability. Table 1D.1 presents WHO guidance on management of LTBI for countries grouped according to TB incidence and resource availability.

TABLE 1D.1 WHO RECOMMENDATIONS FOR THE MANAGEMENT OF LTBI

COUNTRY GROUP	Resource-limited and other middle-income countries with an estimated TB incidence rate of more than 100 per 100 000 population High-income and upper middle-income countries with an estimated TB incidence rate of less than 100 per 100 000 population
AT RISK POPULATIONS	1) PLHIV 2) Children under 5 years of age who are household contacts of a TB case Strongly recommended for the following risk groups: 1) People living with HIV 2) Adults and children who are household or close contacts of pulmonary TB cases 3) Clinical indications - patients with silicosis; patients initiating anti-TNF treatment; patients on dialysis; transplant patients
TESTING ALGORITHM	Exclude active TB using TB investigations. An LTBI test is not required prior to LTBI treatment, but is encouraged for PLHIV IGRA should not replace TST Exclude active TB using TB investigations A positive test, either a TST or IGRA test is required to diagnose LTBI
TREATMENT OPTIONS	6 months daily isoniazid 9 months daily isoniazid 3 months weekly rifapentine plus isoniazid 3 to 4 months daily isoniazid plus rifampicin 3 to 4 months daily rifampicin

Key actors to engage

Key actors include:

- All relevant care providers such as primary care physicians;
- Programmes and stakeholders providing services for HIV-infected persons;
- Programmes and stakeholders providing services for immigrants, harm reduction services, prison health services, mining health services and immunocompromised persons and;
- Nongovernmental actors, civil society and patient networks.

Health system requirements

Health systems should have the following in place for effective LTBI management:

- Multisectoral mechanisms for collaboration between national TB control programmes or their equivalents, other relevant clinics, service delivery programmes and stakeholders;
- National LTBI policy based on adaptation of WHO guidelines;
- Recording and reporting system for LTBI with standard indicators;
- Well-established supply chain system which ensures access to LTBI diagnostic test and treatment;
- Adequate financial allocation to LTBI interventions and a system to reduce financial barriers for patients receiving treatment of LTBI and;
- Trained health-care workers in relevant settings, not limited to the TB programme, but including those providing services to above-mentioned at-risk populations.

Key implementation steps

It is recommended that NTPs design flexible interventions that respond to the local context and needs of the population to ensure acceptable initiation, adherence and completion of LTBI treatment.

FIGURE 1D.1
PROGRESSION FROM EXPOSURE TO TB DISEASE

- Implementing this component should begin with an assessment of the national and local TB epidemiological situation to determine the need and importance of establishing a public health approach for treatment of LTBI. This includes identification of populations most at risk; bottlenecks and opportunities for implementation; adoption of appropriate national policies within a conducive legal framework; evaluation of the supply chain system of tests for LTBI and treatment; and involvement of responsible staff for the implementation of LTBI activities.
- Algorithms should be developed for screening, testing and treatment of eligible people, in line with national guidelines.
- Although LTBI treatment does not need to be directly supervised, regular follow-up of patients is suggested to ensure safety of treatment.
- Efforts will be required to train human resources to scale up implementation of LTBI activities.
- All relevant care providers need to be trained and engaged in the management of LTBI.
- The introduction of functional and routine monitoring and evaluation systems aligned with national patient monitoring and surveillance systems is recommended.
- Appropriate recording and reporting tools need to be developed and standardized indicators established to regularly inform decision-making for programme implementation.
- Adequate financial investment for training, implementation, and monitoring and evaluation of adopted interventions should be ensured.
- Priority research gaps in the implementation of LTBI management should be identified and addressed.
- There is no evidence to indicate that use of isoniazid or rifamycin-containing regimens for the treatment of LTBI increases the risk of drug resistance. However, establishing national TB drug resistance surveillance systems in countries implementing national latent TB management programmes is advised.

1D-2 Vaccination against TB

Adequate investments in research to develop new tools are expected to yield truly effective vaccines that protect both populations – those infected with TB and the uninfected – from getting the disease. Yet a new vaccine is unlikely for a decade.

Until new and better vaccines are available, BCG (Bacillus Calmette-Guérin) vaccination should be a part of the immunization schedule for children (70). BCG has been shown to prevent disseminated diseases including TB, meningitis and miliary TB, which are associated with high mortality in infants and young children. However, its preventive efficacy against pulmonary TB, which varies among populations, is only about 50%. Current WHO recommendations on BCG vaccinations are summarized in Box 1D.1.

BCG vaccination soon after birth should continue for all infants except for those with HIV living in high TB prevalence settings. The risk-benefit ratio of BCG vaccination becomes more unfavourable with decreasing TB transmission rates. Low-incidence countries should consider directing BCG vaccination to children in high-risk groups, or phasing out BCG vaccination entirely, depending on national TB epidemiology. As presented in Pillar 3, new vaccines will be an essential tool to break the trajectory of the TB epidemic and move towards its elimination.

BOX 1D.1 WHO RECOMMENDATIONS ON BCG VACCINATION

1. In countries with a high burden of TB, a single dose of BCG vaccine should be given to all infants as soon as possible after birth;
2. Revaccination of children and adolescents is not recommended;
3. There is a high risk of disseminated BCG disease developing in HIV-infected infants and therefore the BCG vaccine should not be used in children who are known to be HIV infected, even if asymptomatic[a];
4. Countries with a low incidence of TB[b] may choose to limit BCG vaccination to neonates and infants of recognized high-risk groups for the disease or to skin-test negative older children. In some low-incidence populations, BCG vaccination has been largely replaced by intensified case detection and supervised early treatment;
5. BCG vaccination of adults is not normally recommended.

a. Revised BCG vaccination guidelines for infants at risk for HIV infection. Weekly Epidemiological Record, No. 21, 25 May 2007

b. Low-incidence countries have adpated BCG vaccination policies for their epidemiological settings. As an example, BCG vaccination policies may be accessed at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148511/Green-Book-Chapter-32-dh_128356.pdf

EXAMPLES OF INDICATORS TO MONITOR END TB STRATEGY IMPLEMENTATION: PILLAR 1

INDICATOR	REQUIREMENTS FOR MEASUREMENT
PERCENTAGE OF NEWLY NOTIFIED TB PATIENTS TESTED USING WHO-RECOMMENDED RAPID TESTS Patients tested using a WHO-recommended rapid test at the time of diagnosis, divided by the total number of new and relapse TB patients, expressed as a percentage.	Requires additional routine data collection compared with 2013 WHO recording and reporting framework. Case-based electronic recording and reporting systems facilitate the addition of new variables to routine data collection efforts
NUMBER OF NOTIFIED TB CASES NB: COULD ALSO BE EXPRESSED AS A RATE	Routine recording and reporting system is consistent with 2013 WHO recording and reporting framework.
NUMBER OF NOTIFIED CASES OF DRUG RESISTANT TB (RR OR MDR-TB)	
CONTACT INVESTIGATION COVERAGE (%) Number of contacts of people with bacteriologically-confirmed TB who were evaluated for TB divided by the number eligible, expressed as a percenta	This requires additional routine data collection compared with 2013 WHO recording and reporting framework; adding variables is easier if case-based electronic recording and reporting is in place.

INDICATOR	REQUIREMENTS FOR MEASUREMENT
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	Routine recording and reporting system consistent with 2013 WHO recording and reporting framework
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	For notifications, routine recording and reporting system is consistent with WHO recording and reporting framework. TB incidence is estimated by WHO using methods that are periodically reviewed by an expert group convened under the umbrella of the WHO Global Task Force on TB Impact Measurement. The main reasons for a gap between incidence and notifications are: 1) under-reporting of detected cases; 2) under-diagnosis of cases. Levels of under-reporting can be measured using an inventory study. Levels of under-diagnosis require assessment of factors associated with under-diagnosis, such as the extent to which UHC and social protection are in place. This indicator can only be estimated with reasonable precision once UHC and social protection are in place.
ENROLMENT ON TREATMENT FOR DETECTED CASES OF DRUG-RESISTANT TB (%) on treatment, divided by the number of RR/MDR-TB cases detected in the same period	Routine recording and reporting system consistent with 2013 WHO recording and reporting framework. The treatment success rate can be reported separately for drug-susceptible and drug-resistant 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	
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	Routine recording and reporting system consistent with 2013 WHO recording and reporting framework and the 2015 WHO guide on monitoring and evaluation of collaborative TB/HIV activities.
ART COVERAGE, HIV-POSITIVE TB PATIENTS (%)	
LTBI TREATMENT COVERAGE (%) Number of PLHIV 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)	Routine R&R system for people in HIV care, including specific reporting for treatment of LTBI. Collection of data on number of children eligible for treatment and the number initiated on treatment.
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	National (or sample) vital registration system of high coverage and quality for measurement of TB deaths. For TB incidence, see explanation for treatment coverage above. Notifications can be used as a proxy for incidence when target levels for treatment coverage. Catastrophic costs and under-reporting are reached
BCG VACCINATION COVERAGE AT 1 YEAR (%)	Routine immunization reports, vaccine coverage surveys

PILLAR 2 : KEY COMPONENTS

A. Political commitment with adequate resources for TB care and prevention

B. Engagement of communities, civil society organizations, and all public and private care providers

D. Social protection, poverty alleviation and actions on other determinants of TB

C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

Migrant workers wait outside the train station in Wuxi, Jiangsu Province, China. TB particularly affects poor and vulnerable populations; migrants are a key affected population.

PART III - PILLAR 2

Bold policies and supportive systems

• • •

KEY MESSAGES

- Effective implementation of the End TB Strategy requires effective government stewardship, high-level political commitment and enhanced resources.
- Active coordination across government ministries as well as engagement and collaboration with communities, civil society and all public and private care providers are essential.
- A sound, fully budgeted national TB strategic plan should be developed and implemented with all stakeholders in line with overall national health and social sector plans.
- The linkages necessary to advise on and secure TB-sensitive UHC strategies and schemes should be developed.
- The regulatory framework should be strengthened and enforced to enable mandatory TB case notification; wider efforts are needed to strengthen vital registration, quality assurance and rational use of drugs, and infection control.
- Practical steps by government agencies and all stakeholders are required to ensure that TB is addressed in social protection, poverty alleviation and related social policy agendas and programmes, with special attention to the needs of affected communities and vulnerable populations.

Implementing Pillar 2 demands a multidisciplinary and multisectoral approach and therefore rests not only with the health ministry, but also with other ministries including finance, justice, labour, social welfare, housing, mining or agriculture.

Introduction

The second pillar encompasses strategic actions within and beyond the health sector that will enable effective transformation and strengthening of policies and systems to support TB care and prevention. These actions include enhancing government stewardship and accountability, as well as pursuing TB-sensitive policies across government and systems to significantly improve access to needed health services, mitigate the social and economic consequences of TB, and act on its socioeconomic determinants.

The full implementation of the pillar requires action across the ministry of health with special roles for its national TB programme or equivalent, as well as by other ministries, nongovernmental partners and civil society. This needs to be linked to overall efforts to improve the financing, evidence-based policymaking and organization of health systems, as well as strengthening social and development policies. This work demands a multidisciplinary and multisectoral approach and therefore rests not only with the health ministry, but also with other ministries including finance, justice, labour, social welfare, housing, mining or agriculture.

Component 2A. Political commitment with adequate resources for TB care and prevention

2A-1 Enhancing government stewardship

As described in Part I, the establishment of a national high-level coordination mechanism could help design and drive the implementation of the End TB Strategy. Eliciting actions from across diverse ministries will require direction and commitment from the highest levels of government. In some countries, this may be undertaken through an existing overarching public health or communicable disease body. Government stewardship needs to manifest itself in setting ambitious targets, driving cross-government engagement, enabling resource mobilization from domestic and international sources, overseeing implementation and monitoring progress. Ensuring that ending TB is addressed as an SDG target in the national development agenda and reporting is another important step. Implementing the End TB Strategy will require substantially increased funding in most countries and financing through more streams of national budgeting, within and beyond the ministry of health.

A well-resourced central NTP team within the ministry of health with a TB-specific budget is another critical element of stewardship. The size and capacity of the NTP's central coordination team and the level of decentralization and integration of specific services depend on many factors including the country's size, governance and administrative structure, and TB epidemiology.

Box 2A.1 highlights the major suggested stewardship functions of an NTP or a TB-dedicated coordinating team or health authorities within integrated health systems at provincial and local levels.

2A-2 Developing a comprehensive national TB strategic plan

As noted in Part I, an essential step in driving political commitment is wide stakeholder participation in developing or updating a NSP for 2016 and beyond, with a clear vision of the 2030 and 2035 goals and targets to end TB, and strategic actions over the first three to five years. Box 2A.2 gives an illustrative list of stakeholders who, depending on the setting and relevance, may need to be appropriately engaged in all stages of planning, and implementation. WHO has developed a toolkit to help NSP development (1).

BOX 2A.1 **STEWARDSHIP FUNCTIONS OF A NATIONAL TB PROGRAMME**

- Developing and adapting evidence-based TB care and prevention, and insertion of TB policy within broader national health policy;
- Regular planning, budgeting and management review, engaging a wide range of stakeholders;
- Securing well-functioning oversight and management of TB care and control, with strong referral, notification and information mechanisms among primary care, hospitals, and specialist services – public and private, as well as a network of laboratory and radiology services involved in TB diagnosis;
- Human resource planning, capacity strengthening, supervision and monitoring of service quality on all levels, and continuous medical education, integrated within wider systems of human resources development;
- Providing targeted information on TB strategies and policies for all levels of care, all relevant specialist services, and both the public and the private sector;
- Designing and delivering enhanced educational materials for patients, families, affected communities and partners across and beyond government, and including them in the design process;
- Supporting, with others responsible in ministries of health, the uninterrupted supply of quality-assured drugs and diagnostic tests, based on forecasting, drug management capabilities and a strategy for rational drug use;
- Collecting and analysing high-quality data and capacity of all levels of the health system in surveillance and programmatic monitoring and evaluation, including joint reviews involving stakeholders and periodic public reporting and;
- Engaging with government and NGO counterparts working on health financing, social policy, social protection, justice, labour, migration etc. to define roles and create referral and support systems.

The NSP, the Strategy's backbone at country level, guides national health authorities in managing and implementing appropriate TB care and prevention activities, and building effective linkages with other programmes and health and non-health sector partners.

The NSP needs to be aligned within the national health plan and linked to plans of other sectors. It should be ambitious and comprehensive, and incorporate budgeting, implementation, monitoring and evaluation, research and technical assistance. A clear course towards agreed TB targets needs to be set and monitored. As recommended, new NSPs need to incorporate an expanded set of post-2015 baseline assessments of national and subnational TB epidemiology, including health system structure and functions as well as identification of key affected populations and communities. The NSPs also need to include specific analyses of procurement and supply systems, resource availability including human resources, 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 missions, undertaken with partners, as outlined in WHO guidance (2).

Based on the NSP, detailed operational planning and milestones by year can be pursued. Regular consultation, with all stakeholders, to take stock of progress and associated reporting of results and lessons learned should be pursued and financed.

In many countries which receive development aid for the TB response, NSPs may have recently been revised or in the process of revision. As a result, the first steps will be to revise such NSPs where feasible or make changes to annual operational plans to enable the modifications required in interventions and targets in line with the End TB Strategy.

NSPs should be seen as living documents and used as the basis for annual operational planning and periodic review meetings. The full range of TB stakeholders should be engaged in the implementation, monitoring and evaluation of NSPs.

2A-3 Mobilizing resources for an ambitious agenda

Most low- and middle-income countries lack sufficient resources even for current programmes of work, let alone more ambitious NSPs. They require a prioritized and well-budgeted plan that justifies increases in national and international financing. Resource mobilization needs to involve all stakeholders with budgetary responsibility over TB prevention and care, related social protection, surveillance and research. Financing estimates must be determined locally since each country has a different starting point and will require adjusted targets and different timelines.

The basics: core TB budgets within NSPs and national health plans

NTPs hold the primary responsibility for developing NSP budgets, additional budgets for operational planning in the Ministry of Health, or external donor proposals. WHO provides a number of tools to guide and support this work, as well as related technical assistance. The "WHO TB planning and budgeting tool" (3) is regularly updated and helps assess financial needs and funding gaps by intervention area. The "One Health Tool" (4), initially developed for health sector planners in low- and middle-income countries, helps estimate the cost and feasibility of strategic plans and has been further refined to allow detailed budgeting for TB prevention, diagnosis and treatment.

Special assessments to drive resource mobilization to support innovations

Innovative ways to mobilize additional resources may include undertaking special assessments of the costs and benefits of launching new elements under the End TB Strategy such as, for example, expansion of DST for all patients, scaling up of access to second-line drugs for treatment of DR-TB, shifting from hospitalized care to ambulatory care for DR-TB patients, introducing patient support packages or initiating special programmes for engagement with the private sector

BOX 2A.2 ILLUSTRATIVE LIST OF STAKEHOLDERS TO BE ENGAGED IN ALL STAGES OF PLANNING & IMPLEMENTING THE END TB STRATEGY

All relevant government ministries and departments at the central, provincial and local levels including health, finance, planning, social welfare, justice, migration, urban development, food and nutrition etc.

Nongovernmental and other civil society organizations

Private medical sector, professional societies and associations, and corporate and business sector

Academia and research institutions

Affected communities and patient organizations including representatives of vulnerable populations and high-risk groups

Technical, financial and implementing partners and development agencies.

through public-private mix approaches. These assessments could include in-depth descriptions of roll-out planning and start-up costs, as well as management and human resource requirements. They could also encourage discussions within the ministry of health and with the ministry of finance, external donors or other players. Where benefits can be estimated or costs of inaction elaborated, these documents can be powerful tools in building political momentum to change current practice and drive change.

The assessments may also help access special resources for innovation or novel financing mechanisms already available for special initiatives within government or from international financing and development partners.

Component 2B. Engagement of communities, civil society organizations, and all public and private care providers

2B-1 Engaging communities and civil society organizations

A strong coalition with communities, nongovernmental and other civil society organizations is one of the four principles of the End TB Strategy. A robust alliance could transform policies, programmes, and practices and help mobilize resources, design and roll out national TB plans and strategies, and undertake local action. Furthermore, some communities find it difficult to access health facilities for reasons that are often social (stigma, discrimination), economic (health-care expenditure, transport income loss, and other costs) or political (cross-border services, particularly for migrants). To reach all people needing TB prevention and care services, health authorities need to partner with communities, NGOs and other CSOs for TB care and prevention.

Community-based TB activities can be carried out either by NTPs or by NGOs and other CSOs. CSOs, as equal partners under government stewardship, are especially well-placed to effectively approach hard-to-reach communities or marginalized populations. See Box 2B.1 for key terms and operational definitions.

The ENGAGE-TB Approach describes the basic operational principles and steps for effective engagement and collaboration between NTPs, NGOs and other CSOs, primarily for integrated community-based TB activities (5). It emphasizes close alignment of systems, especially in TB monitoring and reporting, to ensure national data adequately reflect the contributions of community-based TB activities. The section below provides guidance on community-based TB activities initiated and supported by the NTP, NGOs and other CSOs. Certain actions and prerequisites are needed. Community-based TB activities should be conducted in an integrated manner with other activities whenever feasible (Box 2B.2). Country examples are presented in Box 2B.3.

Policies and strategies

The following policies, strategies and actions need to be considered for effective engagement of communities and CSOs:

- A legal framework that gives communities, NGOs and other CSOs a voice in the TB response, developed in close collaboration with the affected community and anchored in an enabling environment that allows organizations including those not yet engaged in TB, to work without impediment;
- An enabling policy and programmatic environment of national policies and laws, based on equity, equality and mutual respect, to encourage smooth roll-out of integrated community-based TB services, including the establishment of a task force or working group for community engagement or the creation of a national coordinating body to facilitate effective NGO and

other CSO engagement in integrated community-based TB prevention, diagnosis, treatment and care services;

- Policies and practices that allow the voice of affected communities to be heard at all stages of national and local policy development and programme implementation, for example by including community and patient advocates in various TB forums;
- Systematic collaboration between the NTP, NGOs and other CSOs, for example through independent NGO coordinating bodies (NCBs), supported by ongoing dialogue and collaboration to share experiences and information about needs and constraints and to identify timely solutions and;
- Integration of community-based TB activities in health services delivery.

Key actors to engage

Depending on the country context, the key actors and stakeholders in community and CSO engagement may include:

BOX 2B.1 KEY TERMS AND OPERATIONAL DEFINITIONS

Community refers to those individuals, their family members and members of a geographical area or a social or economic interest who are affected by tuberculosis and other related health and social issues and who are beneficiaries of and contributors to efforts to address these issues.

Community engagement is the process of working collaboratively with and through communities to address TB and other related health and social issues affecting their well-being. It often involves partnership and coalitions that can result in behavioural, environmental and social changes that will improve the health of the community and its members.

Community-based TB activities cover a wide range of activities contributing to prevention, diagnosis, treatment and care that positively influence the outcomes of drug-sensitive, drug-resistant and HIV-associated TB. The activities also include community mobilization to promote effective communication and participation among community members to generate demand for and increase confidence in TB services, as well as advocacy activities aimed at decision-makers and key stakeholders to influence policy, laws, regulations, programmes or funding. Community-based TB activities are conducted outside the premises of formal health facilities (e.g. hospitals, health centres and clinics) in community-based structures (e.g. schools, places of worship, congregate settings) and homesteads. These activities can be conducted by community health workers (CHW) or community volunteers (CV), supported by governmental structures notably the national TB programme or NGOs and other civil society organizations.

Community health workers are people with some formal education who are given training to contribute to community-based health services, including TB prevention and patient care and support. Their profile, roles and responsibilities vary greatly among countries, and their time is often compensated by incentives in kind or in cash.

Community volunteers are community members who have been systematically sensitized about TB prevention and care, either through a short, specific training scheme or through repeated, regular contact sessions with professional health workers.

Nongovernmental and other civil society organizations are non-profit organizations that operate independently from the state and from the private for-profit sector. They include a broad spectrum of entities such as international, national and local NGOs, community-based organizations, faith- and patient-based organizations as well as professional associations.

BOX 2B.2 **EXAMPLES OF COMMUNITY-BASED TB ACTIVITIES**

Awareness-raising, behaviour change communication and community mobilization

Reducing stigma and discrimination

Screening and testing for TB and TB-related morbidity (e.g. HIV counselling and testing, diabetes screening), including through home visits

Facilitating access to diagnostic services (e.g. sputum or specimen collection and transport)

Initiation and provision of TB prevention measures (e.g. isoniazid preventive therapy, TB infection control)

Referral of community members for diagnosis of TB and related diseases

Treatment initiation, provision and observation for TB and co-morbidities

Treatment adherence support through peer support and education and individual follow-up

Social and livelihood support (e.g. food supplementation, income-generation activities)

Home-based palliative care for TB and related diseases

Community-led local advocacy activities

Source: ENGAGE-TB Operational Guidance. Geneva, World Health Organization, 2012 (WHO/HTM/TB/2012/8).

- NTPs or their equivalent;
- Other national programmes involved in RMNCAH, HIV, primary health care, agriculture, livelihoods development or WASH into which TB can be integrated;
- CSOs, such as NGOs, CBOs, FBOs;
- Patient organizations, networks and associations and;
- Community health workers and community volunteers supported by governments or civil society groups.

Health system requirements

Engaging communities, NGOs and other CSOs requires the following:

- Human and financial resources commensurate with an enhanced scope of activities for community and CSO engagement;
- Synergies with relevant community-based initiatives in other health programmes (for example HIV or RMNCAH or PHC) and ministries to integrate TB into their portfolios, possibly through the creation or designation of a central-level task force or working group;
- Standardized implementation of aids and tools to ensure a smooth roll-out of activities, including training manuals and referral forms to help CHWs or CVs effectively refer persons with TB symptoms to health facilities; registers and tools for household contact screening, and registers and reports to summarize monthly community-based activities and;
- A routine monitoring system to measure contributions to TB notifications from community referrals and to community-based treatment support for registered TB patients.

BOX 2B.3 COUNTRY EXAMPLES OF INTEGRATED COMMUNITY-BASED TB ACTIVITIES THROUGH ENGAGEMENT OF EXISTING PREVIOUSLY UNENGAGED NGOS (ENGAGE-TB)

In Kinshasa and Kikwit, Democratic Republic of the Congo, the NGO Femme Plus has integrated TB services into its community-based HIV activities. This approach has strengthened collaboration between public TB facilities, NGOs and communities and improved data quality at local level. Public TB officers and NGO focal points meet quarterly to review community-based TB referral and treatment support activities and validate community engagement data, which are then reported to the national level. In 2013, community-based activities in the two operational Femme Plus project sites resulted in 1088 newly notified TB cases, representing a contribution of 40% of all new TB notifications in the project area.

In Ethiopia, Save the Children integrated community TB and TB/HIV services into its existing community Maternal, Newborn and Child Health (MNCH) Programme for pastoralist communities in Dollo Abo and Dollo Bay Woredas of the remote Somali Region. Coupled with health systems strengthening activities, the pilot resulted in an increase in TB patients on treatment from 52 TB patients in 2012 before the start of the programme to 427 in 2013.

In Kenya, a strong partnership at the national level between NGOs and other CSOs and the National Tuberculosis and Leprosy Programme (NTLP) has resulted in increased participation of civil society in national planning and policy-making. Community engagement is included as part of the new NSP. Another NGO, previously unengaged in TB, has been welcomed as a new member of Kenya's TB-Inter Coordinating Committee (TB-ICC) allowing a broader set of voices to be heard in this forum.

Key implementation steps

The ENGAGE-TB Approach for effective engagement and collaboration between NTPs, NGOs and other CSOs includes the steps outlined below (more details on steps for effective engagement of communities are available in the WHO guidance) (6):

- A situation analysis and mapping with information gathering at all levels to assess programmatic needs and challenges, priority activities, actors and existing community-based initiatives by the government, NGOs and other CSOs;
- Engagement and consultation of CSOs in developing national strategic and operational plans for TB, including guidelines (such as for community-based screening of TB) and tools (for example a training manual for community health workers and volunteers);
- Joint consultation between communities, CSOs and NTPs for task identification for CHWs and CVs;
- Increased training for and activities by CHWs and CVs to integrate community-based TB services within activities related to HIV or RMNCAH or PHC;
- Routine monitoring and evaluation to measure what is being done and provide feedback to all stakeholders and;
- Capacity building to ensure that all stakeholders have the abilities, skills and resources to plan, implement and scale up TB activities.

The investments in scaling up public-private mix approaches do not match the real needs on the ground.

2B-2 Engagement of all public and private care providers

The composition of health-care providers – public, voluntary, private, or corporate – approached by people with TB varies within and across countries. Yet, provider engagement through some type of public-private mix (PPM) approaches is relevant to all settings. As a result of scaling up successful PPM initiatives, about 10 to 30 per cent of TB cases in countries as diverse as India, Kenya, Malawi, Myanmar, Pakistan and Tanzania are served by private and other non-state and public sector care providers operating in line with NTP guidelines. Despite scaling up of PPM initiatives, many TB patients managed in large public and private hospitals still go unnotified; a large proportion of qualified and non-qualified and formal and informal private providers continue to provide uneven care; workplace TB programmes are scarce; quality assurance of tests performed in private laboratories is uncertain; and quantities of TB medicines of questionable quality are sold in private retail pharmacies, especially in Asia. The capacity of NTPs and investments in scaling up PPM do not match the real needs on the ground.

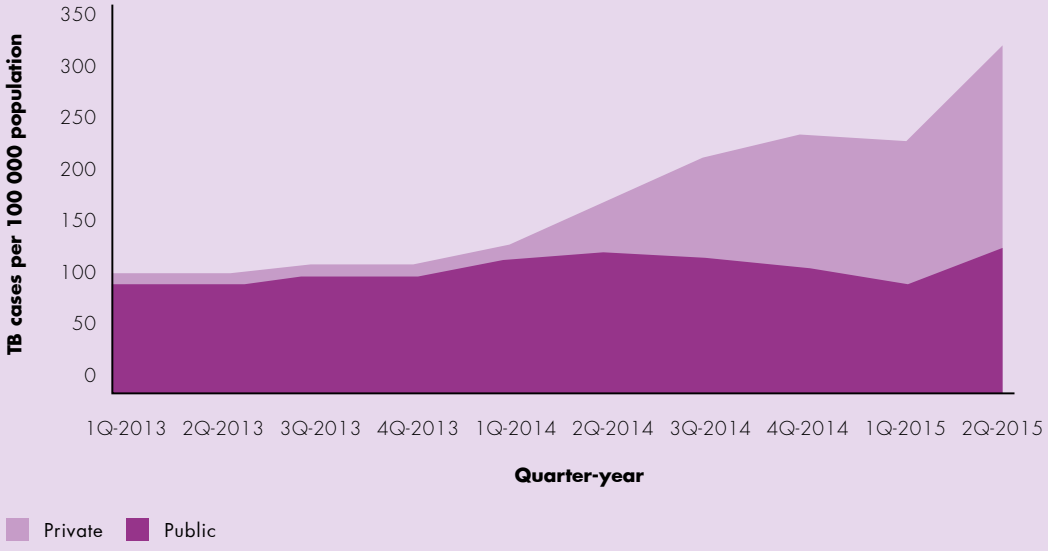
BOX 2B.4 **FINDING INDIA'S MISSING TB CASES USING TECHNOLOGY-ENABLED SERVICES FOR PRIVATE PROVIDERS AND PATIENTS**

One-third of the world's "missing TB cases" are attributed to India, and nearly a million such cases are believed to be managed by Indian private providers. Although TB notification has been mandatory in India since 2012, there are no consequences for non-participation. In Gujarat State, in the District of Mehsana with a population of two million, an innovative service has been successfully eliciting TB notifications, enabling near-complete surveillance and improved quality of care.

The incentive to make private providers notify their TB cases is the offer of convenient, free TB drug vouchers for notified TB patients. When a TB case is diagnosed, the doctor or an assistant makes a toll-free call to a call centre, where operators collect TB notification information and generate e-vouchers for standard first-line TB medicines. Patients show the code received on their mobile phone through a short text message to enrolled pharmacies, which validate and issue TB medicines without any charge. The call centre contacts the patient by phone and verifies the receipt of free TB medicines. The local TB officer signs off on payments every few days, and confirmation of each e-payment is sent to the pharmacy by text message. Notification is the gateway to monitoring treatment adherence. The patient's adherence is ensured via an escalating algorithm of reminders, alerts, self-reporting and if required, contacting family members and a visit by programme staff.

After one year, this system is now regularly used by 30% of qualified providers, and >70% of all anti-TB drugs dispensed by private chemists in the district are under e-vouchers. TB case notification has tripled (figure), and for the first time adherence monitoring and support is being provided to the large number of privately-treated TB patients. The Mehsana model is showing that with innovation, India's TB programme can tackle the problem of "missing TB cases" in the private sector.

Quarterly TB Case Notification Rate (Annualized) Public and Private sector, 2013-15, Mehsana



The PPM approach cuts across all components of the End TB Strategy. Early diagnosis of TB requires engaging relevant informal and formal providers first visited by people with TB symptoms; expansion of collaborative TB/HIV activities and programmatic management and prevention of MDR-TB requires collaboration with all care providers; rapid and rational uptake of new diagnostics and drugs for patients in private clinics requires allowing qualified private providers to access new TB drugs for their eligible TB patients; and optimizing current PPM models and developing scalable and sustainable requires operational research.

Based on country approaches and experiences, WHO has developed overall guidance and tools for implementing public-private mix approaches for TB care and prevention (7, 8), guidance on how to conduct a national PPM situation assessment (9), inventory studies of all care providers (10), engaging all care providers for TB/HIV collaborative activities (11), and programmatic management of drug-resistant TB (12). The International Standards of TB Care (13) set out standards for all public and private care providers.

In recent years, innovative and new models of scaling up PPM for TB, such as social franchising and social business models, have been successfully implemented in Asia. Many of these models successfully used digital health tools in care delivery (Box 2B.4).

Policies that should be in place, depending on country context

Effective engagement of all public, voluntary, private and corporate care providers requires an enabling environment:

- An explicit policy outlining the contribution of relevant public and private providers to the NTP's goals and objectives, essential in mobilizing the human and financial resources needed to scale up PPM programmes;
- Clear national guidelines and practical tools to engage the vast range of public and private providers – from traditional healers to chest physicians – who cater to people with TB, including the very poor;
- National standards of TB care in line with the International Standards of TB Care available to all providers with guidance on how to put them into practice and the support available from the NTPs;
- Certification and accreditation systems to identify, equip, provide incentives and link providers to the NTPs and enable them to provide quality TB care to their patients free of charge;
- Policies to bring TB patients and providers in the private sector under the umbrella of UHC and social protection strategies and schemes;
- Policies and guidance to apply digital health tools to facilitate PPM expansion and;
- A regulatory framework for TB control that includes mandatory TB case notification by all care providers and restrictions on irrational sale and use of anti-TB drugs (Box 2B.5).

Key actors to engage

- Ministries of health and the NTP who can act as stewards for PPM programmes by providing policies, guidance, tools, technical support, finances and monitoring;
- All public sector care providers, especially hospitals and those outside the purview of NTPs or ministries of health (such as academic institutions, health insurance organizations, prison health services, social security institutions) should follow national and international standards for TB care;
- National and provincial supply and regulatory authorities who can ensure uninterrupted supply and rational use of quality-assured TB medicines (including newly available drugs) and WHO-endorsed diagnostic technologies;

- National professional associations and other intermediary organizations who can help link loosely organized private providers to the NTP, including NGOs, FBOs and private institutions such as social franchising and social business organizations;
- Corporate and private laboratories and radiology services that offer TB screening and diagnosis;
- Corporate and business sector involvement, which is essential to diverse aspects of TB care and prevention including workplace TB programmes for employees, their families and communities and;
- Communities and civil society organizations, who play a significant role in educating, enabling and supporting people and providers for patient-centred TB care (see section on the ENGAGE-TB approach under Key implementation steps in section 2B.1 above).

Health system requirements

- An enabling systemic environment and willingness of NTPs to work with all relevant care providers - public sector staff at all levels need to be convinced about the necessity of engaging all care providers and oriented appropriately;
- Enhanced human and financial resources to scale up and sustain PPM implementation;
- Enhanced capacity and mechanisms to:
  - » set up certification and accreditation systems to identify and support collaborating care providers including laboratories;
  - » enforce regulatory approaches such as mandatory TB case notification, rational use of TB drugs and infection control in health facilities using information and communication technology for ease of implementation and;
  - » identify and contract intermediary organizations with the mechanisms and capacities to engage numerous individual practitioners;
- Integration of supportive supervision and monitoring of PPM programmes into overall TB programme surveillance and monitoring and;
- Where possible, integration of TB care into public-private partnerships for other public health programmes and vice versa.

Key implementation steps

Large-scale implementation of PPM to engage all care providers in TB care and prevention generally requires a strategy mix based on a thorough national situation assessment and the status of PPM implementation in the country. The following strategies should be considered for inclusion:

- Ensuring first that the human and financial resources available to scale up engagement of all care providers are commensurate with the magnitude of the problem, taking into account the number of TB cases managed outside the NTPs, and the strengthening of capacity needed within the public sector;
- Optimizing and expanding engagement of large hospitals, academic institutions and nongovernmental organizations;
- Sharing the burden of engaging numerous solo private practitioners with "intermediary organizations" such as social franchising and social enterprise institutions, NGOs with capacity and skills to work with private practitioners, and professional societies and associations;
- Engaging and accrediting first-level and referral laboratories offering TB diagnosis;

- Mobilizing and supporting the business sector to initiate and expand TB programmes;
- Implementing regulatory approaches such as mandatory case notification, rational use of TB medicines, and certification and accreditation systems to identify and support collaborating providers; and
- Engaging communities and civil society to create demand for quality TB care from all public and private care providers.

BOX 2B.5 **MANDATORY TB CASE NOTIFICATION IN HIGH TB-INCIDENCE COUNTRIES: POLICIES AND PRACTICES**

A large proportion of the so-called "missed" cases – more than three million every year globally – are not, in fact, missed or left undiagnosed and untreated. They may be detected and treated but are not notified by care providers who manage them. WHO is documenting TB case notification policies and practices in high-incidence countries. Understanding the reasons behind under-notification would be a first step to identifying how to address the problem within the larger context of public health surveillance and infectious disease notification in high TB incidence countries.

While most high-incidence countries include TB in their list of notifiable diseases, notification requirements and enforcement are usually lax or absent. Notification of TB cases detected in facilities linked to NTPs is often systematized. However, systems and tools to facilitate notification from private care providers are not in place. Private providers usually fail to notify cases due to lack of awareness about reporting requirements; indifference towards notification; misconceptions about notification and confidentiality issues; lack of training, support or feedback from health authorities; and cumbersome paper-based notification systems where they exist.

Weak public health surveillance and infectious disease notification systems pose barriers to establishing mandatory TB case notifications. However, working mechanisms in low-incidence countries and innovations using digital technology in countries like China, India, South Korea and Thailand provide useful lessons for mandatory TB case notification. In preparing to implement the post-2015 End TB Strategy, all countries need to have a national mandatory TB case notification policy with built-in sanctions for non-compliance. Effective enforcement of such a policy will require identifying and putting in place simple methods of TB case notification by private providers. Smart application of digital technology seems to be the logical way forward for rapid progress in this area.

Component 2C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control

UHC is defined as "the situation where all people are able to use the quality health services that they need and do not suffer financial hardship paying for them". The aim is progressive movement towards UHC.

Policies and strategies

Move towards universal health coverage

Since people generally approach health services for help with an undefined illness rather than visiting a clinic for specific TB care, access barriers to general health services must be removed. This requires a guarantee of full access for everyone to general health services, not just to TB-specific tests and treatments (14). Geographical and financial barriers for general health service use, such as out-of-pocket expenditure, must be minimized and systemic changes made to overcome these barriers. Furthermore, TB-specific (TB tests and treatment) costs should continue to be fully free of charge, as has been the case in many, but not all, countries.

Few countries have achieved UHC, defined as "the situation where all people are able to use the quality health services that they need and do not suffer financial hardship paying for them". The aim is progressive movement towards UHC.

Such progress can be achieved through adequate, fair and sustainable prepayment financing of health care with full geographical coverage, combined with effective service quality assurance and monitoring and evaluation (15). A well-functioning health system requires building blocks: service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance (stewardship) (16). All countries should aim for rapid progress towards UHC, while ensuring that all essential health systems building blocks are strengthened.

Policies, strategy and systems towards UHC should expand the following:

- Access to the full range of high-quality services recommended in this strategy, as part of general health services;
- Financial coverage, including costs of general (pre-TB diagnosis) consultations and testing, medicines, follow-up tests and all expenditures associated with staying in complete curative or preventive treatment, in the public and private sectors and;
- Access to services for all people in need, especially vulnerable and marginalized groups with least access to services.

Appropriate TB diagnosis, treatment and prevention should be free of charge. This can be achieved within a national health service package or through a national health insurance scheme. Ensuring access and minimizing financial barriers to TB diagnosis and care are not enough. Mechanisms need to be put in place to promote appropriate use of quality-assured medicines and diagnostic technologies, for example by defining packages of TB diagnosis and treatment within health insurance schemes, and linking quality assurance systems to reimbursement.

Major opportunities exist for countries embarking upon or scaling up UHC schemes. In the early stages of design of such schemes, TB care and public health functions should be addressed specifically and contained within essential service packages. Social insurance models that begin with an interest in serving all, especially low-income and other vulnerable populations, are recommended. Furthermore, every effort needs to be made to ensure that populations at high risk for TB are reached early in the roll-out of schemes. In any case, NTPs and their partners should assess likely implications for their services and for key populations affected by TB. This will allow them to address gaps in coverage and ineffective outcomes. To avoid reimbursement of inappropriate or unnecessary services, essential and specific TB service packages with quality standards should be defined. Furthermore, UHC health financing models should carefully address the need to fund public health functions along with clinical services.

In addition to policies for health-care financing and access to high-quality health-care services, several other system-wide regulatory frameworks need to be developed in a TB-sensitive manner. These are outlined below.

Regulation of production, quality and use of TB diagnostics and medicines

Poor-quality TB medicines put patients at great risk. Irrational prescription of treatment regimens leads to poor treatment outcomes and may cause drug resistance. Use of inappropriate diagnostics such as serological tests leads to inaccurate diagnosis. Regulation and adequate resources for enforcement are required for the registration, importation and manufacturing of medical products. Regulation should address how medical products are subsidized and the types of health professional authorized to prescribe or dispense TB medicines. These efforts should be supported by proper information to prescribers and users about rational use, as well as by monitoring of use. Data on drug quality, drug resistance, drug utilization and diagnostic practices can be used to advocate for stricter regulation of medical products.

Mandatory notification of TB cases

Many TB cases are not notified, especially those managed by private care providers or NGOs not linked to NTPs. Under-notification of cases hampers disease surveillance, contact investigation, outbreak management and infection control. As noted earlier, an effectively enforced infectious disease law, or equivalent, that includes compulsory notification of TB cases by all health-care providers, is essential (17).

Improved recording of TB deaths within vital registration

Most countries with a high burden of TB do not have comprehensive vital registration systems, and the quality of information about the number of deaths due to TB is often inadequate. Effective vital registration systems need to be developed or strengthened to ensure that each death due to TB is properly recorded. NTPs are not natural drivers of this process, but can advocate for attention to TB and help monitor the quality of results while larger agendas for building vital registration systems are developed.

Comprehensive infection control measures

Appropriate regulation is required to ensure effective infection control in health-care services and other settings where the risk of disease transmission is high. Managerial, administrative, environmental and personal measures for infection control should be part of infection disease law, and regulations related to construction and organization of health facilities (18). TB-specific strategies for infection control are addressed in Pillar 1, including the example of the FAST approach, but these measures need to be complemented by systemic strengthening of general infection control across health systems. Box 2C.1 summarizes Cambodia's comprehensive approach to TB infection control. WHO has provided guidance on a systemic approach for integrated infection prevention and control (IPC) programmes ("core components for infection prevention and control") (19). NTPs and implementing partners are involved in broader health system and service networks in some, but far from all, countries. Where not engaged, this is a missed opportunity, especially given overall rising interest across health systems on antimicrobial resistance and on health security.

BOX 2C.1 CAMBODIA STEPS UP TB INFECTION CONTROL

TB infection control in Cambodia is an integral part of the National Infection Control Policy of Cambodia (2009). Based on this policy, Cambodia has published many key documents; e.g., National Infection Control Strategic Plan (2011-2015), National Infection Control Guidelines (2010), National Guidelines on Healthcare Waste Management (2011) and TB Infection Control Standard Operating Procedures (2014). These documents provide guidance for the annual operational plans at provincial and district levels for infection control activities. In addition, these documents have helped in designing a video, posters and other materials for TB infection control.

At the national level, the Infection Control Steering Committee has the overall responsibility for approving and ensuring implementation of infection control policies, strategic plans and guidelines, including strengthening capacity building. The National Centre for TB and Leprosy Control, in close collaboration with the Department of Hospital Services and the Department of Communicable Disease Control, is responsible for scaling up TB Infection Control. Other ministries, such as the Ministry of National Defense and the Ministry of Interior, are responsible for TB infection control in facilities that fall under their jurisdiction.

In 2014, the NTP launched a model project for improving TB infection control in five major urban hospitals. The main steps included a baseline assessment, awareness creation and trainings, supplying necessary protective equipment, development of supervisory checklists for quarterly supervisory visits, and progress review workshops. After a year of implementation, the NTP reassessed the status of infection control. Compared with the results from the baseline assessment, the implementing hospitals showed many desired positive changes. The NTP has learned major lessons from this project. This will help it to scale up infection control strongly across the country in the coming years.

Key policy implementation steps

Situation assessment

The current state of health insurance schemes, their coverage and the conditions for reimbursing TB services should be mapped. This will help identify the required policies and steps to optimize access to TB diagnosis and high-quality care, while minimizing perverse incentives for unnecessary, cost-ineffective or harmful tests and treatments. The regulatory environment needs to be assessed with regard to notification of infectious diseases, over-the-counter sales of antibiotics, prescription rights, vital registration and infection control.

Intersectoral dialogue and role division

The pursuit of explicit policies towards UHC and the development and implementation of related regulatory frameworks require the engagement and commitment of many different stakeholders, both within and outside the health sector. The role of NTPs is to ensure that policies are sensitive to the needs of people ill with TB ("TB-sensitive") and coherent with national TB care and prevention policies. This can be achieved through dialogue with key stakeholders and active involvement in the development, monitoring and evaluation of UHC policies and regulatory frameworks. Persons responsible for TB care, prevention and surveillance need to "make the case" for TB, highlighting the crucial importance of equitable access, quality control, rational use of medicines and other processes to the extent possible based on evidence from surveillance data and operational research. If TB programme leaders, affected communities or other stakeholders are not invited to engage in such wider policy and systems discussions, then patient organizations, professional societies and civil society can help make the case for engagement. One of the strongest arguments will be the risks to poor and marginalized populations of failing to enable access for TB care and effective regulatory policies protecting the public in the face of infectious diseases, including TB.

People with TB and their households often face severe economic hardship related to the direct and indirect costs of illness and health care.

Component 2D. Social protection, poverty alleviation and actions on other determinants of TB

Policies and strategies

Relieve financial hardship related to TB

People with TB and their households often face severe economic hardship related to the direct and indirect costs of illness and health care including income loss, health-care costs and transport expenses (20). Adverse social consequences may include

Poverty alleviation reduces the prospect of TB transmission and progression.

stigmatization and social isolation, interruption of studies, loss of employment, or divorce. These negative consequences often extend to the family of persons ill with TB, and indirectly to the wider community, with a negative economic impact on the whole society. Even when TB diagnosis and treatment are offered free of charge, social protection measures are needed to alleviate the burden of income loss and non-medical costs of seeking and staying in care. Social protection should cover the special needs associated with TB through the following policies:

- Schemes for compensating the financial burden associated with illness such as sickness insurance, disability pension, social welfare payments, other cash transfers, travel or food vouchers or food packages;
- Legislation to protect people with TB from such discrimination as expulsion from workplaces, educational or health institutions, transport systems or housing, or deportation and;
- Other instruments to protect and promote human rights, including addressing stigma, with special attention to gender, ethnicity, and protection of vulnerable groups.

As noted in Pillar 1, many NTPs are already collaborating with financing partners and NGOs in providing some form of patient support packages, often funded as short-term projects. Sometimes linkages have been made with national nutrition, insurance, and welfare or social protection bodies, to support patients in mitigating the economic and social consequences of TB. However, the patient support schemes often lack explicit criteria on who can benefit (such as income level or disability), clear management and delivery practices, or regular monitoring and evaluation. Patients and their families may not be well-informed of what is available. Furthermore, mechanisms to help link TB patients to available social services are weak or lacking. Systematic approaches are needed to reach more of those in need of support and to sustain the linkages across programmes. Boxes 2D.1 and 2D.2 provide example of efforts made in Kenya and Moldova to move towards more large-scale sustainable approaches.

Address social determinants and risk factors

Poverty is a powerful determinant of TB. Crowded, polluted and poorly ventilated living and working environments constitute direct risk factors for TB transmission. Undernutrition is an important risk factor for developing active disease. Poverty is also associated with poor general health knowledge and a lack of empowerment to act on that knowledge. This could lead to exposure to several TB risk factors such as HIV, smoking and alcohol abuse. Poverty alleviation reduces the prospect of TB transmission and progression from infection to disease and helps improve access to health services and adherence to recommended treatment. Actions on the determinants of ill health through "health-in-all-policies" approaches will benefit TB care and prevention (21).

The required social, economic and public health policies include those that:

- Pursue overarching poverty reduction strategies and expanded social protection;
- Reduce food insecurity;
- Improve living conditions, including in prisons and other congregate settings;
- Improve environment and working conditions, including reduced exposure to silica and indoor air pollution;
- Address the social, financial, and health situation of migrants and;
- Promote healthy diets and lifestyles, including reduction of smoking and harmful use of alcohol and drugs.

BOX 2D.1 **BUILDING ON EXISTING SOCIAL PROTECTION POLICIES AND SCHEMES IN KENYA**

A new Constitution was adopted in Kenya in 2010 that guarantees social protection measures. In 2012, the Government of Kenya issued a new Social Protection Policy, and in 2014 created a National Social Protection Secretariat in its Ministry of Labour. A national conference on the theme was held in 2015 and a cash-transfer system for specific groups is being expanded. This momentum is also evident in the health sector. The Health Sector Strategy 2014-2018 explicitly addresses social protection, including movement in removing financial barriers to health services. Also in 2015 the National TB and Leprosy Programme, aligning with these efforts and the End TB Strategy, finalized its next strategic plan, including actions to reduce the financial burden of TB care and the burden beyond medical costs, such as transport, lost income and nutritional needs. This work builds on underlying mapping and analysis of different forms of social support currently provided to some drug-sensitive TB patients, those determined to be moderately or severely malnourished, and drug-resistant TB patients. Current support is provided through the national nutrition programme, World Food Programme (WFP), and a grant from The Global Fund. Three innovations are underway to advance social protection for those affected by TB: (a) formulating a proposal to support households affected by TB and leprosy through the cash transfer programme, given underlying disability and vulnerability; (b) linking the TB data system and the single registry system of the National Social Protection Secretariat (NSPS), to ease application of wealth-related eligibility criteria in line with other social protection schemes; and (c) additional links with the WFP system and hotline to further enable patient-responsive support.

Source: WHO-supported case study on expanding social protection for TB and leprosy patients, Hanson C et.al., 2016 – in process of publication.

Key implementation steps

Interdisciplinary situation assessment

The first essential step is to conduct a situation assessment of the key socioeconomic drivers of TB. The importance of direct TB risk factors (which are linked to socioeconomic determinants) at population level also needs to be mapped out, including HIV, undernutrition, diabetes, smoking, drug and alcohol abuse, crowded living conditions, silica exposure in workplaces, indoor air pollution and other factors. This should reveal the key determinants for improvement of TB prevention on population level, which entry points exist for intervention, and which stakeholders need to be responsible and accountable for pursuing these interventions, within and beyond the health sector.

The situation assessment should also document social and financial consequences for TB-affected households, as well as major costs (such as direct health-care costs, cost of transport and food during travel to health services, income loss, cost of coping mechanisms such as removing children from school, selling household items or taking out a loan).

The assessment should be coupled with an analysis of existing financial risk protection mechanisms already built into the health system. These could include free or subsidized diagnosis and treatment, decentralization of services, streamlined diagnostic procedures, minimization of unnecessary hospitalization or patient-friendly case management. It should also include a country's existing general social protection schemes in such areas as sickness insurance, disability pension, social welfare payments or other cash transfers. Strengths, weaknesses and opportunities to reduce costs and improve social protection should be explored. In particular, existing national or local schemes for such processes as conditional or unconditional cash transfer, income replacement in times of sickness or travel and food support during sickness need to be well understood to make these schemes sensitive and responsive to the needs of TB-affected households or to develop complementary TB-specific social protection schemes.

Existing schemes that provide TB patients with access to support should be further documented and evaluated. Schemes may have been informally organized, without clear objectives, beneficiary definition, management systems and related monitoring and evaluation.

Fundamentally, this planning and review process requires consultation with patients and affected families to ensure their own views on social protection needs and the most client-friendly approaches to providing for them are addressed. Lessons should be learned from other public health programmes that might already have strong social protection links. In some countries, these include HIV/AIDS and maternal and child health programmes.

BOX 2D.2 **EVOLUTION OF SOCIAL SUPPORT FOR TB PATIENTS IN THE REPUBLIC OF MOLDOVA**

The Republic of Moldova is a small European country of 3.5 million people. It is among the 27 countries with a high burden of MDR-TB, and is also among the poorest countries in Europe. Provision of social support to TB patients, including MDR-TB patients, has been a core element of treatment and care. The National TB Institute in the Ministry of Health collaborates with an outside NGO partner to provide social support to TB patients through a range of district and municipal services, and an increasing number of community centres and NGOs. The Ministry is moving towards providing outpatient treatment for TB care.

Social and financial support are provided in collaboration with various institutions including the National Office of Social Insurance. A recent study suggested significant improvement in outcomes when financial support was provided to drug-susceptible TB patients: an increase from 79% to 88% in treatment success rates; decline in loss to follow-up (10% to 5%); and decline in treatment failure (5% to 2%). Food provisions and food vouchers to TB patients are being replaced by e-transfers to patients' bank accounts to help cover transport, food and other expenses. They are financed by the National Insurance Company as well as through The Global Fund. Psychosocial support systems also exist. In 2014, the National Health Insurance Company expanded its operations and now supports 50% of all TB patients (50 Euros per patients per month). The Global Fund grant supports the other 50% of TB patients and 75% of MDR-TB patients, enabling progress towards a nationally sustainable model.

Source: Seicas R, Severin L. Social Protection of TB patients in Moldova (presentation at WHO consultation).

Assessing the determinants and social consequences of TB and identifying appropriate interventions is linked to overall mapping of the TB epidemic ("know your epidemic" approaches). It requires a combined analysis of surveillance data (for example, geographical distribution of TB in relation to poverty maps), epidemiological research and social science approaches and policy and financing reviews. An interdisciplinary, multisectoral approach is needed, with broad engagement of stakeholders within and outside the health sector, including affected communities and researchers.

Intersectoral policy dialogue

The NTP should invest the necessary time in intersectoral policy dialogue and identify and take advantage of opportunities for policy change by tracking development processes and mapping key counterparts in other sectors.

Most actions on social determinants and consequences of TB hinge on policies developed outside the health sector. Non-health sector stakeholders – such as ministries of social welfare, finance, education, labour or the interior – have a clearer mandate to formulate and take action on social determinants. Nongovernmental actors, including the private sector and civil society should also be engaged in the policy dialogue, as should UN agencies and other major development organizations and mechanisms at country level.

The health sector plays a key role in identifying and communicating the potential health impact of policies on food security, improved housing, poverty reduction, employment protection, human rights protection for migrants and prisoners and other often marginalized groups. The NTP plays a similar role in communicating the importance of public health policies shaped outside the domain of infectious disease control, such as those addressing smoking, alcohol abuse or inappropriate diet.

In order to progress towards the End TB Strategy target that "no TB-affected family should experience catastrophic costs due to TB", an effective policy dialogue is needed with relevant ministries, government agencies and nongovernmental entities with a mandate to enable progress on securing income security in times of sickness. Moreover, it is essential to engage with the labour sector. Trade unions and employer organizations can be approached to develop TB-sensitive strategies for workers' health and safety protection in line with the international conventions defining TB as an occupational disease (22).

Available social protection schemes vary greatly across countries, as will the starting point for a policy dialogue. High-income countries normally have near-universal schemes. Many middle-income countries are expanding their schemes from the formal labour sector to the informal sector, whereas most low-income countries have rudimentary schemes that often cover only pilot populations. Still, there is new momentum on social protection policy and programmes in more low-income settings, along with additional opportunities for linking TB and social services.

It is essential for NTPs to further assess their current systems of social support, as seen in the examples on the Kenyan and Moldovan experiences. The aim needs to be to ensure effective systems that are well-designed and managed, with information made available to patients, their families and health providers. If schemes are TB-specific and externally funded, every effort should be applied to make a transition to sustainable domestic social protection schemes (for example social welfare, disability and other social protection platforms targeting low-income populations) that are expanding in many settings. Documentation of the economic costs of TB for patients and affected families can provide required evidence to support inter-ministerial discussion, decisions and their implementation.

Capacity strengthening

The central management unit of an NTP should have the capacity to collect and analyse surveillance data and conduct ad-hoc operational research that identifies relevant determinants and social consequences of TB. Where there is no such capacity, the NTP should develop links with other capable partners, such as academia. Capacity building is also needed for effective cross-sectoral communication on TB risk factors and determinants.

For optimal financial risk protection for TB-affected households, health workers managing TB need to be aware of available social protection schemes and their eligibility criteria. They should also have a strong grasp of the administrative procedures involved in accessing social protection schemes, in particular the responsibility of health-care workers to issue certificates of disability, mandated work absence for infection control, or support documentation for other entitlements. Similarly, social sector employees need to be trained in the rights and conditions for people with TB to access such schemes. Proper documentation on the use of social protection schemes is needed for both the health sector and the social sector. Nongovernmental and community-based partners may be of critical help in facilitating liaison between services, especially when health workers are over-stretched in many low-income settings.

Capacity building is also needed for affected communities to be able to express their needs and protect their rights, and to ensure accountability for human rights violations. Such capacity building can also enable communities to become directly involved in the design, implementation and monitoring of new programmes and schemes aiming to enhance social protection, and eliminate poverty and social exclusion. Experiences from other programmes, such as HIV/AIDS, in such engagement can be path-finding in many settings.

Monitoring implementation

As outlined above, many of the required social interventions be implemented by stakeholders other than the NTP. The intersectoral policy dialogue should produce a clear role division with assignment of tasks to different government sectors, and should seek contributions from nongovernmental and civil society organizations.

The NSP should clearly outline the actions required by the central management team (synthesis of data on social determinants and consequences of TB; policy dialogue and interagency collaboration; monitoring) and health workers responsible for TB diagnosis and treatment or partners to help patients navigate existing social protection schemes, and issue medical certificates and documentation. Information about eligibility and use of social protection should be included in TB treatment cards and registers, the format and routines of which need to be adapted to local conditions. Further operational guidance is in preparation, based on experiences in a range of countries. Appropriate indicators and targets for implementation need to be defined locally, in line with the NSP objectives. Research will also be essential to further document and assess the progress of UHC policies and regulatory practices, the results of social support schemes on treatment outcomes and economic security, and the impact of social development policies on reducing TB risk factors for specific populations and communities.

EXAMPLES OF INDICATORS TO MONITOR END TB STRATEGY IMPLEMENTATION: PILLAR 2

INDICATOR	REQUIREMENTS FOR MEASUREMENT
PROPORTION OF ANNUAL BUDGET DEFINED IN TB NATIONAL STRATEGIC PLANS THAT IS FUNDED (%)	Budget data and data on available sources of funding
CASE REPORTING COVERAGE (%) Proportion of detected TB cases that were reported to national health authorities	An inventory study that measures the level of under-reporting is required. Inventory studies require a case-based electronic reporting system to be in place or the establishment of such a system, to allow cross-checking of cases detected by all care providers with those notified to national authorities. It is not expected that inventory study would be implemented every year.
PROPORTION OF TOTAL TB NOTIFICATIONS COMING FROM COMMUNITY REFERRALS (%) Percentage of notified TB patients (all forms) who were referred by CHWs or CVs	Core indicator in countries with integrated community-based TB prevention and care activities. Routine data collection requires information on 'referral by CHW or CV' in basic management unit TB register and in all quarterly report formats to the national level. Indicator refers to activities by CHWs or CVs supported by NTP, NGOs and other CSOs
TREATMENT SUCCESS OF TB PATIENTS WHO RECEIVED COMMUNITY-BASED TREATMENT SUPPORT (%) TB patients (all forms) who were successfully treated (cured plus completed treatment) who received support for treatment adherence by CHWs or CVs	Core indicator in countries with integrated community-based TB prevention and care activities. Routine data collection requires information on 'treatment support by CHW or CV' in basic management unit TB register and in all quarterly report formats to the national level. Indicator refers to activities by CHWs or CVs supported by NTP, NGOs and other CSOs
HEALTH INSURANCE COVERAGE Percentage of population covered by health insurance (or equivalent)	Surveys or routine data. Clear definitions of the types of services that are covered, and to what extent the full service cost is covered, are needed
PUBLIC HEALTH SPENDING PER CAPITA (US$)	National health account data produced according to the system of health accounts (SHA)
PERCENTAGE OF TOTAL HEALTH EXPENDITURES (THE) ACCOUNTED FOR BY OUT-OF-POCKET (OOP) EXPENDITURES	National health account data produced according to the system of health accounts (SHA). Along with adequate public health spending per capita, it has been suggested that OOPs need to be 15% of THE for UHC to be considered in place
PERCENTAGE OF TB PATIENTS AND THEIR 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	Special surveys are required

INDICATOR	REQUIREMENTS FOR MEASUREMENT
CASE NOTIFICATION IS MANDATED BY LAW (YES/NO)	Review of relevant laws
VITAL REGISTRATION (VR) SYSTEM IN PLACE THAT MEETS INTERNATIONAL STANDARDS OF COVERAGE AND QUALITY (YES/NO)	There are standard methods for evaluating the coverage and quality of cause of death VR data
PERCENTAGE OF PEOPLE WITH TB WHO RECEIVE APPROPRIATE SOCIAL PROTECTION	Surveys or routine data; "appropriate" needs to be clearly defined according to the country setting. Can also be measured through assessment of the indicator on catastrophic costs
PERCENTAGE OF POPULATION ADEQUATELY NOURISHED	Routine assessment is done by the Food and Agricultural Organization and the World Food Programme

Nelly Cuéllar from El Buen Pastor women's prison in Colombia thanks Claudia Jeréz, a health technician who motivated and helped Nelly complete her TB treatment successfully.

PILLAR 3: KEY COMPONENTS

A. Discovery, development and rapid uptake of new tools, interventions and strategies

B. Research to optimize implementation and impac, and promote innovations

PART III - PILLAR 3

Intensified research and innovation

KEY MESSAGES

- In order to end the TB epidemic, new diagnostics, drugs, vaccines and innovative ways of delivering them are necessary. Countries that carry a moderate or high burden of TB can play a critical role in stimulating and pursuing research along with high-income, low TB-burden countries.
- A coherent national TB research plan that includes a country-specific prioritized research agenda across a continuum from basic to operational research is a core requirement for the development of TB research capacity in countries with moderate or high TB burden.
- Mechanisms should be in place to allow for effective collaboration among the various research and health institutions, the national TB programme and other public health programmes, ideally through the establishment of a national TB research network.
- National TB research networks should establish links with recognized international stakeholders, including scientists, research institutions, other research networks and donors.
- Sustained public investments are the key to developing infrastructure and capacity for TB research.

Introduction

As indicated in Part II, ending the TB epidemic will require newer and better tools to detect, treat or prevent TB in addition to optimizing the use of currently available tools. There is an urgent need to galvanize research and innovation to achieve both. This calls for intensifying global and national investments in research and creating an enabling environment for the current and next generation of scientists, especially in countries with a high TB burden.

To facilitate effective implementation of Pillar 3, WHO and partners have developed a Global Action Framework (GAF) for TB Research for 2016-2025 (3). While the GAF addresses research required at both the global and national levels, this section covers country-level implementation of Pillar 3, which has two closely interlinked components: 3A deals with discovery, development and rapid uptake of new tools, interventions and strategies and 3B examines research to optimize implementation and impact and to promote innovations.

Component 3A. Discovery, development and rapid uptake of new tools, interventions and strategies

This component covers all types of research along the continuum, from basic research through clinical and epidemiologic research to implementation research (1) (Box 3A.1). Many middle-income and some low-income countries have the capacity to engage in the full spectrum of research. They can strengthen that capacity by collaborating with researchers and institutions in high-income countries. Global priorities for research on new tools have been identified (Box 3A.2) and estimates for the required research investments over the next five years are presented in the Global Plan to Stop TB 2016-2020 (4).

Component 3B. Research to optimize implementation and impact and promote innovation

This component tackles innovative strategies designed to improve programme implementation and the impact of interventions in all countries. This critical research would help understand the challenges facing care delivery and would lead to improved policies, better design of health systems and more efficient methods of service delivery (2). Evidence from this research could multiply the benefits of existing and new control strategies and is essential if the 2035 targets are to be met. Operational research does not require major investment in higher education of personnel, equipment and facilities, and will have a more rapid impact (2).

To ensure TB becomes a research priority in high-burden countries, each country should develop a comprehensive national TB research plan, fully integrated into the NSP. It should include objectives, activities and mechanisms to strengthen country-level research capacity. Box 3B.1 lists the steps to implement Pillar 3 at the country level, which are elaborated on pages 104-105.

BOX 3A.1 THE SPECTRUM OF RESEARCH

FUNDAMENTAL SCIENCE

Basic/fundamental research:
investigation of the characteristics of the germ and analysis of the host-pathogen interaction to decipher the basic mechanisms of transmission, infection, latency and disease, including response to therapy and to vaccination. This includes disciplines such as molecular biology, immunology and biochemistry.

TRANSLATIONAL STUDIES

Clinical and translational research:
assessment of the safety, efficacy and validity of new interventions or approaches (algorithms) in patient populations. This includes research on new diagnostics, new drugs or regimens and vaccines (Phase 1 to 3 randomized trials).

PRECLINICAL STUDIES

Operational and implementation research:
research into strategies, interventions, tools or knowledge which can improve programme performance and/or health care delivery. It is generally the simplest, quickest and least costly research methodology. This research examines the conditions, requirements and barriers to implementation, as well as interventions to enhance the use of new or existing tools and strategies by patients and health systems. It also contributes to documenting the safety profile of new interventions (drug, regimens, vaccines) during routine use in large populations. To be successful, this type of research requires identifying clear questions that are amenable to study, have a direct impact on major policy and implementation issues, and can be answered by low-cost research methods

CLINICAL STUDIES/TRIALS

Epidemiologic research:
examination of the natural course of TB infection and disease and the various determinants and consequences of TB. This includes analysis of surveillance and population-level data (such as prevalence surveys or drug resistance surveys), as well as personal, medical and social determinants of TB transmission, infection, progression to active disease, drug resistance, and disease outcomes. This also includes studies to estimate the socioeconomic consequences of TB for the individual, households and society

DEPLOYMENT AND SCALE-UP IMPLEMENTATION / OPERATIONAL RESEARCH

Policy, health and social system research:
investigation of the interplay of social, population and personal factors that affect health-seeking behaviours, and wider health systems organization and dynamics. This research also investigates the effectiveness of policy and regulatory interventions on TB prevention and care, particularly the means to ensure UHC, through social protection and actions on the social determinants of health.

BOX 3A.2 GLOBAL PRIORITIES FOR RESEARCH IN NEW TOOLS

Research for new diagnostics: priorities include the development of an accurate and rapid point-of-care test for drug-susceptible and drug-resistant TB, as well as LTBI, the technology transfer needed to take new tests from proof-of-concept to manufacturing scale-up, and the transformation of sophisticated laboratory and digital technologies into robust point-of-care platforms which will make TB diagnosis more accurate, affordable and widely available for patients and care providers.

Research for development of new drugs and regimens: the pipeline of new anti-TB drugs has expanded substantially over the last decade, with a series of new molecules currently in clinical trials (Phases 1 to 3). However, due to high attrition rates, further new compounds are needed, and trials must be conducted to investigate new combinations of drugs for shorter and simplified treatment of drug-susceptible, drug-resistant TB, and LTBI. Investments are required to expand the drugs pipeline, facilitate the transition of promising new compounds from the pre-clinical to the clinical stages of development, and build the necessary capacity to conduct large clinical trials for the evaluation of short regimens using novel trial designs in low and middle-income countries with high TB incidence.

Research for new vaccines has resulted in a number of vaccine candidates currently in various stages of clinical development. Most are designed for the prevention of infection or of progression to disease in latently infected persons. In the absence of known immune correlates for protective immunity against disease or infection, the portfolio must be further diversified to allow candidates to explore additional potential immunological routes for prevention. There should be greater emphasis on early experimental trials to address basic questions about TB immune responses and vaccine delivery methods as well as to evaluate different efficacy endpoints. In terms of clinical research, investments are needed also needed to prepare for the conduct of large population-based vaccine trials in high TB endemic countries.

BOX 3B.1 KEY STEPS IN DEVELOPING AND IMPLEMENTING A NATIONAL TB RESEARCH PLAN

Establish mechanisms for collaboration between all stakeholders at national and international levels: the development of a national TB research network

Develop country-specific TB research priorities based on the current TB epidemic, an assessment of the national health system and research capacity, and an understanding of what is needed to achieve the WHO End TB Strategy targets by 2030/2035

Plan for relevant training and sustainable capacity building, including researchers and research careers development from an early stage

Developing and implementing a national TB research plan

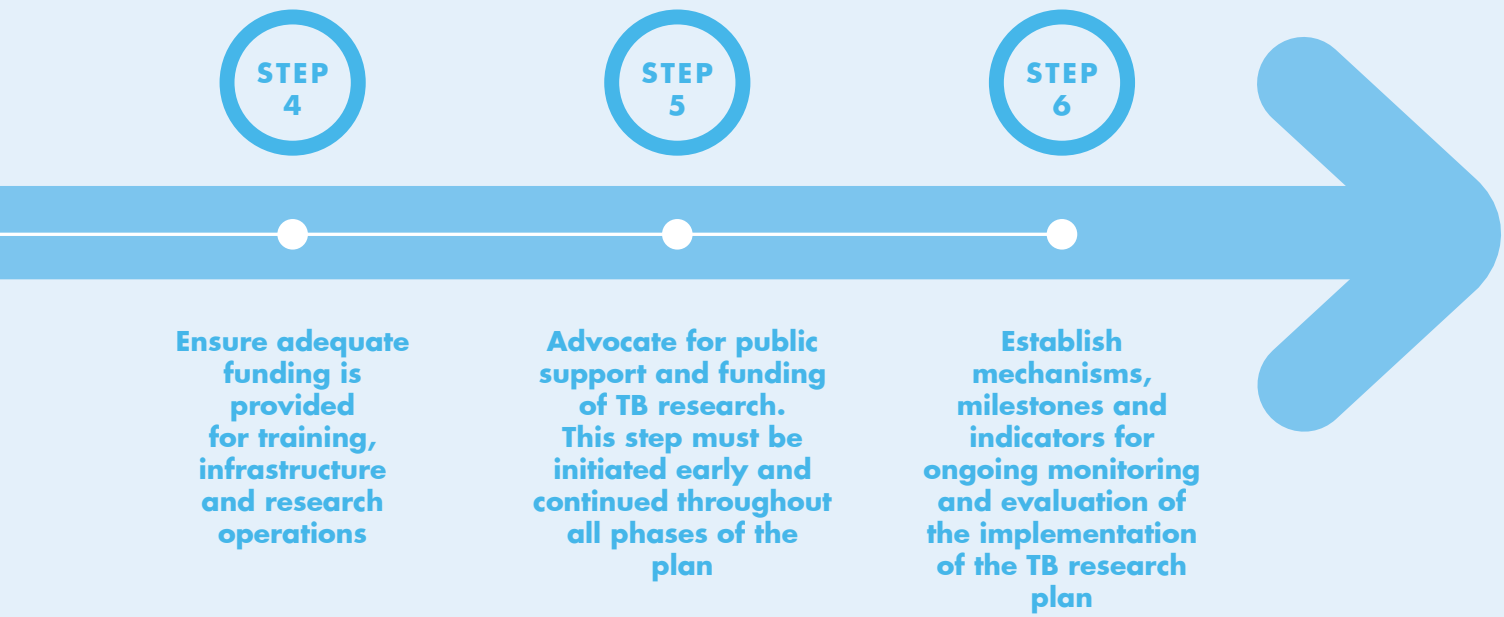
1. Establish a national TB research network

Establishing or strengthening a national TB research network is an important early step in coordinating and using often scarce resources. This network would be a partnership between public sectors in which health practitioners and researchers from government agencies, particularly the NTP[a] of the Ministry of Health, would collaborate closely with TB researchers from various disciplines at national universities, research institutions and associations. In certain countries collaboration could extend to other government agencies or ministries, such as the Ministry of Science and Technology. Research beneficiaries should be included in any collaborative effort, along with community groups, civil society, the private sector and international experts. The network could help build an inventory of relevant research and researchers and also help formulate the national TB research agenda and priorities. Box 3B.2 gives an example of a TB research network in Brazil (2).

2. Establish national TB research priorities

A priority list of the country's most important research questions should be a cornerstone of any TB research plan. Priorities would be based on a thorough understanding of the current TB epidemic, the research most needed to achieve the End TB targets, and an inventory of existing TB research capacity at country level. The national TB research network would establish these priorities in alignment with broader national health research strategies. While working at their own pace, countries could follow the framework below.

a. It is suggested that each NTP designates a TB research focal point, preferably with a background in research. Domestic research institutions would similarly designate one of their researchers (ideally with a clinical or public health background) to be the TB focal point so as to encourage ongoing dialogue and exchange.



2.1 Situation assessment

A baseline assessment of a country's TB epidemic and TB research capacity would help identify required research and opportunities while addressing potential bottlenecks. It should include the following (a checklist for a country situation assessment is provided in the Annex):

2.1.1 Description of the TB epidemic at country level

This is based on estimated incidence, prevalence, case detection and mortality, as well as TB case notification and treatment outcomes by type of TB (drug-susceptible, MDR-TB, TB/HIV) and age/sex. These data are generally provided by ministerial authorities for the WHO Global TB Report (3) and are available in individual TB country profiles in WHO's global TB database[b]. Available data should also be reviewed on subnational geographical distribution, particular situations (such as transmission 'hot-spots') or vulnerable groups (migrants, refugees, prisoners, indigenous populations). Important additional data can also be gathered from national or subnational prevalence or drug resistance surveys and surveys on TB/HIV co-infection, as well as other determinants of the TB epidemic (such as smoking, malnutrition, diabetes)[c].

2.1.2 The broader health context

This is a description of the broader health context, including structure and financing of the national health system and national health research, along with strengths and weaknesses. Lessons learned from research and priority setting in other health or disease research areas could be applied (good practices in priority setting are reviewed in the WHO World Health Report 2013) (4,5,6).

2.1.3 The inventory of TB research capacity

The inventory of TB research includes existing capacity (human resources, physical infrastructure and operations). Since a thorough inventory can be time-consuming and information rapidly outdated, its rationale, objectives, planned use and level of detail should be agreed by all stakeholders. The inventory should include the following:

- Mapping of institutions involved in TB-related research

  These could include key government agencies, public or private research entities and NGOs, as well as international institutions with significant involvement in the country. Ideally strengths and weaknesses would be listed, along with any recent TB-related publications. The mapping exercise should also describe physical infrastructure and equipment, available human resources (with detail on type of training or positions), and the NTP's current engagement in research.

- TB-related research training

  Information should be gathered on planned or existing training courses, funding for trainees, institutions providing training and links with international training courses. Information is also needed on type of training (fundamental, epidemiologic, clinical, laboratory, health system, social sciences, or operational research) and level of training (undergraduate, Master's, PhD or Post-Doctoral).

- TB-related research funding

  National funding sources should be identified from public (national, provincial or state governments) and private entities (industry, philanthropic institutions or NGOs). External sources such as international agencies, bilateral agencies, industry or philanthropic donors should also be listed, along with potential partnerships with international investigators (for example from multicentre studies).

- Research ethics

  The current research ethics review process and capacity within the country needs to be carefully documented as a prerequisite for any in-country research activities.

b. See http://www.who.int/tb/country/data/profiles/en/.

c. Guidelines for surveillance of drug resistance in tuberculosis. 5th ed., Geneva, World Health Organization (in press), 2015. (See also http://www.who.int/tb/challenges/mdr/surveillance/en/).

BOX 3B.2 THE BRAZILIAN TB RESEARCH NETWORK (REDE-TB)

Before 2001, Brazil had substantial research capacity but very little cooperation and no coordination between industry, universities, the various research institutes, and health services including the NTP. In 2001 the Ministry of Science and Technology launched a call for applications to promote the creation of research networks in all areas. The TB network was funded, which led to the creation of REDE-TB. REDE-TB is a multi/interdisciplinary group of researchers and students from Health Sciences, Engineering and Education, with civil society partners and health service representatives from all levels of TB and AIDS (federal, state and municipal). The main objective of REDE-TB is to promote research and educational activities in an integrated manner to contribute to TB and TB/HIV control. REDE-TB researchers were invited by the Ministry of Science and Technology and the Ministry of Health to help define a National TB Research Agenda in 2004, 2007 and 2010. Research topics were identified by REDE-TB researchers, TB and AIDS programme coordinators, representatives from the Oswaldo Cruz Foundation (Fiocruz) and civil society. In 2004, REDE-TB initiated a project for research training with NIH funding. The creation of REDE-TB helped build bridges between university-based researchers, the public health system (particularly the NTP), industry and civil society. The university-based researchers helped produce scientific knowledge that responds to local demands, through operational and health system research approaches. The network helped the NTP by conducting studies of strategic importance to the NTP, and through expert guidance committees on specific technical issues (such as diagnosis and treatment of LTBI).

Source: REDE-TB - www.redetb.org.br.

2.2 Developing TB research priorities

After the situation assessment, the national TB research network should develop a list of research priorities (Box 3B.3) in close collaboration with the NTP and key stakeholders, including those best-placed to address both national and global TB within the context of the End TB Strategy.

Priorities should respect three key principles. They should be tailored to the country's needs and capacity; include the full continuum of research in that country, from fundamental to operational; and capitalize on the country's assets.

The priority list should be realistic. Instead of a long 'shopping list' reflecting every stakeholder's interests, a few should be selected to tightly focus efforts and resources, improving the likelihood of success. Priorities should be established for the next five years and a process outlined for review and revision.

3. Plan for research training and capacity building

Implementing the research pillar requires strong and self-sustained TB research capacity within countries, while taking advantage of necessary international funding and training.

3.1 Health research training

National needs for high-quality researchers should be met and graduate training (MSc, PhD) made available in operational, clinical, epidemiological, social sciences, health system and bio-statistical research methods. While most degree-granting programmes are for general health research, supervision of students involved in TB research should be encouraged.

Training should align with national research priorities and trainees and their national universities should receive adequate support (Box 3B.4). The government's role should be clear, and collaboration developed with the private sector and civil society groups. Countries should also investigate international and regional training and funding opportunities.

BOX 3B.3 THE TUBERCULOSIS RESEARCH ADVISORY COMMITTEE (TRAC) IN ETHIOPIA

Background: In 2001, the TB and Leprosy Control Team (TLCT) of the Federal Ministry of Health organized a landmark TB Research Workshop (with support from TDR/WHO and the Ethiopian Science and Technology Commission) during which TRAC was appointed to conduct research within the country, based on national priorities and needs. TRAC is a voluntary network of NTP and other relevant MOH departments, public research institutions, major national universities, professional associations and other key TB stakeholders. It is a core technical advisory body to the NTP, and sets TB research priorities and builds national capacity to conduct TB research. Over the last 14 years TRAC has been actively engaged in the promotion, conduct and dissemination of operational research in TB control and has been a forum for dialogue and interaction between researchers and NTP staff in Ethiopia. The NTP acts as the Secretariat for TRAC, while the chairperson rotates each year among member institutions.

Objectives: 1) Define national TB research priorities; 2) Create a conducive environment for TB research; 3) Review current status and problems of operational and other forms of TB research in the country; 4) Recommend effective and efficient mechanisms for coordination, management, and evaluation of TB research, as well as dissemination and uptake of results; 5) Identify potential TB research funding institutions or organizations; 6) Identify needs for capacity building to facilitate TB research in Ethiopia; 7) Promote TB research and innovation at all levels of the health system.

Activities: TRAC has organized annual research conferences for the past 10 years during which the number of participants and papers presented has significantly increased. Consultations and side meetings are held on selected thematic areas of national implication for programmatic design and scale-up of services, and a list of priority research projects are discussed and endorsed by all conference participants. To date, TRAC has organized 12 rounds of operational research methodology training for 240 experts working at all levels of the health system from across the country. TRAC has also provided operational research training courses and developed an operational research grant mechanism to provide funding for researchers from public institutes and universities and health-care delivery systems working collaboratively. As part of ongoing monitoring and evaluation, TRAC, in collaboration with the NTP, has initiated mapping and review of TB operational research activities and publications in Ethiopia.

3.2 Recruitment and retention of TB researchers

Sustaining TB research requires retaining a critical number of TB researchers and securing their long-term salary, infrastructure needs and funding support from stable national public funds.

3.3 Formal linkages to enhance career opportunities, mentoring and collaboration

Formal collaboration among TB researchers, training institutions, NTPs and international research and training universities can strengthen research capacity. Nationally this type of collaboration can stimulate interest in TB research, enhance its quality by making it more relevant to policy-making, and facilitate the entry of programme personnel into research training, helping trainees in their field work and knowledge translation activities. Links with international universities and institutions could provide mentoring opportunities, reinforcing research and training skills among national faculty and graduate students (Box 3B.5). For example, in Ethiopia a researcher is paired with an NTP staff member from planning through implementation of the research process.

BOX 3B.4 NATIONALLY FUNDED RESEARCH CAPACITY BUILDING: SCIENCE WITHOUT BORDERS, A BRAZILIAN PROGRAMME FOR ACADEMIC MOBILITY

Particular challenges for Brazilian science include the need to increase the number of PhDs, strengthen interaction between academia and industry, promote international collaboration, and increase the number of discoveries leading to patents. To address these challenges, the Government of Brazil introduced the Science without Borders programme in September 2011.[4] Its main goals were to increase the presence of students and scientists in international institutions, encourage young talents and highly qualified researchers from abroad to come work in Brazil, and increase the international focus of universities. In its first four years, the programme would provide scholarships to 100 000 Brazilian students for academic studies and research. By September 2014 over 70 000 scholarships had been awarded. In July 2014, the President of Brazil renewed the programme, funding an additional 100 000 positions for 2015-19. In the first four years, 64 000 undergraduate students and 15 000 doctoral students received scholarships to attend international institutions for up to one year. Funds were also provided for an additional 4 500 students for full doctorates abroad, 6440 for post-doctoral studies and 7 060 for technological development and innovation studies. The programme also funded 2 000 young talents and 2 000 visiting scientists from international institutions to work in Brazil. It provides training in 17 areas with the greatest number of awards in Engineering and Technology (46% of positions), followed by Health and Biomedical Sciences with 17% of scholarships. The USA is the preferred destination, with 29% of students, followed by the United Kingdom (13%) and Canada (9%).

4. See http://www.cienciasemfronteiras.gov.br/web/csf-eng/.

BOX 3B.5 INTERNATIONALLY FUNDED RESEARCH TRAINING: THE STRUCTURED OPERATIONAL RESEARCH AND TRAINING INITIATIVE (SORT IT)

Launched in 2012, SORT IT supports countries to: 1) Conduct operational research that addresses their priorities; 2) Develop adequate and sustainable operational research capacity in public health programmes; 3) Increase organizational acceptance of operational research and use of research results to improve programme performance.

This global initiative, led by the Tropical Disease Research (TDR) Programme at WHO, supports operational research in TB, as well as a range of other public health programmes including HIV, malaria and neglected tropical diseases. A number of donors actively support SORT IT including DFID, USAID and the Bill & Melinda Gates Foundation. Implementation of SORT IT activities relies upon a strong international partnership of other organizations with experience in operational research, research capacity-building and knowledge management. These include the International Union Against Tuberculosis and Lung Diseases (The Union), Médecins sans Frontières (MSF), KNCV, the US Centers for Disease Control, the Evidence into Policy Network (EVIPNet) and a number of academic institutions. SORT IT partners work closely with ministries of health and the WHO regional and country offices to implement multi-phase SORT IT programmes. These phases include: research prioritization and planning of capacity building; conduct of prioritized operational research by health-care workers in the context of a one-year modular training and mentorship programme; publication of research and dissemination of research findings; active engagement with stakeholders to promote translation of research into policy and practice; supporting further operational research by trained health-care workers through small grants; and building leadership through SORT IT operational research fellowships that can lead to higher degrees. As of mid-2015 more than 300 health-care workers in over 75 countries had received training, conducted operational research and participated in other SORT IT activities.

4. Ensure adequate operating funding for research

A successful TB research programme requires sustained national funding for a range of research efforts, demonstrating a country's commitment and helping attract investment (Box 3B.6) from abroad, for example through participation in multicentre studies and trials (Box 3B.7). Some countries will have greater capacity to invest in the full spectrum of TB research; others with fewer resources may focus on such areas as clinical, epidemiological and operational research.

Much national funding for TB research should go towards the research priorities identified in the national research agendas. However, there must be some flexibility to allow for novel, investigator-initiated ideas emerging from new research findings and directions. Funding should support capacity building (such as training and mentoring), salaries, infrastructure, maintenance of networks or consortia, and direct research costs such as staff, supplies, services and equipment, as well as dissemination of results. Many high-income countries with publicly funded health research successfully apply an open and transparent competitive process for time-limited grants, with external judging by peer-review committees.

BOX 3B.6 INNOVATIVE FUNDING MECHANISMS: SOUTH AFRICAN MEDICAL RESEARCH COUNCIL; STRATEGIC HEALTH INNOVATION PARTNERSHIPS (SHIP)

Driven by a pressing need to develop new or improved health interventions to address South Africa's major health problems, the South African Medical Research Council launched Strategic Health Innovation Partnerships (SHIP) in 2013. SHIP utilizes funding from the South African Government to leverage international funding. Funds from both these sources support the National Biotechnology Strategy, which fosters research and innovation. The primary objectives of SHIP are to:

1. Seek, fund, and manage product research development from discovery to proof-of-concept;
2. Enhance the South African research capacity for development of novel or improved drugs, vaccines and other biologicals, diagnostics and medical devices – for priority diseases;
3. Facilitate, through partnerships with local universities, science councils and the private sector, the transfer of research outputs from the laboratory to the marketplace, resulting in improved health outcomes or social benefits.

In just over 18 months, this new initiative attracted US$ 70 million in international funding from the Gates Foundation, Wellcome Trust, Grand Challenges, Newton Fund and private sector donors. One example is a fund to which SAMRC committed R30 million over three years and which will be matched by funds from the UK Medical Research Council and GlaxoSmithKline, as part of a broader collaboration for scientific research between the UK and South Africa. Currently 45 projects are funded, ranging from vaccine discovery to drugs and diagnostics and health systems strengthening in TB, HIV, malaria and maternal and child health.

5. Advocate for public support and funding of TB research

Advocacy can help stimulate investment in TB research and broader R&D funding on TB by effectively engaging public and private donors, the scientific community, NTPs and civil society. Advocacy can strengthen the government's commitment to funding TB research and enhance community engagement in research by promoting community involvement in areas such as clinical trials. Advocacy is essential and must be initiated early and maintained throughout all phases of the national plan for TB research. It can be very usefully promoted by all stakeholders including national NGOs (Box 3B.8).

BOX 3B.7 PUBLICLY FUNDED COLLABORATION BETWEEN RESEARCHERS IN HIGH INCOME AND IN LOW-MIDDLE INCOME COUNTRIES: RePORT INTERNATIONAL

The National Institute of Allergy and Infectious Diseases (NIAID) of the US National Institutes of Health (NIH) has long recognized the need for TB research collaboration and coordination, as prioritized in the International Roadmap for TB Research. Partially in response to this need, NIAID and collaborating biomedical research entities in Brazil, India, Indonesia and South Africa initiated RePORT (Regional Prospective Observational Research in Tuberculosis) International.

The objective of RePORT International is to provide a platform for coordinated TB research by establishing a common set of standards and definitions, harmonized observational cohorts with well-characterized populations, consolidated bio-specimen banks, and integrated data collection and analysis strategies. A common protocol with corresponding clinical research forms, a manual of operations, data definitions and other pertinent standards have been developed. These documents and the study designs developed by RePORT International may eventually serve as templates for global collaborative TB clinical research. It is envisioned that each participating country will support local research teams to develop RePORT cohorts, which will be available for clinical studies to address questions of local, regional and international importance. Investigators are encouraged to work with colleagues developing national RePORT networks in other countries to undertake jointly-developed common protocols, using the cooperatively developed common standards and practices. Such an approach will enable large clinical research projects and trials (as the need arises) that cannot be undertaken by a single group. In essence, the strategy is to create a multifaceted, collaboratively funded global TB research network that can address important questions with locally and globally relevant answers, which could expand to include additional collaborators in the future.

6. Establish milestones and indicators for on-going monitoring and evaluation

Progress in implementing the national TB research plan must be monitored and evaluated with relevant indicators and milestones. These include "process" indicators (how TB research is being strengthened) and "content" indicators (the extent of the TB strategy's development and its impact on the End TB Strategy in each country).

Process indicators (Yes/No) include:

- Whether a national TB research network has been established, receives funding from national public sources and meets regularly;
- Whether a plan for TB research has been developed through a multi-stakeholder process and is integrated within the national TB strategic plan (NSP);
- Whether national TB research priorities have been developed through a multi-stakeholder process and are widely disseminated;
- Whether a national plan for health research capacity building – including mechanisms for national funding of health research training and infrastructure support – has been established and;
- Whether a national mechanism for funding TB research operating costs has been developed.

Content indicators include:

- The number of researchers trained at Master's and PhD levels;
- The amount and type of research operating funds from national public sources;

- The number of publications in international peer-reviewed journals and;
- Changes in TB diagnostic, treatment or preventive policies and in NTP strategies resulting from domestic research.

The following are suggested five- and ten-year milestones for monitoring and evaluating Pillar 3 at country level.

By 2020, it is expected that all countries with a substantial TB burden will have:

- Established a national TB research network that includes at least leadership from national universities and research institutes, the national TB programme and civil society;
- Integrated TB research within the national TB strategic plan and developed TB research priorities;
- Initiated in-country research training with national faculty (with at a minimum the capacity to deliver operational research training) and;
- Evaluated the implementation of TB research within the NSP.

By 2025, it is expected that all countries with a substantial TB burden will have:

- Developed and implemented a national TB research plan with a TB-specific prioritized research agenda within a larger health research agenda, based on mapping of resources and activities, with a process to review and renew it every five years;
- Established sustained national TB research funding mechanism(s) for a broad spectrum of research efforts on TB (from basic to operational, according to a country's resources and research capacity), based on newly developed national research agendas;
- Created a strong TB research capacity, including training, mentoring and career support, with well-defined roles for government agencies and NTPs, universities or research institutions, private sector and NGOs and;
- Empowered a strong and self-sustained TB research community (a critical mass within the country), which is productive, addresses national priorities, and has links to regional hubs and international research networks.

BOX 3B.8 THE ROLE OF NGOS IN SUPPORTING PILLAR 3

NGOs are key stakeholders in the promotion of TB research at country level and could play a salient role in the following areas:

- Strong and carefully focused advocacy activities to expand and increase the engagement of various stakeholders in TB research at national level;
- Active participation in the TB research network;
- Development of the country specific TB research plan;
- Obtaining full government commitment for sustained public funding of TB research and research capacity building;
- Engagement of all stakeholders in the implementation of the TB research plan;
- Monitoring the national TB research plan and ;
- Strengthening community engagement in research.

Advocacy activities should be initiated early and continued throughout all phases of the national plan.

THE 10-YEAR VISION

To achieve the targets set by the WHO End TB Strategy for 2030/2035, there is a need for intensified research to deliver new tools and strategies to combat the disease, including rapid and sensitive point-of-care diagnostic tests, short regimens for the treatment of TB disease and LTBI, and an effective vaccine. These novel tools, as well as any innovation, must be linked with relevant epidemiological, health systems, and operational research to ensure their adoption and implementation to scale. To achieve this vision it is essential that, over the next decade, countries with substantial TB burden progressively establish their leadership for TB research by ensuring the necessary funding through domestic public investments (especially in the middle-income high burden countries, including the BRICS) and by building strong domestic capacity with the necessary international collaboration within the larger context of health research. It is also crucial that high-income countries and their institutions enhance their engagement and investments in TB research overall, including multidisciplinary TB research, to address specific barriers impeding TB elimination, and that they collaborate with, and support, institutions in high-incidence countries. This vision also relies on ongoing global commitment to addressing health as a development priority and to research and innovation across the globe.

The **Global Action Framework for TB Research** has been designed to help achieve this 10-year vision, with two fundamental objectives:

1. **To promote, enhance and intensify TB research and innovation at country level, with a focus on low- and middle-income countries, through the development of country-specific TB research plans and strong research capacity;**

2. **To promote, enhance and catalyse TB research at global level through advocacy, sharing innovations, discussion of global priorities in TB research and development of regional and international networks for research and capacity building.**

It sets the principles for action on TB research and recommends the roles, responsibilities and deliverables for major stakeholders, both global and national. It is designed for use by a wide range of groups and individuals including ministries of health and their NTPs, ministries of science and technology, national research institutes, academia, researchers, international and national donors and technical agencies, NGOs and civil society.

The Framework is composed of three parts:

Part I:
Strengthening TB research in low and middle-income countries most affected by TB

Part II:
Supporting and facilitating research at global level

Part III:
The role of WHO

GLOBAL ACTION FRAMEWORK
MILESTONES AND DELIVERABLES AT A GLANCE

	2020	2025
COUNTRIES	**ALL COUNTRIES WITH HIGH TB BURDEN WILL HAVE:** • Established a national TB research network; • Integrated TB research within the National TB Strategic Plan; • Developed a list of national TB research priorities; • Initiated in-country research training.	**ALL COUNTRIES WITH HIGH TB BURDEN WILL HAVE:** • Developed and implemented a national TB research plan; • Established sustained mechanisms for national TB research funding; • Created a strong TB research capacity; • Empowered a strong and self-sustained TB research community.
GLOBAL	**IT IS EXPECTED THAT:** • At least three new cross-national TB research networks will be established; • At least three large multicentre and cross-cutting collaborative studies will be initiated; • At least two new innovative financing mechanisms will be implemented; • Full funding of TB research will be ensured at least in the BRICS countries.	**IT IS EXPECTED THAT:** • High-income countries will have enhanced their commitment and investments in Research and Development (R&D) for TB; • Mechanisms will be in place for global networking on TB R&D; • Novel funding mechanisms will be implemented to enhance TB R&D; • At least five large-scale, multicentre, cross-cutting collaborative research projects will be conducted.
WHO	**WHO WILL HAVE:** • Worked with at least three model countries to develop and implement a national TB research plan; • Organized a multi-country meeting on lessons learned from model countries; • Published an updated version of the Global Action Framework for TB Research; • Published TB research investment case studies; • Included progress in TB R&D at country level within the WHO Global TB Report.	**WHO WILL HAVE:** • Assisted high TB burden countries to develop and implement a national TB research plan; • Worked with countries and donors at national and international levels to expand the funding base for TB research along the continuum; • Assisted countries to create a strong TB research capacity; • Supported the creation of regional hubs and international networks for TB research; • Included progress in TB R&D at country level within the WHO Global TB Report.

EXAMPLES OF INDICATORS TO MONITOR END TB STRATEGY IMPLEMENTATION: PILLAR 3

INDICATOR	REQUIREMENTS FOR MEASUREMENT
IMPACT INDICATORS	
PERCENTAGE OF NEWLY NOTIFIED TB PATIENTS TESTED USING WHO-RECOMMENDED RAPID TESTS Number of new and relapse TB patients tested using a WHO-recommended rapid test at the time of diagnosis, divided by the total number of new and relapse TB patients, expressed as a percentage	Requires additional routine data collection compared with 2013 WHO recording and reporting framework. Case-based electronic recording and reporting systems facilitate the addition of new variables to routine data collection efforts.
TREATMENT COVERAGE, NEW TB DRUGS Number of TB patients treated with regimens that include new TB drugs, divided by the number of notified patients eligible for treatment with new TB drugs, expressed as a percentage	
PROCESS INDICATORS	
ESTABLISHMENT OF A NATIONAL TB RESEARCH NETWORK THAT RECEIVES SUSTAINABLE FUNDING AND IS MEETING REGULARLY (YES/NO)	Establishment of a National TB research network
A NATIONAL PLAN FOR TB RESEARCH WITH IDENTIFIED RESEARCH PRIORITIES HAS BEEN DEVELOPED THROUGH A MULTI-STAKEHOLDER PROCESS, AND IS INTEGRATED WITHIN THE NATIONAL TB STRATEGIC PLAN (NSP) (YES/NO)	Availability of a National plan for TB research
A SUSTAINABLE NATIONAL MECHANISM FOR FUNDING TB RESEARCH HAS BEEN DEVELOPED AND IS IN PLACE (YES/NO)	The extent of funding resources and the presence of a clear and transparent mechanism to access these resources
A SUSTAINABLE MECHANISM FOR TB RESEARCH CAPACITY BUILDING IS IN PLACE (YES/NO)	Setting up or otherwise of a sustainable mechanism for capacity building
NUMBER OF OPERATIONAL RESEARCH STUDIES CONDUCTED TO INFORM THE IMPLEMENTATION OF THE END TB STRATEGY	TB-related operational research and its results
CHANGES IN NTP CONTROL STRATEGIES RESULTING FROM RESEARCH CONDUCTED NATIONALLY (YES/NO – TYPE OF POLICY CHANGE)	New policies/strategies informed by operational research

Note: A detailed list of indicators are under development and will be available online soon.

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Annex 1

Methods for producing projections for setting national targets

Methods for producing projections for setting national targets Methods for producing projections for setting national targets

Step 1

The annual decline in TB incidence rate is calculated for the baseline year n0 (here 2015) and denoted c0. In Table 2, c0 = -0.025 (the decline is -2.5%/year). The targeted decline in the incidence rate by target year nt is ct = -0.1 (an annual 10% decline by 2025). We assume that the decline will accelerate from c0 to ct at a constant rate. Values for the decline cn at year n can then obtained by exponential interpolation using equation

$c_n=c0(c_t/c_0)^{((n-n_0)/(n_t-n_0))}$, $n_0<n<n_t$ (1)

The same method is applied to compute the series of annual incidence declines from 2025 (new baseline year n_0) to 2035 (new target year n_t), using a 2035 target value of -0.3

Step 2

The same interpolation method as above is applied to obtain the case fatality ratio F_n by replacing c with F in equation (1)

Step 3

The incidence rate In for the year n is obtained from the incidence rate of the previous year I_{n-1}, using recurrence

$I_n=I_{(n-1)}.e^{c}_{n}$ (2)

where e is the mathematical constant that is the base of the natural logarithm (approximately equal to 2.718)

Step 4

The mortality rate M_n for year n is obtained by multiplying the case fatality ratio F_n by the incidence rate:

$M_n=F_n.I_n$ (3)

Step 5

The number of TB deaths per year is obtained as usual by multiplying the annual mortality rate with the average population size of the year divided by 10^5.

Annex 2

Suggested checklist for assessment of TB research situation at country level for preparedness and planning

Objective: This checklist is intended to assist countries in conducting the assessment of the TB research situation in order to inform the development of a national TB Research Strategy. It can be used by NTP managers and key stakeholders (universities), external consultants, or during a monitoring mission.

Questions can be answered with a simple Yes/No, but some require further explanation. If documents are available to answer some questions, or a section of questions, these should be referred to, or attached.

DOMAIN	Questions / assessment	Yes/ No	Yes – to be strengthened	No – to be established
PLANNING AND PRIORITIZATION	1. Has an inventory of current TB research been conducted in the country in the last 10 years[1]? If yes, did this inventory include the following elements: - a research network with links to NTP - a national Health Research strategic plan with TB research priorities - funding – for operating, training, infrastructure, and investigators salary support - list of researchers and institutions involved in TB research - national or international TB research training			
	2. Is there currently a national TB research network? If yes: - does it include national and international TB researchers - does it include public health officials, especially TB programme focal point (or managers)? - does it include representatives of the private sector – industry, NGOs? - does it focus on all research or is it restricted to certain types (operational, epidemiologic)? - is it linked formally with other countries in the region to foster TB/health research?			
	3. Has a national TB research strategic plan been developed[1]? If yes: - does it include the following aspects? - training - funding - development of networks - priority setting - was the plan developed through a 'multi-stakeholder' process[2]? - is there a process for regular review and revision of this plan? - if yes – at what frequency?			

1. If yes, pls attach the document/report.
2. with at least researchers, national universities, government / TB programme officials, community and private sector representatives.

DOMAIN	Questions / assessment	Yes/ No	Yes – to be strengthened	No – to be established
PLANNING AND PRIORITIZATION	4. Have National TB research priorities been established?* If yes: - by what group (list the stakeholders who were involved)? - in what year?			
RESEARCH CAPACITY	5. How many full time TB researchers (independent investigators) are there in the country? 0 1-9 10-19 20-29 30-49 50			
	6. Are there institutions within the country that have physical facilities and human resources to conduct TB research? If Yes: - how many are there- based in the following? Universities: _ _ _ Research Institutes: _ _ _ TB programmes/Public health programmes: _ _ _ Other (specify _____) : _ _ _ - how many are considered national centres for TB research?			
RESEARCH TRAINING	7. Are there national universities that offer graduate training in health research? If yes: - at Master's level? - at PhD level? - are any of these specifically targeted to TB research? - is there graduate level training in Clinical/Epidemiologic/ Biostatistical research? - is there graduate level training in Basic research (eg molecular biology, genetics, immunology)?			
	8. Are there formal links between TB programme and national universities/institutes – for graduate level research training[3]?			
	9. Are there formal links between TB programme and international universities/institutes – for graduate level research training? If yes, with which universities: _____ _____ _____			
RESEARCH FUNDING	10. Is there a mechanism for national (public) funding of operating funds for TB research (to which health research and TB researchers may apply)? If yes: - is the mechanism competitive & peer-reviewed? - is the competition: annual/twice a year/other? - for how many years has this funding mechanism been in place? - what is the total value awarded annually (amount and currency)? _____ - what is the source of funding (Ministry/national agency providing funding? _____ - any other ministry? specify _____ - is there any other mechanism? specify: _____			

3. This means agreements for research training of NTP staff, formal agreements re field work for research trainees within the TB programme.

DOMAIN	Questions / assessment	Yes/ No	Yes – to be strengthened	No – to be established
RESEARCH FUNDING	11. Are there other sources for health (or TB specifically) research funding? If yes, specify _____			
	12. Is there national funding for TB research infrastructure (facilities, equipment, human resources)?			
	13. Is there a national (public) programme explicitly for salary support of TB researchers (or health researchers)? If yes: - is it based on universities or research institutes (ie block funding to these institutions who then hire researchers on contract? - is this a national competitive funding for salary support for TB/health researchers? - is the mechanism open & peer-reviewed? - is the competition: annual / twice a year / other - for how many years has this funding mechanism been in place? - what is the total value awarded annually (amount and currency)? _____ - source of funding: - what is the Ministry providing funding? _____ - any other Ministry – specify _____ - other mechanism – specify _____			
	14. Is there national funding to support TB (or health) research training? If yes, - at Master's level - at PhD level - only at national universities (in-country training) - at national and international universities			
	15. Is there funding available from national industries (drugs/ diagnostics/vaccines) to support TB research?			
	16. Does the country receive funding from the Global Fund? If yes: - since what year? - what is the amount for TB (specify average amount annually, and currency)?: _____ - is there any funding allocated for TB research in the current Global Fund award? _____ If yes: How much (specify average annual amount in past 5 years, and currency)?: _____ - What percentage of total Global Funds disbursed in the country, go to TB research? ___% - Is this only for operational research? - If other types of research – specify _____			
	17. Are there other substantial and regular external sources of research funding? If yes: - specify source(s) _____ - average annual amount and currency (if known): _____			

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WHO Staff and consultants

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Michel Gasana

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Beatrice Mutayoba

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Mariam Sianozova, Alexander Trusov

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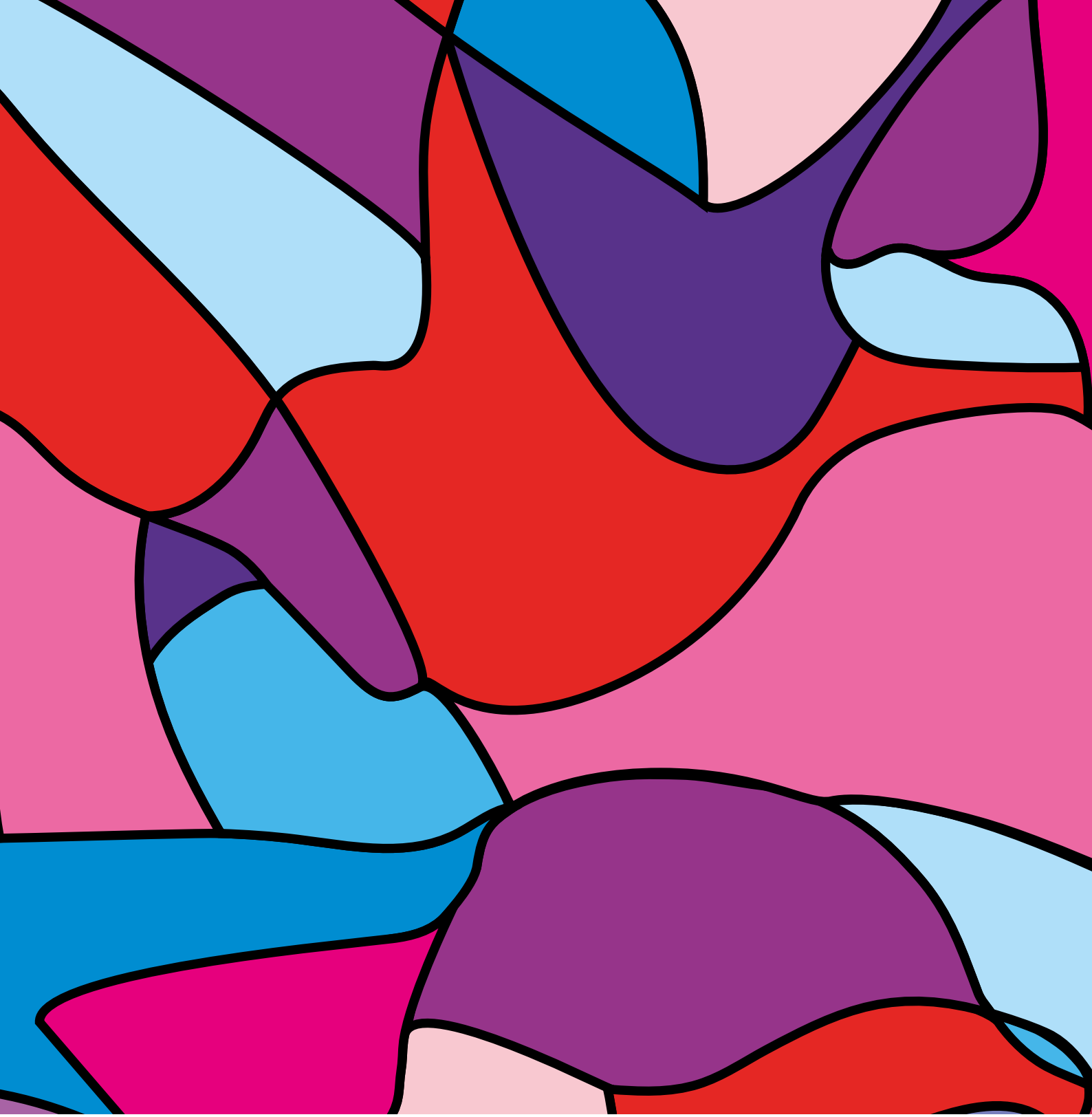

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