

Guidance for national strategic planning for tuberculosis



World Health
Organization

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ISBN 978-92-4-005205-5 (electronic version)

ISBN 978-92-4-005206-2 (print version)

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Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

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The text was edited by the team at Cadman Editing Services.

Designed by minimum graphics.

Cover illustration by Adele Jackson.

Contents

Foreword	v
Acknowledgements	vii
Abbreviations and acronyms	viii
Glossary	ix
Chapter 1: Introduction	1
1.1 Background and rationale for developing the guidance	1
1.1.1 End TB Strategy	1
1.1.2 SDGs	1
1.1.3 2018 UN high-level meeting on TB	1
1.1.4 2018 Global conference on primary health care	1
1.1.5 UN high-level meeting on UHC	1
1.1.6 COVID-19 pandemic	2
1.2 Scope and structure	2
1.3 Target audience	2
1.4 The role of strategic planning in national efforts to end TB	2
1.5 Good practices for TB strategic planning	3
1.5.1 Government stewardship and ownership	3
1.5.2 Alignment with the End TB Strategy and other relevant global and regional strategies	3
1.5.3 Alignment with the national health strategy and other health programmes	4
1.5.4 Multisectoral and multistakeholder engagement at national and subnational levels	4
1.5.5 Adapting the NSP at subnational level	4
1.5.6 Promoting quality care that is effective, safe and people centred	4
1.6 Components of an NSP	5
Chapter 2: Process for developing a TB NSP	6
2.1 Overview	6
2.2 Phase 1 – planning and preparation	6
2.2.1 Establishment of a core organizing team	6
2.2.2 Development of a costed roadmap for the NSP development process	8
2.2.3 Confirming allocated funding and mobilizing additional resources for the strategic planning process	8
2.3 Phase 2 – conducting the situation analysis	8
2.3.1 Review of epidemiology and determinants of TB	8
2.3.2 TB programme review and review of relevant components of the health system	10

2.3.3	Data and evidence consolidation	10
2.3.4	Synthesis of the situation analysis	11
2.4	Phase 3 – formulating goals, objectives, interventions and activities	16
2.4.1	Formulation of goals and objectives	16
2.4.2	Identifying priority interventions	16
2.4.3	Determining epidemiological (coverage) targets	19
2.4.4	Formulation of activities and subactivities	22
2.4.5	Contingency planning	22
2.5	Phase 4 – developing the metrics and activities for monitoring, evaluation and review of the NSP	23
2.5.1	Development of the M&E component of the NSP	25
2.6	Phase 5 – estimating the cost of the strategic plan	26
2.6.1	Overview	26
2.6.2	Key steps for costing the TB strategic plan	27
2.6.3	Managing the funding gap	30
2.7	Phase 6 – consensus and endorsement, dissemination and resource mobilization	31
2.7.1	Consensus and endorsement	31
2.7.2	Dissemination and advocacy	31
2.7.3	Resource mobilization	31
	Chapter 3: Structure and components of a TB NSP	33
3.1	Overview	33
3.2	Summary of the findings from the situation analysis	34
3.2.1	The country context	34
3.2.2	The national health and social care system	35
3.2.3	Epidemiology of tuberculosis	36
3.2.4	The national TB programme	37
3.2.5	Summary of the review of implementation of the previous TB strategic plan	39
3.2.6	Programmatic gaps analysis	39
3.3	Goals, objectives and interventions	39
3.3.1	Goals	39
3.3.2	Objectives and strategic interventions	39
3.4	Activities and subactivities	44
3.4.1	Key elements to include in the activities (and subactivities)	44
3.5	M&E component of the NSP	48
3.5.1	Continuous M&E	48
3.5.2	Mid-term strategic plan review	48
3.5.3	End-term strategic plan review	48
3.6	Costing	52
3.7	Contingency measures	52
	References	54

Foreword

Global efforts to end tuberculosis (TB) are primarily guided by the World Health Organization's (WHO's) End TB Strategy. In line with the United Nations (UN) Sustainable Development Goals (SDGs), the strategy has targets to reduce TB deaths and TB incidence by 90% and 80%, respectively, by 2030 compared with 2015. It also targets eliminating TB-related catastrophic costs by 2020.

At the first UN General Assembly high-level meeting on tuberculosis, held in 2018, heads of state and government adopted the political declaration on the fight against TB, which includes commitment to ambitious targets for TB treatment and prevention through universal access to quality diagnosis, treatment, care and support, without suffering financial hardship, with a special focus on vulnerable and marginalized populations, by 2022.¹

A national strategic plan (NSP) for TB is a key document that guides national authorities and stakeholders in how to comprehensively address the TB epidemic through interventions within the health sector and in other sectors. These interventions are implemented as part of collective efforts towards achievement of the health-related SDGs.

Strategic planning for TB should, where possible, be conducted as part of the overall national health sector planning process. The development of the NSP should be grounded in primary health care (PHC); it should contribute to universal health coverage (UHC),² and to addressing the broader determinants of TB. This guidance is intended for use to develop standalone TB strategic plans, and to develop TB interventions as part of multidisease or national health sector plans. It promotes the development of NSPs that are human-rights based and that comprehensively address interrelated aspects of health and well-being through collaboration

between programmes and sectors within and beyond the health sector. The interventions should put people at the centre, with comprehensive services³ – from promotion and prevention to treatment, rehabilitation and palliative care – for all people in need, without causing financial hardship.

Comprehensive and inclusive engagement of stakeholders, including TB-affected communities and civil society, is critical for implementing the End TB Strategy. This will also facilitate planning for quality TB services that are responsive to the needs of people and affected communities and individuals. Deliberate actions should therefore be taken to ensure that the planning process facilitates input from those most affected by health inequities.

The NSP should respond to the needs of all affected populations, including the most vulnerable, as informed by a comprehensive analysis of the epidemiological, health system and socioeconomic situation.⁴ To foster sustainability, interventions with medium- and long-term outcomes should be prioritized where possible. Use of innovative approaches, including digital technologies, should also be considered to address gaps and needs along the care continuum, as informed by the situation analysis.⁵

The coronavirus disease (COVID-19) pandemic has demonstrated the extent to which health systems must be able to respond in a timely and appropriate manner to unanticipated events. Thus, contingency planning for TB should be included in the national health sector emergency preparedness plan.

The process of developing the guidance included a quality assessment of NSPs for nine countries, an online survey targeting key stakeholders in the strate-

¹ United Nations General Assembly. Resolution 73/3: Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis. New York: United Nations; 2018 (https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/3).

² Universal health coverage (UHC). Geneva: World Health Organization; 2021 ([https://www.who.int/news-room/factsheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/factsheets/detail/universal-health-coverage-(uhc))).

³ Primary health care: Declaration of Astana [website]. Geneva: World Health Organization; 2021 (https://www.who.int/health-topics/primary-health-care#tab=tab_2).

⁴ Walugembe DR, Sibbald S, Le Ber MJ, Kothari A. Sustainability of public health interventions: where are the gaps? *Health Res Policy Syst.* 2019;17(1):8 (<https://doi.org/10.1186/s12961-018-0405-y>).

⁵ Handbook for the use of digital technologies to support tuberculosis medication adherence. Geneva: World Health Organization; 2018 (<https://www.who.int/publications/item/9789241513456>).

gic planning process, and inputs to the draft document from key partners and experts.

Quality assessment of NSPs for TB was performed in 2020 for nine countries (Cambodia, Ethiopia, Ghana, Indonesia, Kenya, Rwanda, Uganda, the United Republic of Tanzania and Viet Nam) which had applied the people-centred framework for TB programme planning and prioritization (PCF).¹ The results of this assessment and the experience with applying the PCF during the development of strategic plans were shared and discussed at a joint meeting with participating countries (Ethiopia, Ghana, Indonesia, Kenya, Rwanda, Uganda, the United Republic of Tanzania, Viet Nam and Zambia) and several partners (Action Damien, Avenir Health, Bill & Melinda Gates Foundation, Expertise France, the Global Fund to Fight AIDS, Tuberculosis and Malaria, London School of Hygiene & Tropical Medicine, KIT Royal Tropical Institute, KNCV Tuberculosis Foundation, McGill University, Stop TB Partnership, International Union Against Tuberculosis and Lung Disease (The Union), United States Agency for International Development, United States Centers for Disease Control and Prevention, and WHO) in January 2021.

An online survey was conducted to obtain inputs and perspectives on the challenges and good practices for national strategic planning for TB. This global survey targeted staff working in national TB programmes (NTPs), other departments of ministries of health, relevant staff in WHO regional and country offices, technical and funding partners, other experts in TB strategic planning and implementation, representatives of non-governmental organizations and civil society, affected communities and people affected by TB.

The draft guidance was shared widely to stakeholders and experts for further input and comments, which were consolidated and incorporated.

Finally, this guidance is intended to complement, rather than to replace, national planning processes. It should be used to support strategic planning for aspects of TB services that may not be optimally covered by existing national tools.

¹ People-centred framework for tuberculosis programme planning and prioritization: user guide. Geneva: World Health Organization; 2019 (<https://www.who.int/publications/i/item/9789241516273>).

Acknowledgements

The guidance for national planning for tuberculosis (TB) was produced by a team comprising the following World Health Organization (WHO) staff from WHO's Global Tuberculosis Programme (WHO/GTB): Marie-Christine Bartens, Marzia Calvi, Inés Garcia Baena, Giuliano Gargioni, Philippe Glaziou, Clarisse Veylon Herve, Ernesto Jaramillo, Soleil Labelle, Farai Mavhunga, Cicilia Gita Parwati and Lana Syed. The team was led by Farai Mavhunga, Unit Head of the TB Vulnerable Populations, Communities and Comorbidities (VCC), under the overall guidance of Tereza Kasaeva, the Director of the WHO/GTB.

The following WHO staff contributed to the guidance as internal reviewers: Nana Afriyie Mensah Abrampah, Annabel Baddeley, Vineet Bhatia, Dennis Falzon, Christian Gunneberg, Jean de Dieu Iragena, Tauhid Islam, Avinash Kanchar, Hugues Lago, Marek Lalli, Casimir Manzeno, Richard Ngimbi Mbumba, Ernesto Montoro, Matthew Neilson, Sepideh Bagheri Nejad, Linh Nhat Nguyen, Rafael Lopez Ollarte, Eunice Omesa, Debora Pedrazzoli, Charalampos Sismanidis, Shamsuzzohar Babar Syed, Nicole Valentine, Sabine Verkuijl and Simon Walusimbi.

WHO appreciates the contributions and input of the following external reviewers of the draft guidance: Omar F. Al-Jaff (National Tuberculosis Programme, Iraq), Fatma Al-Yaquobi (Directorate General for Disease Surveillance and Control, Ministry of Health, Oman), Awatef Alshammeri (Ministry of Health, Kuwait), Gilles Cesari (The Global Fund to Fight AIDS, Tuberculosis and Malaria [Global Fund]), Daniel Chin (Bill & Melinda Gates Foundation), Julia Chorna (Civil Society Task Force [CSTF] member), Anand Date (United States Centers for Disease Control and Prevention [US CDC]), Jane Deuve (Expertise France), Egwuma Efo (KNCV TB Foundation [KNCV]), Esty Febriani (CSTF member), Agnes Gebhard (KNCV), Mustapha Gidado (KNCV), Jennifer B. Harris (US CDC), Bertrand Kampoer (CSTF member), Amir Khan (CSTF member), Choub Sok Chamreun Khana (CSTF member), Evaline Kibuchi (CSTF member), Kobto Ghislain Koura (The Union), Charles Macarthur (US CDC), Esam Mohammed Mahyoub (National Tuberculosis Control Program, Yemen), Finn McQuaid (London School of Hygiene & Tropical Medicine), Madhukar Pai (McGill University), Aneeta Pasha (CSTF member), Nyan Win Phyo (CSTF member), Guy Stallworthy (Bill & Melinda Gates Foundation), Sahu Suvanand (Stop TB Partnership), Jamie Tonsing (Global Fund), Emmy van der Grinten (KNCV), Eliud Wandwalo (Global Fund), and Shufang Zang (Global Fund).

Financial support for the preparation and production of this publication was provided by the Bill & Melinda Gates Foundation.

Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
DR-TB	drug resistant tuberculosis
DST	drug susceptibility testing
HIV	human immunodeficiency virus
IPC	infection prevention and control
M&E	monitoring and evaluation
MAF-TB	multisectoral accountability framework to accelerate progress to end TB by 2030
MDR-TB	multi-drug resistant tuberculosis
MOH	ministry of health
NGO	nongovernmental organization
NSP	national strategic plan
NTP	national TB programme
PCF	people-centred framework for TB programme planning and prioritization
PHC	primary health care
RR-TB	rifampicin-resistant TB
SDG	Sustainable Development Goal
SMART	specific, measurable, attainable, realistic and time-bound
TB	tuberculosis
TPT	TB preventive treatment
UHC	universal health coverage
UN	United Nations
WHO	World Health Organization
WRD	WHO-recommended rapid diagnostic test

Glossary

Determinants of health: Many factors combine to affect the health of individuals and communities, and these include social and economic environment, the physical environment, and the person's individual characteristics and behaviours.¹

Engagement: An approach that results in meaningful participation of intended stakeholders in a process. Depending on the role of the stakeholder, this participation may include all or selected aspects of the planning process.

Epidemiological data: Data about the burden of infection or disease, including its distribution (e.g. by age, sex, location or risk factors), determinants and trends.

Evidence-based approach: An approach that promotes the use of the best available evidence to inform decision-making. In the context of development of a national strategic plan (NSP) for tuberculosis (TB), this means the systematic and transparent use of evidence to inform the programmatic interventions included in the strategic plan.

Gender-transformative programmes: Programmes that promote gender equality and achieve their objectives by fostering critical examination of inequalities and gender roles, norms and dynamics, and by transforming the underlying social structures, policies and broadly held social norms that perpetuate gender inequalities.²

Health equity: The absence of unfair and avoidable or remediable differences in health among population groups defined socially, economically, demographically or geographically.³

Health-related risk factor (for TB): A health condition or modifiable behaviour with a known direct impact on health that puts a person at increased risk of TB infection or disease, or at risk of poorer TB treatment outcomes.

Health system: All organizations, people and actions whose primary intent is to promote, restore or maintain health.⁴

Human rights-based TB response: A TB response that promotes public health measures and good clinical practice founded on the dignity and autonomy of people affected by TB and their critical role in all aspects of the response. It places special focus on populations vulnerable to TB to promote rights to health, non-discrimination, privacy and confidentiality, information and liberty, and leveraging existing laws at international, regional and national levels.⁵

Management of TB: The broad package of services to prevent, diagnose, treat and rehabilitate people affected by TB.

Marginalized population: Groups of people that are not traditionally given equal voice in governance processes (e.g. women, low-income communities, ethnic minorities, religious minorities, people with disability, older adults, sexual and gender identity minorities, and migrants).⁶

¹ Determinants of health [website]. Geneva: World Health Organization; 2017 (<https://www.who.int/news-room/questions-and-answers/item/determinants-of-health>).

² Interagency Gender Working Group. The gender integration continuum – training session user's guide. Washington, DC: USAID; 2017 (https://www.igwg.org/wp-content/uploads/2017/12/17-418-GenderContTraining-2017-12-12-1633_FINAL.pdf).

³ Social determinants of health: health equity [website]. Geneva: World Health Organization; 2021 (https://www.who.int/health-topics/social-determinants-of-health#tab=tab_3).

⁴ Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action. Geneva: World Health Organization; 2007 (https://www.who.int/healthsystems/strategy/everybodys_business.pdf).

⁵ Global Coalition of TB Activists and Northwestern Pritzker School of Law Center for International Human Rights. Activating a human rights-based tuberculosis response: a technical brief for policymakers and program implementers. Atlanta: United States Centers for Disease Control and Prevention; 2020 (<https://npin.cdc.gov/publication/activating-human-rights-based-tuberculosis-response-technical-brief-policymakers-and>).

⁶ SDG indicators: metadata repository – Indicator 11.3.2 [website]. New York: United Nations; 2021 (<https://unstats.un.org/sdgs/metadata/files/Metadata-11-03-02.pdf>).

National TB programme (NTP): A national programme that provides technical and managerial leadership to address TB. The structures of NTPs vary across countries, ranging from dedicated standalone TB programmes to those that are fully integrated within the ministry of health (MOH). Most NTPs are under the MOH.

People affected by TB: Any person with TB disease or who previously had TB disease, their caregivers and immediate family members, and members of TB key and vulnerable populations. Populations vulnerable to TB vary depending on local epidemiology, but common populations include children, health care workers, indigenous peoples, people living with HIV, people who use drugs, people in prison and other closed settings, miners, mobile and migrant populations, women, and the urban and rural poor.¹

Prioritization: The process of deciding the relative importance or urgency of interventions, to select strategies to address the most important health needs as highlighted in a situation analysis, and to decide how to allocate (usually limited) resources for the implementation of the plan.

Programmatic gap: The difference between the current state of a programme and the desired state if the programme is to be able to fully meet its objectives. It includes gaps in TB service delivery to ensure universal access to quality services and gaps in the management capacity to optimally coordinate the country's TB response.

Quality of care: The degree to which health services (promotion, prevention, treatment, rehabilitation and palliation) for individuals and populations increase the likelihood of desired health outcomes and align with evidence-based professional knowledge that takes into account the needs and preferences of affected communities and individuals.²

Resilient health system: The capacity of all health actors, institutions and populations to prepare for and effectively respond to crises, maintain core functions when a crisis hits and, informed by lessons learned during the crisis, reorganize where necessary. Health systems are resilient if they protect human life and produce good health outcomes for all during a crisis and its aftermath.³

Social determinants of TB: Nonmedical factors that influence TB and its outcomes. Examples include food security, housing and basic amenities, structural conflict, income and social protection, and access to affordable health services of decent quality. Social determinants can be more important than health care or lifestyle choices in influencing health.⁴

TB comorbidity: A concurrent disease or health condition in a person with TB.

¹ Stop TB Partnership, TB People. Declaration of the rights of people affected by tuberculosis. 2019 (<https://stoptb.org/assets/documents/communities/FINAL%20Declaration%20on%20the%20Right%20of%20People%20Affected%20by%20TB%2013.05.2019.pdf>).

² Quality health services. Geneva: World Health Organization; 2020 (<https://www.who.int/news-room/fact-sheets/detail/quality-health-services>).

³ Kruk ME, Myers M, Varpilah ST, Dahn BT. What is a resilient health system? Lessons from Ebola. *Lancet*. 2015;385(9980):1910–2 (<https://pubmed.ncbi.nlm.nih.gov/25987159/>).

⁴ Social determinants of health: overview [website]. Geneva: World Health Organization; 2021 (https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1).

CHAPTER 1

Introduction

This chapter provides an overview of this guidance document. It describes the background and rationale for developing the document, highlighting some of the key global developments that have informed the proposed approaches to developing a national strategic plan (NSP) for tuberculosis (TB); the scope and structure; the target audience of the guidance; the role of national strategic planning to guide efforts to end TB; good practices to consider when developing a TB NSP; and key components to be reflected in the NSP.

1.1 Background and rationale for developing the guidance

In 2015, WHO published a toolkit for developing an NSP, to support countries with national strategic planning for TB (1). The current document is an update to that toolkit, developed to better align with global commitments, strategies and approaches. Given the significant global developments in TB and public health, the current guidance incorporates new tools and approaches to TB programming and planning, and lessons learned in using the 2015 toolkit.

The key global commitments and developments that have informed the content and focus of this guidance are given below.

1.1.1 End TB Strategy

The End TB Strategy, endorsed by the World Health Assembly in May 2014, provides strategic direction for the achievement of the TB targets within the United Nations (UN) Sustainable Development Goals (SDGs), including the provision of universal health coverage (UHC) to all people affected by TB. The strategy outlines a range of medical and socioeconomic interventions to address TB morbidity and mortality, and to facilitate the provision of people-centred services and the elimination of TB-related catastrophic costs (2).

1.1.2 SDGs

Goal 3 of the SDGs focuses on ensuring healthy lives and promoting well-being for all at all ages. It includes targets to end the epidemics of AIDS, TB, malaria and

neglected tropical diseases, and to combat hepatitis, waterborne diseases and other communicable diseases by 2030. It also includes a target to attain UHC, including financial risk protection and access to quality essential health care services. Goal 1 of the SDGs focusses on ending poverty through ensuring substantial coverage of social protection for all, and by 2030 achieve substantial coverage of the poor and the vulnerable.

1.1.3 2018 UN high-level meeting on TB

The political declaration of the 2018 UN high-level meeting on TB, endorsed by heads of state and government, commits to ambitious targets to end TB (3). Included in this declaration is the commitment to develop or strengthen TB NSPs through multisectoral mechanisms and the engagement of civil society and affected communities, central and local government, and other stakeholders within and beyond the health sector.

1.1.4 2018 Global conference on primary health care

At the 2018 Global conference on primary health care (PHC) in October 2018 (4), heads of state and government signed the Declaration of Astana (5). The declaration includes commitments to making bold political choices for health across all sectors and building sustainable PHC to meet all people's health needs through comprehensive preventive, promotive, curative, rehabilitative services and palliative care. It envisages sustainable PHC to enhance the resilience of health systems to prevent, detect and respond to infectious diseases and outbreaks.

1.1.5 UN high-level meeting on UHC

The first UN high-level meeting on UHC, held in September 2019, resulted in a political declaration with commitments to accelerate efforts towards achieving UHC by 2030 through expanded population coverage with quality essential health services, and financial risk protection to eliminate impoverishment due to health-related expenses (6). The declaration also

includes commitment to strengthen efforts to address communicable diseases (e.g. HIV, TB, malaria, and hepatitis) as part of UHC, and through comprehensive approaches and integrated service delivery.

1.1.6 COVID-19 pandemic

The coronavirus disease (COVID-19) pandemic has destabilized the global economy and reversed progress in health and development worldwide. Progress in TB care and prevention has been particularly affected, with redirection of human, financial and other resources to the COVID-19 response. Furthermore, public health measures restricting movement of people have resulted in reduced access to TB services.

The pandemic has highlighted the critical need to ensure maintenance of quality essential health services during emergencies. According to the *Global TB report 2021 (7)*, between 2019 and 2020, there was a year-on-year increase in TB deaths for the first time in more than 10 years, because of marked reductions in people with TB who were diagnosed, treated and notified (from 7.1 million in 2019 to 5.8 million 2020). About 1.5 million people died from TB in 2020 (including 214 000 people with HIV). There was also a 21% drop in the number of people receiving TB preventive treatment (TPT) between 2019 and 2020.

National strategic planning is a critical step for ensuring that the TB response at country level reflects the changing context at national, regional and global level. The NSP guides efforts to end TB, and it should contribute to strengthening PHC and the attainment of UHC and the SDGs.

1.2 Scope and structure

This guidance includes key principles and steps for developing a TB NSP in line with the World Health Organization's (WHO's) End TB Strategy. It outlines a participatory, multidisciplinary and multisectoral approach, with involvement of all key stakeholders, including civil society and communities affected by TB.

The guidance comprises three chapters. The contents of this chapter, **Chapter 1**, have been outlined above.

Chapter 2 describes the various phases of developing an NSP, from the preparatory phase to the endorsement and dissemination of the plan, and its use for resource mobilization.

Chapter 3 outlines the proposed structure and components of an NSP, providing some examples of how different sections of the NSP can be presented.

1.3 Target audience

The guidance is intended for use by all stakeholders involved in national strategic planning for TB (e.g., ministry of health [MOH], other government ministries, private sector, civil society and affected communities, academic and research institutions, and technical and funding partners). The stakeholders involved vary across countries, depending on factors such as the epidemiology and determinants of TB, the institutional arrangements for the coordination and provision of TB services, and the degree of devolution of the political and health governance system.

1.4 The role of strategic planning in national efforts to end TB

It is important to plan for all major diseases affecting a population. TB is a disease of poverty and inequity, thus addressing TB is critical for the attainment of equity in health. A TB NSP provides medium-term¹ direction for the country's efforts to end TB. It outlines the overall goal, strategies and interventions prioritized by national health authorities and stakeholders, and provides guidance on how these are coordinated across various sectors. The NSP translates global, regional and national commitments into national and subnational targets and activities to be implemented to achieve these targets, and provides the basis for mobilization of domestic and external resources for the TB response.

When well-planned and coordinated, the strategic planning process:

- ▶ provides an opportunity to assess the country's situation, and adopt and adapt international commitments and recommendations to the local context;
- ▶ facilitates the identification of relevant stakeholders and their engagement to:
 - comprehensively identify the needs of people affected by TB;
 - address TB using a multisectoral approach comprising both biomedical interventions and interventions that address the social determinants and the medical, social and economic consequences of TB;
- ▶ builds capacity of TB-affected communities, non-governmental organizations (NGOs) and other stakeholders on planning for TB, and strengthens their meaningful engagement in the TB response;

¹ In this guidance, "medium term" refers to plans of about 3–5 years that are also aligned with the WHO publication, *Strategizing national health in the 21st century: a handbook (8)*.

- ▶ facilitates critical interdisciplinary and multisectoral review of the country's TB situation, contributing to a shared understanding of the burden, distribution and determinants of the disease;
- ▶ facilitates collective exploration of the underlying causes and system factors that need to be addressed to end the TB epidemic;
- ▶ facilitates holistic planning, ensuring linkage with other national strategies, and correct placement of the TB response in the context of the broader UHC and PHC agenda, with a human rights-based approach to reduce inequalities;
- ▶ provides a platform for collectively identifying and building consensus on the NSP interventions, and differentiation of services according to the needs and preferences of people affected by TB; and
- ▶ provides an opportunity to increase awareness and strengthen the commitment of political and other leaders to the TB response, and to mobilize the required resources.

It is therefore critical to ensure that the planning process is given as much priority as the resultant product.

1.5 Good practices for TB strategic planning

This section describes good practices for developing a TB NSP. Although the focus of this guidance is on national level planning, these practices are also relevant for planning at subnational level in countries with devolved governance systems, where strategic planning takes place at lower levels.

1.5.1 Government stewardship and ownership

National strategic planning should be led and coordinated by the highest level of leadership possible within the MOH, at national and subnational¹ levels, to ensure alignment with national and subnational health priorities, and to facilitate adequate engagement and participation of other key institutions and agencies within and beyond the health sector. This will also foster high-level leadership awareness of the country's TB situation and buy-in from key stakeholders, to facilitate resource allocation and leadership support for strategic plan implementation. Furthermore, government leadership can facilitate ownership and government accountability for national and international commitments (e.g. the international commitments related to SDGs, UHC, PHC and ending TB, highlighted above).

¹ This is particularly important in countries with devolved government structures.

1.5.2 Alignment with the End TB Strategy and other relevant global and regional strategies

The End TB Strategy guides the global effort to end TB, based on three pillars and four underlying principles, as outlined in [Table 1.1](#). The NSP development process should consider all components of the End TB Strategy, adapted to the local context, and the NSP should be aligned with other relevant global and regional strategies.

The TB epidemic exposes existing inequalities in almost every country. TB incidence rates are usually much higher in marginalized populations than in the general population. Given that marginalized populations are often a minority, contributing a small proportion of the national TB disease burden, the costs of reaching such populations with services are often higher than for the more accessible populations. Strategic planning to end TB therefore requires careful collection and assessment of relevant data, and deliberate steps to ensure that the interventions are ethically sound, protect human rights and promote equity.

1.5.3 Alignment with the national health strategy and other health programmes

The TB strategic plan should be in line with the national health strategy, and should complement plans for programmes responsible for addressing TB comorbidities, disability and social protection, and other relevant programmes. This harmonization is facilitated by high-level MOH leadership and by engagement of all key stakeholders, at the appropriate level within the organizational hierarchy, to promote programmatic synergies.

The strategic planning cycle for TB should be synchronized with the health sector planning cycle. This is critical for multisectoral planning and domestic resource mobilization that aligns with the country's financial planning cycle, and for optimizing synergies across programmes. In situations where the TB NSP is *not* aligned with the national health sector plans, efforts should be made to re-align these (e.g. by extending existing TB strategic plans, or by developing interim plans to cover the period until the beginning of the next national health plan).

1.5.4 Multisectoral and multistakeholder engagement at national and subnational levels

The success of the NSP largely depends on buy-in by all government authorities and public and private stakeholders involved in its development and implementation, within and beyond the health sector (10). Thus,

Table 1.1 Principles, pillars and components of the End TB Strategy (9)

Principles
<ol style="list-style-type: none"> 1. Government stewardship and accountability, with M&E 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
<p>1. Integrated, patient-centred care and prevention</p> <ol style="list-style-type: none"> A. Early diagnosis of TB including universal DST, 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 comorbidities D. Preventive treatment of people at high risk, and vaccination against TB
<p>2. Bold policies and supportive systems</p> <ol style="list-style-type: none"> 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. UHC 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
<p>3. Intensified research and innovation</p> <ol style="list-style-type: none"> A. Discovery, development and rapid uptake of new tools, interventions and strategies B. Research to optimize implementation and impact, and promote innovations

DST: drug susceptibility testing; HIV: human immunodeficiency virus; M&E: monitoring and evaluation; TB: tuberculosis; UHC: universal health coverage.

full engagement and participation of relevant stakeholders and partners, including those from civil society and TB-affected communities, is required throughout the development process.

WHO's multisectoral accountability framework to accelerate progress to end TB by 2030 (MAF-TB) (11) provides a basis for planning for multisectoral and multistakeholder engagement and accountability at national and local levels (Box 1.1). The aim of MAF-TB is to ensure the alignment and synergy of complementary efforts with other sectors, to address the broader determinants of the TB epidemic. Stakeholder mapping at national and subnational levels should therefore be conducted during the preliminary steps in strategic planning and should be updated regularly (Box 2.1, in Chapter 2).

Sensitization and orientation of agencies across government and other stakeholders may be required early in the process, especially for stakeholders who have not previously been actively engaged in the country's TB response. Deliberate efforts should be made to engage affected communities and civil society, both during the planning process and throughout the implementation phase of an NSP. The planning process should thus include resources for sensitizing and building capacity among communities and other stakeholders, to enable their meaningful engagement and participation at both national and subnational levels.

Effective stakeholder engagement ensures that the NSP responds appropriately to the needs of the population and fosters ownership of the plan. Since most of the stakeholders will be involved in the implementation of the NSP, it is important to ensure that they fully understand and contribute to its development.

1.5.5 Adapting the NSP at subnational level

Implementation of interventions included in the NSP mainly occurs at community and facility levels. Considering the diverse settings in most countries (e.g. heterogeneity of populations, geographical variations, infrastructure, local health financing mechanisms, and TB disease burden and determinants), it is crucial to consider these variations and adapt the national plan at subnational level. The subnational planning process depends on the degree of devolution of the health governance system. Lessons learned from implementation of previous plans can also help to inform the administrative levels of the health system which should participate in the planning process.

1.5.6 Promoting quality care that is effective, safe and people centred

WHO promotes quality care across the health system (12). Data suggest that inadequate quality of care is responsible for significant mortality in low- and middle-income countries (13). The WHO handbook

BOX 1.1 WHO MAF-TB

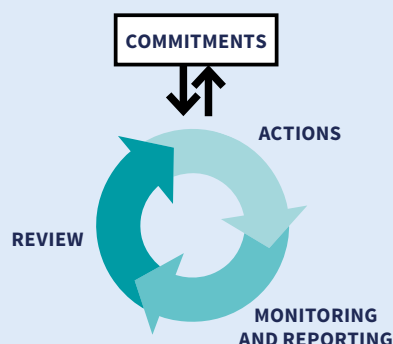


The WHO MAF-TB aims to accelerate progress to end TB by supporting and strengthening the TB response beyond the health sector, and the accountability of governments and all stakeholders at global, regional and country levels. Civil society, TB-affected communities and patient groups play a fundamental role in the adaptation and implementation of this framework. The framework has four components: national commitments made, actions taken on those commitments, monitoring and reporting approaches, and progress on any high-level multisectoral collaboration and review mechanisms.

MAF-TB cycle and elements

Launched in 2019, the MAF-TB document (11) outlines the components, elements and principles of the framework. It also includes checklists and annexes to support countries in assessing the status of the TB response and the accountability of ministries and governmental bodies (Annex 1), the engagement of civil society and affected communities (Annex 2), and the adaptation and implementation of WHO TB guidelines. The checklist supports Member States and their partners to identify which multisectoral components already exist in the country, which need strengthening, and which do not yet exist but are relevant and should be put in place. This assessment should involve, for example, government ministries and institutes, local government, civil society, TB-affected communities, parliamentarians, the private sector, public-private partnerships (including product development partnerships), philanthropic organizations, professional associations, research institutes and universities (and associated research networks). Information generated through MAF-TB baseline assessments should also contribute to the situation analysis for the NSP (15).

Informed by the baseline assessment, countries can design interventions to strengthen the four components of the framework according to their national constitutional, legal or regulatory frameworks and other relevant factors. These interventions should be reflected in the NSP.



MAF-TB: multisectoral accountability framework to accelerate progress to end TB by 2030; NSP: national strategic plan; TB: tuberculosis; WHO: World Health Organization.

for national quality policy and strategy highlights the need to address quality in disease programmes (14). It outlines interventions for integration of strategies for such quality (including in TB programmes, which can also act as pathfinders for system-wide efforts to address quality of care).

1.6 Components of an NSP

A TB NSP comprises the key components outlined below. These components are interconnected parts of a single plan and should be collectively developed as part of the overall strategic planning process. Steps to develop these components and their proposed contents are described in [Chapter 2](#) and [Chapter 3](#), respectively.

- ▶ *Situation analysis* – this includes an analysis of all key sociodemographic, cultural, economic, epidemiological, political, institutional and governance aspects that have implications for the country’s TB epidemic and response.
- ▶ *Goal(s), objectives and strategic interventions* – these present the overall strategic vision and direction of the plan.
- ▶ *Activities and subactivities* – these include the key actions, and they should reflect the inputs and technical expertise required for implementation of these actions.
- ▶ *Contingency measures* – these are measures to be activated in case of major disruption to service provision.
- ▶ *Monitoring and evaluation* – this includes indicators to track the goal(s), strategic objectives, interventions and key activities, to inform improvement in coverage and quality of services.
- ▶ *Costing and resource mapping* – this includes the costs for each intervention, activity and subactivity, and other inputs needed to implement the NSP.

CHAPTER 2

Process for developing a TB NSP

2.1 Overview

This chapter describes the process for developing an NSP. The proposed steps should be adapted to the country context, considering the good practices outlined in **Chapter 1**. The process is articulated in six phases, from planning and preparation, to consensus, endorsement and dissemination of the plan. Although the process is presented as a series of sequential steps, many of the steps overlap and are iterative; therefore, it is preferable for the teams responsible for developing different components of the plan to be involved throughout the planning process.

Fig. 2.1 outlines the steps for developing an NSP. The indicative timeline for the entire process is 6–12 months; however, in practice this may vary.

2.2 Phase 1 – planning and preparation

This phase involves:

- ▶ establishment of a core organizing team;
- ▶ development of a detailed roadmap for the NSP development process; and
- ▶ mobilization and confirmation of resources for the strategic planning process.

These steps are discussed below.

2.2.1 Establishment of a core organizing team

A core organizing team will serve as the secretariat for the NSP development. This team is usually coordinated by the national TB programme (NTP), and its functions will include:

- ▶ developing a costed roadmap for the NSP development process and mobilizing the required resources for that process;
- ▶ conducting stakeholder mapping and coordinating stakeholder consultations;
- ▶ providing feedback and scheduled process updates to the leadership of the MOH and key decision-makers in other sectors, to ensure that senior manage-

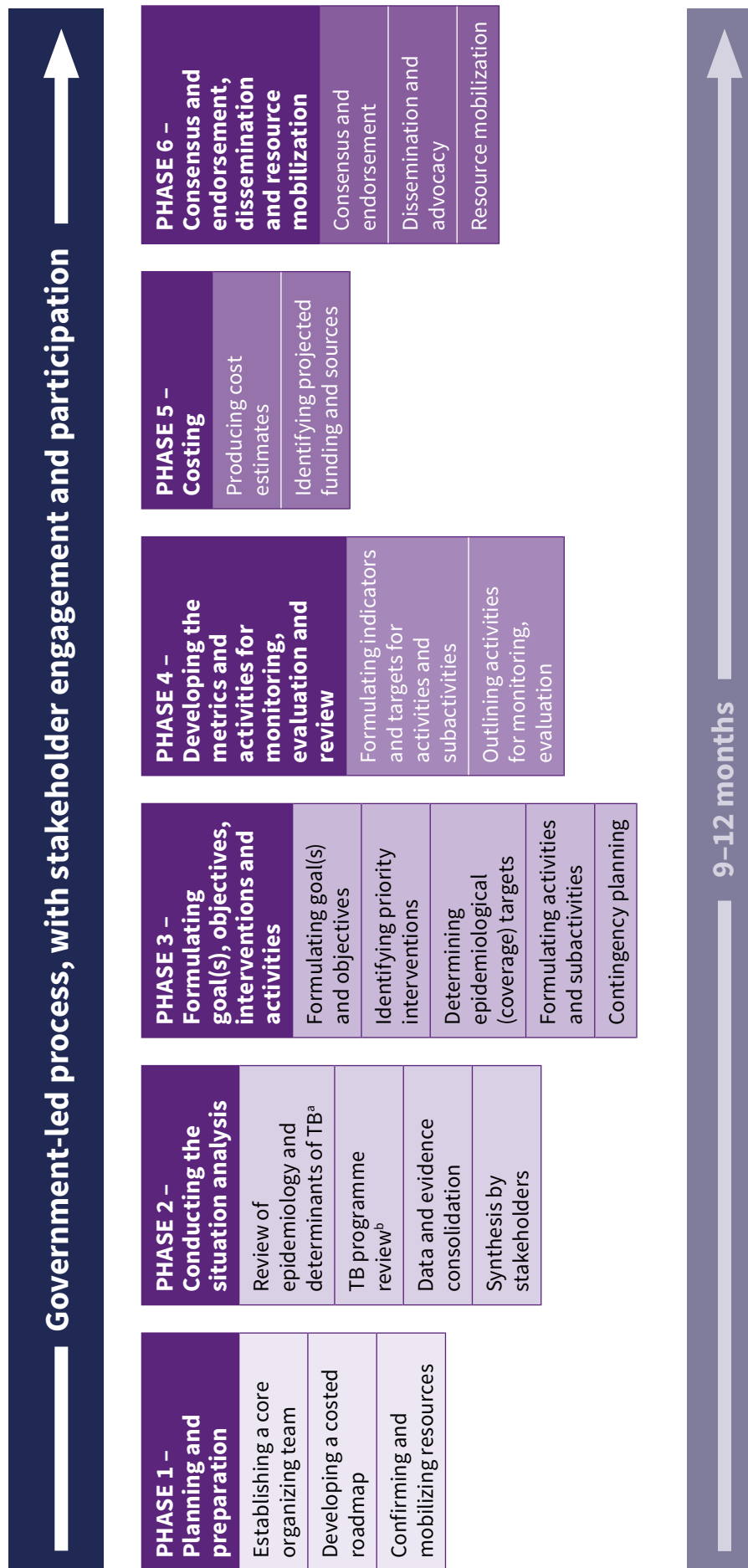
ment are involved and provide leadership throughout the process; and

- ▶ ensuring that all stakeholders are well informed and updated throughout the NSP development process.

The core organizing team should comprise 15–20 people who will oversee and manage the day-to-day process of NSP development, and members should represent the key offices relevant to the planning process. The core team differs from the broader stakeholders who will be involved at various stages of the planning process. It should include representatives from the office or offices of the MOH responsible for planning and budgeting, and from other key sectors relevant to the planning process. Indicative membership of the core team includes the following:

- ▶ A senior manager from the MOH, who will lead the planning process. This should be someone with adequate authority to coordinate across different departments in the MOH (e.g. managers responsible for planning or disease control programmes). Although high-level leadership of the process is ideal, this should be balanced with availability because the process is time-consuming, and it may not be feasible for high-ranking officials to dedicate the required time.
- ▶ Three to five representatives from the NTP, identified to ensure a balance between attending to the strategic planning process and ensuring that other key programme activities continue to receive attention.
- ▶ At least one representative from the department(s) responsible for planning and finance.
- ▶ Two or three representatives from civil society and communities affected by TB and TB comorbidities, and advocates of the key social determinants of TB.
- ▶ Representatives from key development partners within and beyond the health sector (the number of such representatives varies).
- ▶ Others as necessary, based on the country's planning processes.

Fig. 2.1 Summary of the process for NSP development



MOH: ministry of health; NSP: national strategic plan; TB: tuberculosis.

^a This includes review of social determinants.

^b This includes review of aspects of the health system as well as other sectors that are relevant to the country's TB response. This can be primarily informed by a desk review of the relevant reports, as well as inclusion of the most pertinent aspects in the TB programme review.

2.2.2 Development of a costed roadmap for the NSP development process

The roadmap for the NSP development process should outline the following:

- ▶ Key timelines and milestones from initiation of the process to final endorsement of the NSP by national authorities.
- ▶ Detailed identification and mapping of stakeholders (**Box 2.1**) – including civil society, communities affected by TB and TB comorbidities, and advocates of key social determinants of TB (e.g. nutrition and housing) – and identification of stakeholders who may need preliminary sensitization if they have not been engaged in the TB response, especially from sectors beyond health (the roadmap should include deliberate steps and resources to sensitize these stakeholders).
- ▶ Estimated financial and technical resource needs for the process of NSP development, including relevant technical expertise to develop the various aspects of the strategic plan.
- ▶ Endorsement of the roadmap by relevant MOH offices and existing bodies for multisectoral and multistakeholder coordination of the TB response.

2.2.3 Confirming allocated funding and mobilizing additional resources for the strategic planning process

The resources needed for the process of developing the strategic plan should be quantified, and available resources identified and mapped. The plan should also provide details of any resource gaps and additional technical capacities that will need to be externally sourced. The domestic and external resources allocated for the NSP development process should be mapped and confirmed, and local and international partners should be engaged as necessary to help address any gaps in funding and technical assistance.

Key resources needed will be informed by the roadmap – they could include financial resources for the situation analysis (e.g. relevant desk reviews, epidemiological analyses, programme reviews and evidence consolidation); facilities for stakeholder consultations (e.g. venues and travel costs for stakeholders); technical assistance (e.g. local and international external experts); training and orientation of key stakeholders; and information technology (IT) equipment (e.g. computers and internet access).

Many of these resource needs can be met using existing infrastructure. In addition, stakeholders can assist by providing meeting venues and transporting their staff

(such resources should still be costed and documented, so that stakeholders' contributions to the planning process are duly acknowledged).

2.3 Phase 2 – conducting the situation analysis

The NSP needs to consider the factors influencing the TB epidemic, and the purpose of the situation analysis is to systematically collect and study information that will facilitate the development of such an NSP. The analysis of the information collected enables stakeholders to gain a deeper understanding of opportunities, challenges and barriers, which in turn can inform interventions to address TB in the country. The situation analysis should cover all pillars and components of the End TB Strategy (2), identifying the key gaps across all relevant sectors.

As a minimum, the situation analysis should include:

- ▶ epidemiological review of TB and review of social determinants of TB;
- ▶ TB programme review and review of relevant components of the health system;
- ▶ consolidation of data and evidence; and
- ▶ synthesis of situation analysis by stakeholders.

These steps are discussed below.

2.3.1 Review of epidemiology and determinants of TB

An **epidemiological review** is performed to provide background information about the burden of TB and the characteristics of the TB epidemic in the country. It also provides an overview of the TB surveillance system and activities that are necessary to strengthen surveillance and measurement of TB burden.¹ The review comprises an epidemiological analysis to assess the level and trends of TB burden in the country, and an evaluation of the capacity of the surveillance system to directly measure the burden of TB and its distribution across the population. It includes the use of a standardized checklist comprising standards and associated benchmarks to systematically assess data quality, systems coverage, TB mortality and surveillance of TB (including drug-resistant TB, most relevant comorbidities and vulnerable populations) (18). Ideally, the epidemiological review should be conducted before the programme review because some of the findings may require further exploration during the programme review.

¹ Implementation guidance for national TB epidemiological reviews.

Box 2.1 Stakeholder mapping and engagement

Overview

Stakeholders in strategic planning can be defined as people or groups who are affected by, can influence or may have an interest in the strategic plan (16). Stakeholder mapping is the process of identifying the key stakeholders relevant to the country's TB response. Stakeholder mapping is a dynamic process that should be comprehensively and effectively carried out at all stages of strategic planning and implementation. Stakeholder engagement is an approach that results in meaningful participation of intended key actors in a process. Depending on the role of the stakeholder, this participation may include all aspects of the planning process or just selected aspects.

Stakeholder mapping

Stakeholder mapping is an ongoing process that should be informed by the findings at every stage of the planning process. However, it is useful to pre-determine the key stakeholders who will be involved in implementation of the strategic plan, based on the epidemiology of TB, the social determinants, the most relevant actors beyond the health sector, the institutional arrangements for management of TB, and lessons learned during implementation of the preceding plan.

The outline of the situation analysis presented in [Section 2.3](#) can be used to inform the stakeholder mapping, with stakeholders relevant to each aspect of the situation analysis being identified and listed. There are three broad categories of stakeholders: the state (politicians and policy-makers), service providers, and clients or citizens (17). Key considerations for stakeholder mapping include the following:

- ▶ Listing the stakeholders for each aspect of the situation analysis. The “snowball” approach (i.e. asking stakeholders to help in identifying others who should be involved) can be used to ensure that the list of stakeholders is comprehensive.
- ▶ Mapping the stakeholders already engaged in the management of TB and the ones yet to be engaged (the strategies for engaging these two groups will be different).
- ▶ Deciding on a targeted engagement approach for each of the stakeholders (e.g. government stakeholders usually require formal letters to negotiate the bureaucracy, whereas NGOs and representatives of civil society can be engaged through less formal means).

Establishing the interests and stakes of the respective stakeholders in being part of the strategic planning process. This is useful, because it often has implications for the level of seniority of those

participating in stakeholder consultations. It is helpful to identify in advance how the TB planning process can potentially also progress the agendas of the respective stakeholders, because the stakeholders are likely to be more actively involved if engagement also contributes to the achievement of their own objectives.

Key principles for successful stakeholder engagement (16)

Meaningful stakeholder engagement requires mutual recognition of the organizational and institutional mandates, and mutual trust and commitment to a shared vision. The following principles may help to facilitate meaningful stakeholder engagement and accountability:

- ▶ *High-level government leadership and oversight of the strategic planning and implementation.* The strategic planning process should be overseen by the highest possible government office beyond the TB programme. This provides the administrative authority to engage key decision-makers in other MOH departments and in other government ministries and agencies, and stakeholders beyond the health sector.
- ▶ *Understanding of the mandates and perspectives of the partners and stakeholders.* There are often areas where the NTP can meaningfully engage and contribute to the achievement of the mandates of other sectors, to create a symbiotic relationship with benefits for sustainable engagement.
- ▶ *Building on existing collaborative platforms.* Engagement of stakeholders should be done without creating an administrative overload for the partners and stakeholders.
- ▶ *Engaging in dialogue with stakeholders as equals – valuing their knowledge and perspectives.* Stakeholders should be given the opportunity to have internal consultations and help to determine their own engagement in the planning process.
- ▶ *Acknowledgement that stakeholders will differ in their roles or desire to be involved.* It is not possible (or necessary) for all stakeholders to be involved all the time. Careful stakeholder mapping and engagement should consider the impact of stakeholder influence and the relationship dynamics between stakeholders.
- ▶ *Engaging all key stakeholders throughout the planning, implementation and review cycle.* This engagement should give stakeholders opportunities to influence the course of the planning process and to be embedded in the coordinating team where possible.

Continued ▶

- ▶ *Making use of intermediaries who are connected to, and trusted by, different stakeholder groups.*
- ▶ *Ensuring that communications can be easily understood by all stakeholders.* This can be achieved, for example, by avoiding complex or technical language during stakeholder engagement.
- ▶ *Providing timely feedback and updates to stakeholders.* This should include stakeholders who may not be able to attend the consultations.
- ▶ *Providing basic information and data to demonstrate the role of the various sectors in the TB response.* Ideally, partners should be able to determine their own role and propose interventions that will form part of the strategy.
- ▶ *Engaging and involving key opinion leaders at all levels.* It is particularly important to ensure that voices from the periphery are adequately listened to and considered.
- ▶ *Comprehensively mapping and allocating resources for all interventions in the NSP.* This should include mapping and resources implemented in other sectors.

MOH: ministry of health; NGO: nongovernmental organization; NSP: national strategic plan; NTP: national TB programme; TB: tuberculosis.

The aim of the **review of TB determinants, including social determinants** is to identify the most important factors that are key drivers of the TB epidemic, the distribution and weight of those drivers, and the bodies beyond the health sector responsible for tackling them. In addition to biological factors, the review comprises social, economic and anthropological analyses of the influence of the different determinants on the TB epidemic. The data collection and analysis cover a broad range of areas, from the person's individual characteristics and behaviours to housing and employment, food insecurity, stigma, discrimination and gender barriers. This component of the situation analysis will inform multisectoral actions on TB biological and social determinants.

2.3.2 TB programme review and review of relevant components of the health system

A comprehensive programme review¹ is usually performed to assess the implementation of an NSP, evaluate health system factors that need to be addressed to optimize the country's TB response, and address bottlenecks affecting the achievement of targets. The review outlines achievements made by the programme, and best practices and challenges in implementing the NSP. It should preferably be conducted at the end of every strategic plan, so that gaps in implementation of the previous strategy are considered during the planning. The review should also draw from other relevant reviews; for example, health system reviews and reviews of programmes for relevant comorbidities (e.g. reviews of programmes for noncommunicable diseases and HIV).

The key components that should be covered during the programme review to inform a comprehensive situation analysis that aligns with the End TB Strategy are covered in **Chapter 3** of this guidance.

2.3.3 Data and evidence consolidation

Data consolidation refers to the organization of data from multiple sources, to assess and identify gaps to be addressed by the strategic plan. Although this process may take a considerable amount of time and effort, it is essential to facilitate optimal use of available data for the planning process, and transparent discussion and deliberation of the rationale for the interventions to be included in the strategic plan. The *Compendium of data and evidence-related tools for use in TB planning and programming (19)* summarizes information on key tools that can contribute to data and evidence for strategic planning. Data to be consolidated include the following:

- ▶ *The burden of TB, including its distribution (e.g. by age, sex, geographical location and population subgroup) and trends, drug resistance, key determinants and risk factors.* Examples of sources of these data are national surveillance systems, national surveys of TB prevalence and drug resistance, national TB inventory studies, and regional and global TB reports.

¹ The programme review in this context refers to a comprehensive review of the implementation of the NSP, typically structured to cover the entire country; it is usually performed as an end-term review of the NSP but can also be performed at mid-term. This review should not be confused with the regular (quarterly, biannual or annual) review meetings conducted mainly for operational planning and for monitoring the implementation of activities in the NSP.

- ▶ *The TB social determinants*, including their weight in different vulnerable populations across the country, recent trends, and the impact of previous or ongoing interventions. To obtain a comprehensive picture of the social determinants, data from the MOH will need to be supplemented with data available in relevant governmental and nongovernmental offices and agencies dealing with the relevant TB determinants.
- ▶ *Health system capacity, accessibility and performance in providing quality, holistic, people-centred services*. Examples of sources of data include health system reviews, TB cascade of care analyses, reviews conducted for specific health system components (e.g. laboratory and surveillance), MAF-TB assessments, reviews of the TB programme and other disease programmes, service availability and readiness assessments, health expenditure and use surveys, service delivery costing studies, relevant operational or implementation research, patient experience surveys and relevant policy documents (e.g. social protection policy).
- ▶ *Service use, including behavioural, socioeconomic and structural barriers to accessing TB services*. Examples of sources of data are adherence studies, patient pathway analyses, national surveys of TB prevalence, demographic and health surveys, national surveys of costs faced by TB patients and their households, reviews of human rights, gender, ethics, stigma and discrimination, surveys or reviews on nutrition and other risk factors, relevant operational or implementation research, and data on community-led monitoring.
- ▶ multisectoral and multistakeholder collaboration, including participation and engagement of communities, civil society, and all public and private care providers in the implementation of TB policies and strategies, provision of TB services, and monitoring and evaluation (M&E);
- ▶ UHC and social protection schemes, and actions on social determinants of TB;
- ▶ infection prevention and control (IPC) measures; and
- ▶ research and innovation.

2.3.4 Synthesis of the situation analysis

Once the above processes have been completed, the next step is to bring together all key stakeholders (as determined by the stakeholder mapping) to discuss and add relevant context to the data and evidence obtained from the preceding steps. The stakeholder consultation should also facilitate discussion and common understanding of the key gaps and challenges that need to be addressed (e.g. through meetings and targeted consultations with key informants – the modalities will depend on the country context, particularly the degree of devolution of the political and administrative system). Countries with devolved governments will generally need consultations at subnational level (state, regional, county, provincial or district), whereas countries with centralized systems can have national consultations with representation from subnational levels. Lessons learned from implementation of previous strategic plans can also inform how these consultations should be organized. For example, if specific initiatives were not implemented in the previous strategic plan because of lack of buy-in from key stakeholders, the consultations should be structured to ensure active engagement of those stakeholders.

Stakeholder consultation is a critical step to ensure that the data and evidence are contextually interpreted and analysed. The main objectives of stakeholder consultations at this stage are to:

Data consolidation

WHO developed the PCF, to organize data and information on TB along the continuum of care (20). The approach facilitates the systematic use of evidence to inform discussion on and identification of gaps and their root causes along the patient care pathway. Guidance on how to conduct data consolidation can be found in Annex 2 of the framework user guide (20). The PCF can also help to identify gaps in data and information along the continuum of care, to inform determination of research priorities for the strategic plan.

To assess comprehensive implementation of Pillar 2 and Pillar 3 of the End TB Strategy, additional data, information and evidence in the following areas should be collated:

- ▶ political commitment and availability of resources for TB services;
- ▶ share with all stakeholders information obtained from the various reviews (epidemiological, social determinants, TB programme and relevant health system components), and from evidence and data consolidation;
- ▶ conduct root cause analyses to identify the underlying causes of observed challenges and gaps, and the enabling factors for observed successes and achievements;

- ▶ ensure that all key stakeholders relevant to the identified challenges, bottlenecks and successes are represented in the consultations; and
- ▶ reach consensus on the key challenges and gaps to be addressed during the strategic planning process.

Examples of programmatic and data gaps identified along the continuum of care are given in [Table 2.1](#) and [Table 2.2](#). These are provided as indicative examples only; in practice they will need to be disaggregated as much as is possible to inform targeted interventions to address the gaps.

The identified programmatic gaps and data and evidence gaps will be complemented by the perspectives of representatives of stakeholders, including affected communities, civil society, other key informants, technical experts and others as locally relevant. Although some of the interventions appear obvious at this stage, the focus should primarily be on ensuring that all key stakeholders have a common understanding of the issues and their underlying causes and facilitating factors. The NSP development roadmap should therefore dedicate adequate time for these discussions, acknowledging that some stakeholders will need time to fully comprehend the issues. The consultations should be carefully managed to ensure that technical experts or lobbyists do not dominate the discussions or rush the process, potentially leaving other stakeholders behind.

It is important to carefully plan for engagement of affected communities and civil society. Usually, additional steps will be required to empower and communicate with community and civil society groups, to enable meaningful participation in the stakeholder discussions and consultations.

Root cause analysis

Once gaps have been identified, root cause analysis ([Box 2.2](#)) is conducted to understand related determinants and causes for each gap. This analysis often reveals determinants and causes beyond the immediate purview of the MOH (e.g. poverty, food insecurity, stigma, or unfavourable legal or regulatory frameworks). To ensure that root causes are fully explored, all key stakeholders should be engaged during the analysis (*11*).

Identifying domains of action

Once determinants, causes and root causes of problems have been identified, the groups are asked to identify priority action domains to inform the development of strategic interventions. Questions that can be used when identifying priority action domains are:

- ▶ What factors can feasibly be addressed?
- ▶ If factors are addressed, which would have the most impact on the problem (and are therefore priority action domains)?

Box 2.2 Conducting root cause analysis

Participants at the consultative workshop can work in small groups to identify determinants, causes and root causes of the identified gaps and challenges for each component of the continuum of care, and in the supporting systems and policies ([Tables 2.1 and 2.2](#)). Groups may be formed to address issues for specific population groups; for example, issues associated with low diagnostic capacity may differ between adults and children, or a vulnerable population may have specific determinants or root causes for the identified problems.

The groups are asked to review and consider the available data and information, and apply their knowledge and understanding of the situation.

The methods for analysing root causes include fishbone (*21*), five whys (*22*) and a causal tree (*23*). In all methods, there is sequential probing of “why” a problem exists. Each response to a “why” prompt can be considered a determinant or cause of the problem, which can then inform the identification of a domain for action. Eventually, sequential exploration of “whys” will reveal the root cause, which is frequently an economic or social constraint beyond the scope of a TB-specific response. The perspectives of the relevant stakeholders will be important in helping to define the contribution that the TB strategic plan can make to addressing these determinants.

Each problem usually has many valid determinants or causes, or a single cause with many contributing factors that differ by geographical region or care sector; thus, root cause analysis needs to include all relevant levels. Although it can be tempting to rush from problem analysis to intervention planning, this risks leaving behind some of the stakeholders and limiting the exploration of the underlying issues, and hence possible options for addressing the root causes. Time should be invested to ensure that all stakeholders have a clear understanding of the problems to be addressed.

TB: tuberculosis.

Table 2.1 Example of a national evidence consolidation matrix with indicative programmatic gaps for Pillar 1 of the End TB Strategy^a

	People not accessing the health system			People with TB seeking care but either not diagnosed or not notified		People with TB notified but not successfully treated		People completing treatment for TB		
	People with TB infection and at high risk for disease	Asymptomatic disease, not seeking care	Symptomatic disease, not seeking care	Presenting to health facilities, not diagnosed	Diagnosed by non-NTP providers, not notified	Diagnosed by NTP, not notified	Diagnosed, not started on treatment	Started on treatment, not successfully treated	Successfully treated, but not relapse free	Successfully treated, but with TB-associated disability
General	Less than 1% of household contacts aged ≥5 years receive TPT	High (42%) proportion of people with TB who screen negative for TB symptoms but have abnormal X-ray results	Only 58% of people with TB symptoms seek care	61% of TB cases are smear negative	About 30% of incident cases are not detected or notified The estimated level of TB underreporting is 41%		10% of people diagnosed with TB are not started on treatment	27% of new and relapse cases are not successfully treated	2% of people successfully treated relapse within 2 years	5% of people successfully treated for PTB have significant disability according to predefined criteria
DR-TB		69% of DR-TB cases are new patients, suggesting primary transmission		65% of new and relapse TB patients are not tested with WRDs at diagnosis 30% of people with MDR/RR-TB do not have second-line DST	Only 26% of incident MDR/RR-TB cases are notified		24% of diagnosed MDR/RR-TB are not started on treatment Median treatment delay for DR-TB from diagnosis is 41 days	41% of people with MDR/RR-TB are not successfully treated		40% of people treated for MDR/RR-TB have significant pulmonary function impairment at the end of treatment
Vulnerable populations (children presented here as an example only)	Only 4% of the estimated children aged <5 years who are contacts of TB patients receive TPT				54% of children (<15 years) diagnosed with TB are not reported		15% of children (<15 years) diagnosed with TB are not started on treatment	10% of children (<15 years) started on treatment for TB are not successfully treated		40% of children with TB meningitis have neurological sequelae

	People not accessing the health system			People with TB seeking care but either not diagnosed or not notified			People with TB notified but not successfully treated			People completing treatment for TB	
	People with TB infection and at high risk for disease	Asymptomatic disease, not seeking care	Symptomatic disease, not seeking care	Presenting to health facilities, not diagnosed	Diagnosed by non-NTP providers, not notified	Diagnosed by NTP, not notified	Diagnosed, not started on treatment	Started on treatment, not successfully treated	Successfully treated, but not relapse free	Successfully treated, but with TB-associated disability	
TB comorbidities (TB/HIV presented here as an example only)	40% of the estimated people with both TB and HIV are diagnosed annually			10% of people living with HIV were not screened for TB at the last visit 12% of notified people with TB do not know their HIV status			47% and 44% of people with both TB and HIV are being treated with ART and CPT, respectively	33% of people with both TB and HIV are not successfully treated for TB	3% of people living with HIV treated for TB relapse within 2 years		
Data or evidence gaps	Burden of TB in specific sub-populations Burden of selected comorbidities among people with TB	Health-seeking behaviour, particularly among vulnerable populations	Screening and linkage to diagnosis among vulnerable populations	Diagnosis and treatment outcomes for people seeking care in the private sector	Proportion of people who are diagnosed but not notified, but still access TB treatment	Proportion of people who are lost to follow-up before initiation of treatment	Disaggregated data on treatment outcomes for vulnerable populations	Data on palliative and end-of-life care needs and services	Proportion of people with EPTB with significant disability Proportion of children with significant post-TB disability Proportion of people with MDR/RR-TB with significant post-TB disability		

ART: antiretroviral therapy; CPT: co-trimoxazole preventive therapy; DR-TB: drug-resistant TB; DST: drug susceptibility testing; EPTB: extrapulmonary TB; HIV: human immunodeficiency virus; MDR/RR-TB: multidrug-resistant or rifampicin-resistant TB; WRD: WHO-recommended rapid diagnostic test; NTP: national TB programme; PTB: pulmonary TB; TB: tuberculosis; TPT: TB preventive treatment; WHO: World Health Organization.

^a Values provided in the tables are for example purpose only, and do not represent real data.

Table 2.2 Example of a national evidence consolidation matrix with programmatic gaps for Pillars 2 and 3 of the End TB Strategy^a

End TB Strategy component	General health system	Services for people with TB	Data or evidence gaps
Resources for TB care and prevention	60% of the health sector budget is funded from government funding The vacancy rate for health workers is 30%	In 2021, 30% of TB financing came from domestic funding, 14% from international and 56% was unfunded	Human resources dedicated to TB services Subnational budget allocations to TB services
Engagement of communities, civil society organizations, and all public and private care providers	At a national level, informal private sector providers (e.g. pharmacies, drug sellers and traditional healers) are the first place of care seeking for over 30% of patients	37% of PHC facilities are linked to structured community services for TB 12% of people with TB who started treatment in 2019 received adherence support from community health workers 20% of people with TB are notified by private sector providers There is anecdotal evidence of stigma as a barrier to accessing TB services	Proportion of people diagnosed with TB in the private sector who are notified Data on treatment outcomes for people receiving treatment in the private sector Data on stigma as a barrier to accessing TB services
UHC policy and regulatory framework for case notification, vital registration, quality and rational use of medicines, and infection control	Essential medicines (including first-line anti-TB medicines) are available in 70% of PHC facilities 60% of health facilities have focal staff for IPC plans There is no vital registration system in use in the country	Only 30% of hospitals have airborne infection control plans 80% of health facilities reported stock-outs of key commodities for TB infection control during the past 12 months 80% of health facilities have facility TB registers in use Regulatory approval process for new TB drugs takes at least 18 months	Data on incidence of TB among health workers Data on quality of medicines at end-user level
Social protection, poverty alleviation and actions on other determinants of TB	There was a consistent decline in poverty from 47% in 2001 to 31% in 2014 (using the international poverty line) 50% of the population were covered by social protection floors or systems in 2016 Out-of-pocket expenditure on health was 40% in 2016	45% of people with TB and their households experienced catastrophic costs (85% among people with DR-TB), based on TB patient cost survey carried out in 2018 About 20% of people with TB were not covered by any type of health insurance	Proportion of people with TB with documented social assessment Data on social consequences of TB
Discovery, development and rapid uptake of new tools, interventions and strategies	-	Time to the introduction of a new laboratory test once approved by WHO is about 2 years	
Research to optimize implementation and impact, and promote innovations	Only 10% of the national health research agenda was funded	Only one of the three operational research projects developed by the NTP in 2016 was funded	Data on dedicated funding for TB research

DR-TB: drug-resistant TB; IPC: infection prevention and control; NTP: National TB Programme; PHC: primary health care; TB: tuberculosis; UHC: universal health coverage; WHO: World Health Organization.
^a Values provided in the tables are for example purpose, and do not represent real data.

The priority domains of action will inform the interventions to be included in the strategic plan. More details on factors to consider when selecting and prioritizing interventions are given in [Section 2.4.2](#) below.

2.4 Phase 3 – formulating goals, objectives, interventions and activities

Goals, objectives, interventions and activities are core to the NSP, and they can be defined through the steps explained below. Although they are presented as linear steps, some of the processes overlap, and some may continue throughout the planning and implementation cycle. Where feasible, most of the content required to populate the elements of the NSP should be obtained with engagement and input from stakeholders. Technical experts can support and guide the process by providing additional information and ensuring consistency with international guidelines and recommendations. This phase includes the following steps:

- ▶ defining the strategy – formulation of the goals and objectives;
- ▶ identifying and prioritizing the strategic interventions – this should be informed by the gap and the root cause analyses, taking into account the factors to be considered when selecting and prioritizing interventions;
- ▶ defining activities and subactivities – this should also include the technical expertise needed to operationalize the strategic interventions and objectives; and
- ▶ identifying key threats and opportunities – identification of the main threats and opportunities that will inform contingency planning.

2.4.1 Formulation of goals and objectives

The strategic plan should have at least one **goal** that outlines the long-term impact that is expected to be achieved by implementing the strategic plan. The End TB Strategy goals and targets provide a useful reference for defining the strategic plan goal or goals, and it is recommended that the goals be aligned to the national health sector plan goals where these are in place.

An example of a goal is, “reduce the incidence of TB to less than 20 per 100 000 per year by 2025”.

The strategic **objectives** are the outcomes that are to be achieved during the implementation of the NSP, and their achievement should contribute to achieving the goal or goals. A strategic plan would generally include

about 5–10 objectives, which should be ambitious and SMART (i.e. specific, measurable, attainable, realistic and time-bound), and formulated to respond to gaps identified during the situation analysis. Examples of strategic plan objectives are:

- ▶ increase the proportion of patients with multi-drug-resistant or rifampicin-resistant TB (MDR/RR-TB) who are successfully treated from 50% in 2020 to 80% in 2025; and
- ▶ ensure coverage with social protection for 100% of TB-affected people determined to be in need, by 2022.

2.4.2 Identifying priority interventions

The interventions broadly describe what needs to be done to achieve the set objectives. Each objective should have one or more interventions, informed by the gap and the root cause analyses. Once a common understanding of the key gaps and their causes has been reached, the stakeholders in the consultation meeting should propose domains of action to address the main causes and determinants of these gaps. For each priority domain identified for action, up to four high-level interventions should be identified. Examples of strategic interventions include:

- ▶ capacity-building for health workers;
- ▶ assessing and addressing TB-related stigma and discrimination;
- ▶ expanding coverage of rapid molecular testing for TB; and
- ▶ increasing access to social protection schemes for eligible people affected with TB.

Informed by the situation analysis and stakeholder consultations (and modelling data when available), the interventions that are most appropriate, cost-effective and feasible to address the identified gaps and challenges should be outlined. The following criteria should be considered in the discussion about interventions to be prioritized in the NSP:

- ▶ *magnitude of the gap being addressed* – in terms of severity, urgency and the population’s perception of the burden; for example, considerations for capacity-building for health workers would include:
 - the gap in the number of the different categories of health workers who require training (severity);
 - how soon this gap will need to be addressed based on the current implications for services (i.e. the urgency); and

- the perception of health workers and stakeholders (i.e. the population) regarding the capacity gaps that need to be addressed;
- ▶ *effectiveness of the intervention* – that is, the likelihood that the intervention will lead to the expected results;
- ▶ *fairness of the intervention* – based on the principles of ethics, equity and human rights;
- ▶ *acceptability of the intervention* – to both the implementers and the target population;
- ▶ *cost and cost-effectiveness of the intervention* – both affordability and value for money. Information on cost and effectiveness, and (if available) incremental cost-effectiveness, will be important when considering which interventions to prioritize at the intervention planning stage and to manage any funding shortfalls. Generic information on cost and effectiveness for most interventions is available from different sources, but should be adjusted to the local context.

To complement the above criteria, the following questions can be used to further inform the selection of interventions:

- ▶ To what extent is the intervention likely to have a positive impact on the burden of TB (mortality, incidence, morbidity and TB-related catastrophic costs)?
- ▶ To what extent is the intervention likely to have a positive effect on the outcomes and quality of care for people affected by TB?
- ▶ Is the intervention aligned to the national development plan or the national health sector strategy?
- ▶ What are the medium- and long-term impacts of the intervention?
- ▶ Does the intervention address the needs of vulnerable populations, including promoting human rights and equity? The intervention should have an adequate focus on these populations (e.g. TB screening and preventive therapy may benefit children, but this needs to be explicitly included in the intervention description, to inform the rating of this criterion).

Does the intervention respond to the problems perceived to be important by the affected communities and stakeholders?

Some of the tools that can be used to inform prioritization and optimization of interventions include the PCF and modelling (various types are often used, e.g. impact modelling and cost-effectiveness). In addition,

considerations of ethics, equity and human rights should inform the process, as discussed below. In practice, competing interests and power dynamics among stakeholders influence priority-setting and resource allocation practices, and should be considered in addition to the technical evidence and modelling provided for the prioritization process (24, 25).

The PCF

The PCF facilitates stakeholder discussion and understanding of the relative implications of the key gaps in the TB care continuum, and provides a basis for stakeholders to identify and propose domains of action to be considered when formulating interventions. Once interventions have been identified, the above criteria and questions can be used to further inform their prioritization. An example of an assessment of interventions for feasibility and impact is shown in [Box 2.3](#).

Modelling

TB impact modelling can be used to estimate and compare the potential health or non-health (equity, financial protection, poverty reduction) impact of implementing certain intervention scenarios.

When used, modelling should be done in line with the principles and good practices for country-level modelling (26). The absence of local data to inform impact modelling should not be used to downgrade the prioritization of interventions; evidence from other settings can also be considered in assessing the potential impact of an intervention. A formal modelling exercise is *not* a requirement to answer all questions around TB policy and programme strategy. [Box 2.4](#) outlines when to use a model.

Allocative efficiency modelling looks at achieving efficiency by maximizing health impact among competing health priorities within a given health budget. The first step is to cost the identified interventions, after which allocative efficiency modelling can be used to compare the cost-effectiveness of different scenarios and help to identify the package of interventions that will yield the largest overall health benefits for a given budget.

Evidence from economic modelling (e.g. from recent systematic reviews (27, 28), and cost-effectiveness studies (29–31) and analyses) can also be useful to inform interventions in the NSP.

Ethics, equity and human rights considerations

Although the PCF and modelling approaches are useful in informing discussions on the potential implications of various intervention options, development of the

Box 2.3 Example of assessing the feasibility and potential impact of several interventions

Group: diagnostics

Action domain: improve access to TB diagnostic services

Objectives

- ▶ Increase TB case detection rate:
 - ✓ Increase percentage of newly notified patients diagnosed using a WRD from 38% in 2017 to 70% in 2023
 - ✓ Increase coverage of DST to all previously treated TB patients (from 75% to 100%) and to 80% for newly diagnosed cases with bacteriological confirmation
 - ✓ Increase proportion of sites using a WRD for which a connectivity system has been established for electronic reporting to clinicians and to a digital reporting system (from 20% to 50%)

<p>1. Integrated sample referral systems:</p> <ul style="list-style-type: none"> ▶ establish policy and implementation framework across diseases and partners ▶ establish electronic tracking 	<p>2. Optimize diagnostic device placement and network structure:</p> <ul style="list-style-type: none"> ▶ undertake diagnostic network optimization analysis ▶ include engagement of private sector laboratories and providers 	
<p>3. Adopt chest X-ray and other new WHO-recommended tools and approaches within the patient diagnostic pathway:</p> <ul style="list-style-type: none"> ▶ link the GeneXpert LIMS or LIS to TIBU^a and DHIS ▶ link the stool kit for paediatric TB, sequencing, Omni^b and LAM 	<p>4. Remove cost barriers to TB diagnosis:</p> <ul style="list-style-type: none"> ▶ ensure all TB diagnostics are included in the national health insurance benefit package ▶ negotiate diagnostic pricing for the private sector ▶ partner with the MOH and other organizations 	

DHIS: District Health Information Software; DST: drug susceptibility testing; LAM: lipoarabinomannan; LIMS: laboratory information management system; LIS: laboratory information system; MOH: ministry of health; WRD: WHO-recommended rapid diagnostic test; TB: tuberculosis; WHO: World Health Organization.

^a TIBU is an application for digitalizing reporting and routine surveillance for TB in Kenya.

^b GeneXpert Omni is a portable testing system for TB.

Source: Adapted from Fig. A3.8 in WHO, 2019 (20).

Box 2.4 When to use a model

Modelling can provide a logical framework for TB burden projections, which can then be used to inform coverage targets (the number of people targeted by each intervention) and to assess the health impact (or non-health impact) of different intervention coverage levels for each intervention. Thus, models can add substantial value to support planning, advocacy and decisions on funding. To answer policy questions, modelling may be considered alongside other approaches, including direct extrapolation from empirical studies conducted in the setting, generalization from similar programmes or countries, and expert opinion.

If the goal is to predict future health outcomes or resource needs, any approach that is used will involve important assumptions. For example, predicting the outcomes of a programme by directly extrapolating from the results of a research study can make assumptions that health burden, care-seeking behaviour and the capabilities of health service providers are similar between the study and routine health services. In contrast, a formal model may allow future health outcomes to be predicted with more realistic assumptions. However, in answering many programmatic questions it may not be necessary to predict long-term health outcomes. For example, to identify the best approach to improve treatment completion it may not be necessary to estimate the impact on distal outcomes (e.g. survival); rather, it may be adequate to assume that improvements in treatment completion will lead to improvements in these other outcomes.

Compared with other approaches, a formal modelling study requires more time and effort to undertake and will require sustained engagement from local stakeholders if it is to generate useful policy advice. Given the costs and effort required, modelling is most likely to be useful where:

- ▶ decision-makers are considering an important policy decision (i.e. one that has substantial consequences for programme budgets or health outcomes, or that would restrict future policy options);
- ▶ policy options need to be considered in terms of their impact on long-term health and economic outcomes, rather than on more proximal outcomes that could be estimated using simpler methods;
- ▶ there is adequate funding, time, data and technical capacity to implement the modelling application; and
- ▶ there is strong engagement by relevant decision-makers, including willingness to commit the time to scrutinize modelling assumptions and scenarios, and to act based on modelling results.

TB: tuberculosis; WHO: World Health Organization.
Source: Adapted from WHO, 2018 (26)

NSP should also consider the values and perspectives of the affected communities and stakeholders. The proposed interventions should therefore consider the fairness criteria; they should also be ethically sound, be gender transformative and contribute to protecting human rights and promoting equity.

2.4.3 Determining epidemiological (coverage) targets

A key step in the planning process is to estimate the target population to be reached for each of the interventions. These coverage targets will have implications for both the scale and scope of interventions and the eventual cost of the plan. Target setting should consider multiple factors including the epidemiology of TB and its determinants, demography, economic performance, political developments, planned activities in other relevant sectors and the relative significance of TB in the country compared with other health priorities. Thus, there is no standard formula for setting targets; rather, they should be set by stakeholders based on the country context and available information.

The approaches proposed below outline some of the considerations that could inform target setting, focusing on TB notifications. Other targets can then be extrapolated from the estimated notifications, including “upstream” targets (e.g. number of contacts to be traced or to be offered TPT) and “downstream” targets (e.g. number of people to be provided with nutritional support or to be assessed for adverse drug reactions).

Projections of TB notifications

Target setting on future TB notifications at national or subnational levels should primarily be based on trends in recent notifications rather than estimates of incidence. Except for areas with small populations (where random variations in TB detection and reporting are expected), TB notification rates tend to change relatively slowly over time, with the main drivers of year-to-year changes in notifications being:

- ▶ trends in the underlying TB burden;
- ▶ demographic changes (e.g. population growth or movement);

- ▶ changes in the TB surveillance system;
 - changes in TB case definitions;
 - introduction of record deduplication (i.e. to avoid the same person being notified multiple times);
 - changes in the proportion of people diagnosed but not reported (e.g. the level of underreporting is expected to decline after systematic reporting processes have been improved); and
 - changes in the rate of TB diagnosis (through e.g. reductions in financial barriers to accessing health care, improvements in coverage of health and TB services, and other interventions such as active TB case finding).

Box 2.5 provides an example on how to estimate target setting for case notifications.

In countries that have experienced TB service disruption (e.g. due to the COVID-19 pandemic, natural disasters or military conflicts), leading to falls in notifications, a sensible default would be to project notifications to the level of notifications before the disruption. Decreases in case notifications during periods of service disruption will lead to an increase in prevalence and mortality, and probably a slight increase in incidence. The use of dynamic models (33), with support

from modelling experts, could help in predicting the short-term impact of TB service disruptions.

Accurate prediction of future changes in notifications resulting from improvements in the rate of TB detection is challenging. Three categories of interventions that may improve the rate of TB detection are considered here:

- ▶ active case finding in designated population groups;
- ▶ improvements in the population coverage of TB services, including use of more sensitive diagnostics (e.g. replacement of direct microscopy with Xpert® MTB/RIF or Truenat®); and
- ▶ improvements in the population coverage of health insurance and social protection schemes, allowing improved access to quality health care among households in the lowest income quintiles.

Active case finding

Active case finding among people readily accessing the health system (e.g. among hospitalized patients) will shorten the time to diagnosis, but will not necessarily significantly increase overall notifications in the future if most of those diagnosed through the intervention would otherwise have been detected and notified at a

Box 2.5 Example – projection of number of cases to be notified

Let us assume that a particular country (C) notified 1000 people with TB last year. By default, we may expect that about the same number of people with TB will be notified this year; however, changes may occur, depending on the anticipated impact of the various drivers listed above. Thus:

- ▶ if TB incidence rates are estimated to decline nationally at an annual rate of 2% and there is no evidence supporting a change in this trend, $1000 \times (1 - 0.02) = 980$ notifications are expected this year; and
- ▶ if the national population is growing at an estimated rate of 1% each year and there is no evidence supporting a change in this trend, we may expect $1000 \times (1 - 0.02 + 0.01) = 990$ notifications this year.

Let us assume no change in TB case definitions this year, but the introduction of record deduplication at the beginning of the year. For example, systematic record deduplication in Brazil led to an 8.4% reduction in TB notifications in 2004 (32).

Then let us assume that results from a recent inventory study in country C showed that 2% of the national TB database records of last year were duplicated entries and that 35% of the total number of people diagnosed with TB over the study period were not officially notified to public health authorities. A policy of mandatory notifications was introduced at the end of last year, as was corrective action to avoid underreporting of people diagnosed with TB – expected to lead to a reduction of underreporting to a level of about 10% this year (from 35% last year). The result is an anticipated increase in notifications of 25%, or $990 \times (1 - 0.02) / (1 - 0.25) = 1294$ cases, also accounting for the record deduplication.

Similar reasoning and calculations can be applied to a small number of subsequent years. However, ideally, projections would require annual updating because experience indicates that TB projections are seldom accurate, particularly when they forecast significant changes in notifications.

C: country; TB: tuberculosis.

later time, when symptoms had more fully developed. In this scenario the overall number of notifications does not change; it is the proportion notified through active case finding that increases, while the proportion notified through passive detection decreases. However, active case finding among population groups with poor access to health care (e.g. through financial or geographical barriers) may result in a sustained increase in notifications as compared with notifications before the intervention.

Ideally, active case finding interventions would be piloted in specific areas. Data on the yield of such interventions and their observed impact on overall notifications over time are then used to predict future changes in notifications in other areas where the same interventions are planned. If the targeted population groups are small relative to the entire population, it may be assumed that active case finding is unlikely to result in a notable change in future notifications.

More sensitive diagnostics

The effects of replacing smear microscopy for TB diagnosis with rapid and more sensitive diagnostics may include:

- ▶ increasing the proportion of notifications that have bacteriologically confirmed disease (and increasing access to drug susceptibility testing [DST]);
- ▶ reducing the time to diagnosis and treatment (reducing the chance of death or long-term TB sequelae); and
- ▶ increasing notifications in settings where physicians were previously reluctant to notify people clinically diagnosed with TB.

The net effect on notifications is difficult to predict; thus, data from piloted areas should be analysed. There is little evidence linking roll-out of WHO-approved rapid molecular diagnostic tests to systematic increases in notified cases. In the absence of empirical data from piloted areas, no assumption should be made about future changes in the number of notifications caused by the roll-out of rapid diagnostics.

Access to health care

Improvements in health insurance and social protection coverage will result in increased TB notifications because more people may access health services in both the public and private sectors. Such improvements may also lead to an accelerated decline in TB burden because of a reduction in important socioeconomic risk factors for TB (including poverty). Empirical data from piloted areas or newly covered population groups should be used to inform target setting for TB.

Preventive treatment

Current recommendations for TPT target a small proportion of the total number of infected individuals (mostly household contacts of people with bacteriologically confirmed pulmonary TB, and people receiving HIV care). The impact of a national preventive treatment strategy will probably be modest until its coverage expands; its impact on reducing incidence and thus notifications in the short term may be assumed to be negligible for the purposes of projecting notifications.

Subnational projections

In the absence of results from population-based surveys, many countries have relied on national estimates of incidence published by WHO (34), distributing the published estimated count of incident cases across geographical areas based on population size. Because TB incidence rates are generally not distributed homogeneously across geographical areas, the practice leads to overestimation of true incidence in areas with a lower burden and vice versa; this can have adverse consequences when local targets and budgets are based on such estimates. Hence, subnational projections should be conducted as described in **Box 2.5** with no reference to uncertain subnational estimates.

Sample projections of notifications of rifampicin-resistant TB

Having projected the number of notifications, calculating the subset of notifications that will have a confirmed diagnosis of rifampicin-resistant TB (RR-TB) is straightforward:

- ▶ Let us start with the 1294 notifications projected next year from **Box 2.5**.
- ▶ Last year, 50% of notifications had a bacteriological confirmation of their diagnosis; among those notifications, 60% were tested for rifampicin susceptibility.
- ▶ This year, a slight increase in bacteriological confirmation (up to 55%) is expected from a roll-out of WHO-recommended rapid molecular diagnostic tests in new districts, with 80% of people with bacteriologically confirmed TB expected to be tested for rifampicin susceptibility; that is, $1294 \times 0.55 \times 0.8 = 570$ people with DST results.
- ▶ Data from a recent drug resistance survey indicate that 3% of new cases and 12% of previously treated cases have RR-TB. Last year, 80% of notifications were new. Thus, the expected number of people with RR-TB that will be detected this year is $570 \times [(0.8 \times 0.03) + (0.2 \times 0.12)] = 28$ people.

Incidence estimates for RR-TB

National estimates of incidence of RR-TB published by WHO are not suitable for the purposes of target setting for RR-TB because:

- ▶ these estimates include forms of TB not detectable with the current technologies (even in high-income countries, about 20% of people diagnosed with pulmonary TB have no bacteriological confirmation of their diagnosis); and
- ▶ there is a large degree of uncertainty attached to RR-TB incidence estimates, particularly in countries with weak TB surveillance and outdated information on levels of drug resistance.

Experience indicates that targets set for detection of RR-TB based on RR-TB incidence estimates are unattainable; thus, failure to meet such targets may lead to incorrect conclusions of poor programme performance.

2.4.4 Formulation of activities and subactivities

Activities and subactivities to be implemented under each intervention to achieve the objectives should be developed, and should contain sufficient detail for practitioners at each level of the health system to know what they are responsible for (8). This is also referred to as operational planning, and the frequency of updating the operational or implementation plan will be determined in part by the duration of the NSP, the budgeting cycle and the predictability of the operational environment. This guidance recommends an operational plan to cover the duration of the NSP, with the first year or two being the most detailed. However, this increases the uncertainty when the NSP covers a long period (e.g. 5 years or more); in such cases, a mid-term review of the NSP can be used to review and update the operational plan if necessary.

The level at which operational planning takes place, and whether a top-down or a bottom-up approach is adopted, depends mainly on the level of devolution of the health system. The TB planning process should align as much as possible with the country's overall operational planning process. Whichever approach is used, it is important to engage subnational stakeholders, decision-makers and managers who will be responsible for overseeing the day-to-day implementation of the activities during this process.

For each of the strategic plan interventions, the activities that will need to be implemented should be listed. To inform quantification and clear understanding of the inputs, and to facilitate implementation planning, some of the activities will need to be broken down into

subactivities. For each activity and subactivity, the required inputs should be identified and listed, and the target population specified and quantified (informed by the gap analysis and the projected targets, as highlighted above).

Examples of activities are:

- ▶ organizing training workshops for health facility managers in all provinces on airborne infection control (this activity may not require subactivities); and
- ▶ conducting an end-term programme review of the implementation of the strategic plan (this activity may need to be broken down into subactivities to inform costing).

For each activity, at least the following details should be included:

- ▶ timing (when the activity will take place, whether once-off or periodic);
- ▶ quantity, both in terms of the number of episodes (e.g. number of trainings) and the target population or entities (e.g. number of health workers) to be covered for each episode;
- ▶ the person or people and the office or offices responsible for the activity;
- ▶ the resources required, including financial resources and any additional technical support, and the source of those resources; and
- ▶ methods and indicators for measuring progress (monitoring).

Operational planning should be flexible and responsive, with annual and mid-term reviews being used to refine the planning based on lessons learned and other developments in the operational environment.

2.4.5 Contingency planning

Overview

In addition to the activities included as part of operational or implementation planning, the NSP should detail contingency measures to be taken in the event of major disruption to the provision of TB services. These measures should be developed alongside the NSP, and they should include actions to mitigate potential threats to the continuity of TB services, identified during the situation analysis.

Since 2019, the COVID-19 pandemic has had enormous health, social and economic ramifications globally. The pandemic has significantly affected the global response to health priorities including TB, reversing recent progress towards the achievement of the SDGs.

Most high TB burden countries reported large falls in TB notifications in 2020 compared with 2019 (35), highlighting the implications of infectious disease outbreaks on essential health services.¹

WHO's emergency response framework (ERF) guides efforts to respond more predictably and effectively to emergencies (36). Within a country's system for responding to emergencies, the health cluster is a group of agencies, organizations or institutions that work together to provide a humanitarian response for health.

A key aspect of contingency planning for TB is ensuring that coverage and quality of TB services (37) is under the purview of the national health cluster during emergencies (38). The national health strategy and the TB NSP should define ways of preserving the minimum acceptable level of essential services in the event of an emergency that destroys or seriously impairs access to the existing health infrastructure. Specific contingency measures for TB services include designating an NTP focal point for emergencies, ensuring that the NTP participates in the health cluster meetings, involving stakeholders for specific issues (e.g. patient tracing and cross-border activities) and ensuring that TB is included in health cluster guidelines and emergency plans.

Elements to consider for TB contingency planning

The contingency measures for TB in the event of emergencies resulting in significant disruption of TB services should address the following:

- ▶ identification and contact details of the NTP focal point for the contingency plan;
- ▶ measures to be taken by all personnel at all levels if a disaster or crisis is imminent, to prevent loss of critical data;
- ▶ identification of the different levels of the programme that should be involved in the response;
- ▶ description of a bottom-up planning process, with clear roles and responsibilities at each level; and
- ▶ detailed standard operating procedures (SOPs) for all aspects of TB services.

The TB contingency measures shown in **Box 2.6** should be considered, as appropriate, for the acute and chronic phases of emergencies or during any large-scale disruption of the health service.

¹ "Preparedness" is defined as knowledge and capacities developed by governments, professional response and recovery organizations, communities and individuals to anticipate, respond to and recover from the impacts of likely, imminent or current hazard events or conditions.

2.5 Phase 4 – developing the metrics and activities for monitoring, evaluation and review of the NSP

This phase involves elaboration of the monitoring, evaluation and review aspects of the NSP to:

- ▶ track progress with implementation of the activities in the strategic plan;
- ▶ track progress and performance towards the achievement of the NSP goals, objectives and targets; identify challenges; and inform timely corrective actions;
- ▶ monitor and address inequities in the availability of, and access to, quality TB services;
- ▶ facilitate transparency and accountability for all stakeholders involved in the implementation of the NSP;
- ▶ maintain, strengthen and adapt the surveillance system, to be able to provide relevant data to optimally monitor all aspects of the NSP;
- ▶ facilitate the availability of quality data and evidence for decision-making and use in quality improvement processes at different levels; and
- ▶ provide a platform for collectively reviewing implementation, and for documenting and using lessons learned to inform improvements in implementation and subsequent plans.

For the purposes of this guidance, the following functional definitions (8) related to M&E evaluation apply:

- ▶ *Monitoring* involves bringing together all relevant data, to analyse the progress of implementation of activities.
- ▶ *Evaluation* involves assessing whether the expected strategic plan results have been achieved.
- ▶ *Reviews* are used to assess overall progress and performance, using lessons learned to identify and address any problems, gaps and challenges. Types of reviews include:
 - *annual (or more frequent) review* – which focuses on the activity level (primarily input, process, output and some coverage) indicators and targets in the annual operational plans;
 - *mid-term review* – which is usually conducted halfway through the strategic plan; it covers assessment of all the NSP targets and other institutional and contextual factors (the outcomes of this review are used to adjust national priorities and objectives for the remainder of the strategic plan period); and

Box 2.6 Considerations for contingency planning for TB services during an emergency

Acute phase (first 3 months)

During the initial acute phase of an emergency, an early rapid assessment of the impact on essential services, including TB services, should be conducted. Based on this assessment, the following interventions should be carried out:

- ▶ Conduct a situation analysis to:
 - assess the estimated number of people already on treatment; and
 - map health facilities where TB services are still functional, noting the extent to which these services are still being provided and their quality.
- ▶ Establish a mechanism to ensure continuity of TB services in the health facilities providing TB services, including reorienting sample referral and transport mechanisms to ensure continuity of diagnostic services.
- ▶ Secure an uninterrupted supply of key drugs, pre-positioning drugs and other commodities where there is a high risk of supply disruption.
- ▶ Facilitate the availability of relevant guidelines and SOPs in all operational health facilities; where necessary, develop and distribute additional specific SOPs.
- ▶ Ensure linkages with other health programmes and community services for comprehensive integrated health care, including services such as vaccination, nutrition, HIV/AIDS and NCD programmes.
- ▶ Ensure coordination with all partners and stakeholders dealing with health-related issues in the affected area.
- ▶ Ensure that TB is included in the health cluster response, and in the initial and subsequent health-assessment activities, including clear communication of any changes regarding the availability and accessibility of TB services.
- ▶ Ensure that funds needed for TB services during the acute phase are included in the emergency appeals.
- ▶ Ensure that adequate expertise is included in the evaluation of the situation of health services and the drafting of proposals depicting the specific response activities that need to be implemented.

Post-acute phase (after 3 months)

The following interventions are necessary in the post-acute phase of an emergency:

- ▶ Assess (or reassess) TB services, including supplies of drugs and commodities, with attention to quality of care.

- ▶ Ensure the availability of relevant trained staff for affected locations based on local needs.
- ▶ Organize supervision where needed using available modalities (including virtual means where possible).
- ▶ Establish (or re-establish) a tracking mechanism to retrieve the data of people registered for TB treatment.
- ▶ Rehabilitate infrastructure and services for TB in the areas affected by the disaster or crisis.
- ▶ Facilitate the tracing of people whose treatment has been interrupted, to facilitate the continuation and completion of treatment.
- ▶ Disseminate key messages to partners and communities on where to access TB services.
- ▶ Actively pursue involvement of the affected community (leaders and community health workers) in TB care and prevention efforts.
- ▶ Ensure that TB services are included in the post-acute phase needs assessment and resource mobilization efforts.
- ▶ Develop an acceleration plan that adapts to the national TB plan, and budget in line with the post-acute phase situation and needs.

Protracted crises or countries with protracted emergencies

The following interventions should be considered in protracted emergencies:

- ▶ Maintain NTP leadership and strengthen TB programme capacities at national and subnational levels.
- ▶ Ensure that TB is included in the relevant rapid assessments or situation analyses (e.g. mapping and identification of local partners).
- ▶ Ensure that TB is included in the evaluation of resource availability, identification of funding gaps and resource mobilization initiatives.
- ▶ Strengthen integration of TB services in PHC and in community initiatives to reach affected populations.
- ▶ Establish a task force to identify and define the roles and responsibilities of stakeholders, develop SOPs and training materials, and define national guidelines on minimum service packages for quality TB services.
- ▶ Ensure an uninterrupted supply of TB drugs, supplies and commodities.
- ▶ Develop or update strategic planning for TB services in the context of the protracted emergency.

AIDS: acquired immunodeficiency syndrome; HIV: human immunodeficiency virus; NCD: noncommunicable disease; NTP: national TB programme; PHC: primary health care; SOP: standard operating procedure; TB: tuberculosis.

- *final (end-term) review* – which is a comprehensive analysis of progress and performance for the strategic plan.

The M&E system should also facilitate the documentation and sharing of implementation experience that can be used alongside the quantitative data to understand how programmes are performing and inform the delivery of quality TB services. Examples include the incorporation of dedicated learning sessions within TB reviews and the organization of regular fora to facilitate peer sharing and exchanges across different states, counties, regions, zones, provinces or districts.

2.5.1 Development of the M&E component of the NSP

An M&E component of the NSP is used to monitor implementation of interventions and activities – an example is given in [Chapter 3](#). This component should be developed concurrently with the NSP and should involve stakeholders as part of the strategic planning process. [Fig. 2.3](#) summarizes the process of developing the M&E component of the NSP.

Identifying and defining indicators to track the activities and subactivities

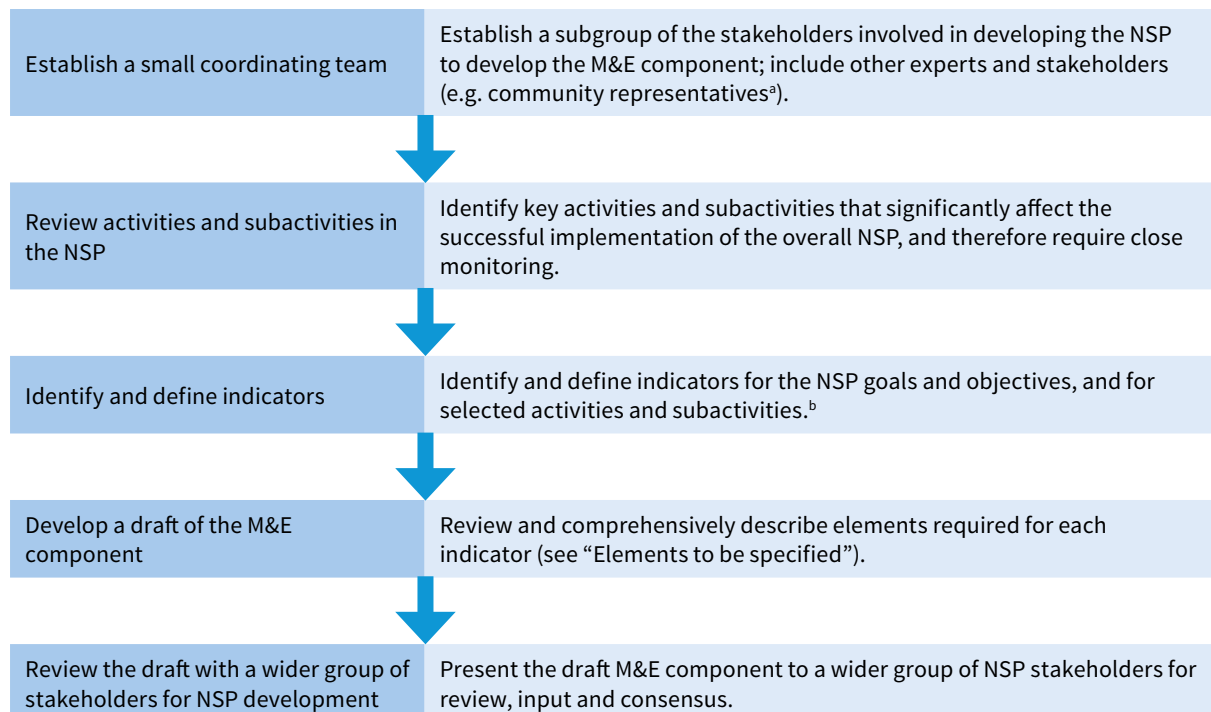
Indicators should be selected to monitor all aspects of the strategic plan, taking into account the internationally recommended indicators for monitoring and evaluating the TB programme (9, 19, 39, 40). Aspects to be monitored include logistics and supplies, staffing levels, coverage of TB services (e.g. diagnosis, treatment and social protection), competency of providers, quality of care (including experience of affected people), laboratory performance (41), community engagement (42), and procurement and supply management (43). To minimize the reporting burden on staff, only the most essential indicators should be included.

The logic model ([Fig. 2.4](#)) can be used to facilitate the selection of adequate indicators for the goal, objectives, interventions, activities and subactivities.

Inputs

The resources required (e.g. human resources, funding or allocated budget) to implement the interventions and activities are tracked using **input indicators**. An example of an input indicator is “the proportion of the annual budget defined in the TB NSP that is funded”.

Fig. 2.3 Developing the M&E component of the NSP

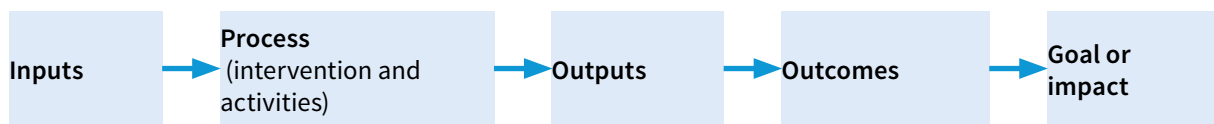


M&E: monitoring and evaluation; NSP: national strategic plan.

^a It is important to have representatives of potential stakeholders involved in collecting the information for the indicators.

^b Process indicators should be considered only for the most important activities.

Fig. 2.4 The basic logic model (44)



Process

Considering the number of activities and subactivities in the strategic plan, it may not be feasible to have an indicator for each activity. However, some **process indicators** are required to allow the measurement of key activities. Examples of process indicators are “number of health workers trained”, “number of supervisions conducted” and “number of operational research studies conducted”.

Outputs

Outputs included in the operational plan are measured using **output indicators**. Examples of output indicators are “number of people diagnosed with TB”, “number of people enrolled on TPT” and “number of TB patients with known HIV status”.

Outcomes

Outcomes of strategic plan objectives are tracked using **outcome indicators**. Examples of outcome indicators are “treatment coverage”, “treatment success rate” and “contact investigation coverage”.

Goal or impact

Impact indicators track the goals to be achieved during the NSP period. Examples of impact indicators are “TB burden (incidence and mortality)” and “percentage of TB-affected households that experience catastrophic costs due to TB”.

Elements to be specified

For each indicator, the following elements must be specified:

- ▶ purpose of the indicator (input, process, output, outcome or impact);
- ▶ procedure of calculation (e.g. absolute number, proportion, ratio, rate and index);
- ▶ sources of information that will be used (if using a rate, ratio or proportion, the sources of information for the numerator and denominator need to be specified);
- ▶ periodicity (and timeliness) of data collection;
- ▶ entity that will collect the information;

- ▶ levels (e.g. national or subnational) at which the information will be collected, compiled and analysed; and
- ▶ values of the indicator at baseline and expected values (targets) at the relevant points covered by the NSP.

Outlining activities for monitoring, evaluation and review

In addition to identification of indicators for monitoring implementation of the plan, it is important to ensure that activities aimed at strengthening the monitoring and evaluation system, and review process are well captured in the NSP activities and subactivities. Results from the epidemiological and programme reviews could inform the development of these activities.

2.6 Phase 5 – estimating the cost of the strategic plan

2.6.1 Overview

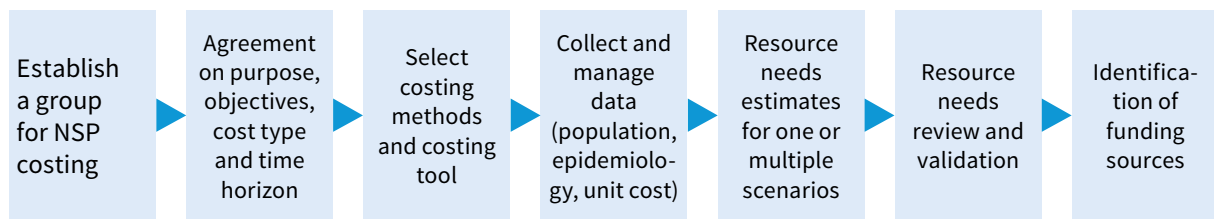
This section covers the basic aspects to be considered for NSP costing. Detailed guidance on costing methods and other aspects of budget and financial management (e.g. cost-effectiveness analyses, cost-benefit analyses, and allocative and technical efficiency¹ analyses) are beyond the scope of this guidance.

Once the activities and subactivities of the NSP have been identified, they should be costed to provide an estimate of the resource requirements for implementing the plan (45). Strategic plan costing is conducted to provide (8):

- ▶ an estimate of the resources required to implement the NSP interventions;
- ▶ credible evidence for mobilization of funds from national sources and external donors;

¹ Technical efficiency is defined as the performance of different production units or decision-making units (DMUs) in producing maximum output from a given set of inputs. The efficiency frontier represents the minimum level of inputs for a given level of outputs that is empirically observed across the different DMUs; alternatively, it can be defined as the maximum level of outputs that can be produced with a particular level of inputs (e.g. maximize prevention, diagnosis and care, given expected resource availability).

Fig. 2.5 Steps for costing the TB strategic plan and identifying available resources



NSP: national strategic plan; TB: tuberculosis.

- ▶ an assessment of funding needs against the forecasted available funding;
- ▶ financial information to use in deciding on programme changes; and
- ▶ a basis for financial monitoring and reporting.

The strategic plan costing is largely informed by the targets and interventions in the strategic plan, and agreed upon by stakeholders, as described in [Section 2.4.2](#) and [Section 2.4.3](#). The costing should be conducted using well described methods (see [Section 2.6.2](#)) and in line with recognized costing standards (46, 47). The cost methodology should be clearly described and should aim to produce costs that are comprehensive, evidenced based and sound. A costing model or tool that can easily produce data on resource needs under several scenarios of services coverage would be ideal; this would allow cost estimates to be generated for different levels of coverage of the various interventions in the plan.

The costing process requires stakeholder participation and consultations, particularly by representatives of offices, agencies and institutions involved in financing (including ministry of finance and finance departments in the MOH) and those implementing the various interventions.

Although it is important to have comprehensive and accurate costing of the NSP, this process ([Fig. 2.5](#)) can be resource intensive. It is therefore important to balance the need for accurate and comprehensive costing with the cost of the exercise (46).

2.6.2 Key steps for costing the TB strategic plan

[Fig. 2.5](#) summarizes the steps involved in costing the TB strategic plan.

Step 1. Establish a group of stakeholders to support the NSP costing and identification of available funding

A core costing team should be established, with members involved in the NSP development process from

the beginning. This core team will be responsible for coordinating the costing process, because it may not be feasible to have all stakeholders involved in the detailed costing activities. The core team should be multidisciplinary (e.g. with representatives from relevant stakeholders and both technical and financial experts or economists) and flexible, to enable establishment of subteams and engagement of additional members as needed. Ideally, the team should include experts with both experience and skills in estimating all cost elements of the NSP, but this usually requires engagement of external experts.

The team should develop a workplan detailing the purpose, objectives and scope of the costing exercise; the data likely to be available and data gaps; and a schedule of activities to be conducted to cost the NSP. The costing process usually requires several consultative meetings.

Step 2. Define costing purpose and objectives, cost type and time horizon for the costing

Before costing the NSP, stakeholders need to reach agreement on the elements outlined below:

- ▶ **Define costing purpose and objectives:** The purpose and objectives of the costing should be clearly defined, to ensure that different stakeholder interests are aligned and that costing meets the different needs. An example of a costing objective is “To estimate the amount of funds needed during the period 2022–2026 for implementation of all activities defined in the TB NSP 2022–2026”.

The NSP provides the basis for costing; a clear description of the activities and subactivities, outputs, time frame and responsibilities is a prerequisite for costing.

- ▶ **Cost type:** NSP costing requires quantification of the resources required for the full implementation of the plan, not just the additional resources (i.e. incremental costs). Costs of existing resources to support the implementation (e.g. costs of staff

time for existing staff) and contributions through volunteers and subsidies should therefore also be reflected.

- ▶ **Time horizon:** This guidance recommends that the costing covers the entire strategic plan period (with the first 2 years being the most detailed). However, this approach increases uncertainties in the estimates if the strategic plan covers a long period (e.g. more than 5 years). A balance between comprehensiveness and credibility of cost estimates is therefore needed, and the cost estimates should preferably be revised annually, on a rolling basis.

Step 3. Select costing methods and costing tools

The costing team should select the costing methods and tools to be used, based on the availability of data and resources for the costing exercise, and the time frame allocated for completing the costing. In practice, a combination of several costing methods and tools is normally used in one costing exercise.

Costing methods: In general, bottom-up and top-down costing for health services should be considered as the main costing methods to estimate health care interventions, with bottom-up being the preferred method but also the most resource intensive and laborious. Unit costs for TB services vary depending on the method used (48–54). Analogy costing and expert opinion are only used in specific circumstances or to validate costing performed through other methods.

- ▶ **Bottom-up costing (or engineering approach)** involves detailed measurement of all resources used in the provision of a specific health service or intervention (47). This is the “ingredients” approach, where all resources (i.e. inputs) used or consumed in the production of a service are costed separately. This approach requires active involvement of staff from the NTP and other sectors that will be implementing the activities, to ensure that each costing accurately reflects the inputs and unit costs.

The main advantage of the bottom-up approach is that it provides the most detailed estimates of costs. However, it is resource intensive in terms of staff time, and requires in-depth understanding of the inputs for each activity as well as an extensive database of unit costs. It is also not suitable in situations where the level of uncertainty is high.

- ▶ **Top-down costing (or parametric approach)** (47) involves estimating the cost of delivering a TB service (e.g. hospitalization for a TB patient) by using a national average figure or expenditure accounts

from a facility. It uses either unit costs for TB services generated through a top-down costing method, or a historic cost of an activity (e.g. laboratory maintenance) to break it down into components (e.g. laboratory maintenance for microscopy). This approach is faster, simpler and less resource intensive to implement but will carry historic inefficiencies forward. Furthermore, it lacks detail, and relevant historical data on which to base the costing are not always available.

- ▶ **Analogy costing** is similar to top-down costing; however, it uses only one similar project to estimate the cost of an intervention, and is therefore quicker. This method is only applicable when the projects are similar because it relies on a single data source.
- ▶ **Expert opinion** is costing that is usually obtained by interviewing several experts and combining the results into one “best” estimate. This approach is highly subjective and should only be used if other data to inform costing are not available (e.g. for new types of projects). It is best used to complement or validate other costing methods.

Costing tools: Costing can be done using various tools (publicly available or tailor-made). Publicly available tools are housed in widely used Microsoft Excel or desktop applications in the Spectrum software. To complement this guidance, the WHO Global TB Programme is updating the OneHealth TB modules (costing and epidemiology projections module) (55) and associated Excel companion tool (56) to support costing of TB NSPs.¹

Step 4. Collect and manage data

Regardless of which methods are used, costing requires collection, analysis and management of data. To ensure that the process is efficient, the costing exercise should use readily available data and the minimum data set needed to produce valid estimates. Priority should be given to large expenditure items, using extrapolation and assumptions if data are not readily available. It is important to document rules and assumptions used during the costing, including all calculation details, methodologies and data sources.

The costs of the NSP are influenced by the intervention targets and coverage (scale-up) as well as the unit costs of the inputs for the activities and interventions. It is also important to ensure that the key cost drivers are well reflected and documented.

¹ The TB costing and epidemiology modules in the OneHealth tool, which are currently a desktop application in Spectrum, will be available in 2023 in a web-based format.

Unit costs

A unit cost is the average cost of an intervention, commodity or output (46). The level at which the unit costs are defined depends on the costing method; unit costs should therefore be clearly documented and communicated. For example, depending on the approach, the unit costs associated with each TB service may or may not include staff time and other infrastructure and equipment costs.

Cost drivers

A cost driver influences the costs of the activities and interventions in the strategic plan. The costing team should ensure that all key cost drivers are included and appropriately costed. Considering the cost drivers could be related to the ways in which activities are implemented, the assumptions used in estimating the costs need to be clearly documented, to allow for analysis of the cost implications of using alternative implementation approaches. Examples of some of the key cost drivers for strategic plans are included in **Box 2.7**.

Step 5. Generate estimates of resource needs

Once the costs of the interventions have been calculated, they can then be aggregated and totalled to produce the NSP cost. In addition to the cost of the NSP, it is useful if the costing tool can estimate costs at various levels of service coverage for the interventions in the plan.

The resource needs estimates can be presented in various formats, such as by objective, by cost category, by service delivery level or by implementing entity. Different output formats will be required for different purposes, so the costing tool used should ideally allow customization of the output formats.

Step 6. Validate the costing

The cost estimates should be validated by the relevant stakeholders, to ensure that the data, assumptions and methodologies used to produce the estimates are accurate and complete and backed by the planning team. Key aspects to be reviewed as part of the validation include:

- ▶ documentation of data sources, assumptions and calculation details, and rationale for the costing approach;
- ▶ completeness of the costing (i.e. ensuring that all activities and cost elements are included); and
- ▶ accuracy, checking for errors and ensuring that the costing reflects the best estimates of the costs based on the available data.

Step 7. Identify projected funding and funding sources

Identification of funding sources for the NSP can be done at different levels. In its most granular forms, this can be at the intervention level (e.g. using Xpert as the initial diagnostic test for TB, or capacity-building for TB prevention), at the activity level (e.g. training of nurses on nutritional assessment), or even at the cost component level (e.g. per diem). Collecting information on the current and future levels of funds available, with the desired level of detail (e.g. for the intervention or activity), is usually done in parallel with estimation of resource needs; however, it can also be done through a separate detailed analysis of health financing for TB.

The following factors can facilitate mobilization and allocation of resources for implementation of the strategic plan from both domestic and external sources:

- ▶ *Involvement and buy-in by key stakeholders and gatekeepers* – Involvement of all key stakeholders (including other ministries or higher levels of government, civil society, private sector and development partners) throughout the entire cycle of strategic planning, implementation and review facilitates ownership of the interventions by various sectors. In turn, this helps to leverage resources in these sectors and facilitates allocation of additional resources where necessary.
- ▶ *Integration and alignment with the national health strategy and other health programmes* – This facilitates resource sharing and pooling, thereby optimizing the resources available and benefiting multiple programmes.
- ▶ *Using the costed NSP as the basis for all resource mobilization efforts* – All efforts to mobilize additional resources during the implementation of the NSP should be guided by the strategic plan. This includes ad hoc funding opportunities that may become available during the implementation. Thus, the costed NSP should be the basis for discussions and negotiations with donors, and for any applications to local and external potential funders.
- ▶ *Drafting credible, well-defined funding proposals* – Developing funding proposals for the NSP in line with the guidance from the ministry of finance and donors is a key aspect of resource mobilization. Key staff who will engage in budget negotiations should therefore have the capacity and the information needed to justify allocations of funding for the TB NSP.

Box 2.7 Examples of common cost drivers for NSPs

Labour costs

Salaries, allowances and other personnel-related expenses are often among the largest cost items for NSPs. To fully reflect the personnel costs of the NSP, the costs should include both existing and additional staff. Costs of staff indirectly supporting the activity (e.g. managers, administrators and drivers) should also be added, using the relevant proportion of their time.

Supplies

Supplies are the materials used during the NSP implementation period; they are typically costed using the bottom-up approach. The quantities needed will depend on the output of the activities (e.g. the number of laboratory test kits to be used will depend on the number of people to be tested).

Vehicle operation and maintenance

Costs related to vehicles are often difficult to measure; they include recurrent operating costs (e.g. fuel, insurance and registration fees, tyres and spare parts). In the absence of reliable estimates, one approach is to use standard rates for official use of private vehicles.

Consultancies

Many strategic plan activities require consultancy inputs, procured either nationally or internationally. Costing of consultancies and any other technical support should be included in the costing for the relevant activities.

Recurrent costs or overheads

At the facility level, overheads can include administrators, cleaning and kitchen staff, utilities, security, laundry, monitoring, evaluation and pharmacovigilance. Estimation of such costs can be challenging when done as part of planning for a single disease, and it might be better to estimate them at the level of a health sector plan. In NSPs, these costs are sometimes included as a mark-up to the direct cost of delivery, or as part of the health sector plan rather than the TB NSP.

NSP: national strategic plan; TB: tuberculosis.

Domestic financing

Identification of domestic funding for the NSP requires either participating in the health sector fiscal space analysis, or making assumptions about expected domestic financing for the NSP based on past allocations. Clear documentation of the health system costs that contribute to the achievement of the TB NSP objectives will help to more accurately reflect the domestic financing for the NSP, as health system costs in most countries are largely financed by domestic funding.

Donor funding

The expected donor contribution (i.e. committed and predicted donor funding) to the NSP should be reflected in the costing. This information is provided by donors during the costing exercise, based on projected funding. This can be either direct funding support, or technical or logistical support; such support should be reflected in the respective activities in the NSP. It is therefore important to involve potential donors in the costing exercise.

2.6.3 Managing the funding gap

The funding gap is the difference between the cost of the strategic plan and the projected availability of funding. Funding may not be adequate to meet the full needs of the strategic plan; thus, in addition to optimizing use of available funding, further resources will need to be mobilized.

2.7 Phase 6 – consensus and endorsement, dissemination and resource mobilization

2.7.1 Consensus and endorsement

Once the strategic plan has been finalized, it should be formally endorsed by the relevant national authority, preferably with involvement and engagement of key decision-makers in the sectors that are included in the plan. To facilitate this, it is recommended to organize a consensus workshop to orient the main decision-makers on the key contents, to ensure their concurrence and buy-in (Box 2.8). This will help facilitate and sup-

Box 2.8 Obtaining consensus and official endorsement of the strategic plan

Obtaining consensus for a strategic plan is not easy as it must balance different and sometimes conflicting interests and perspectives, particularly when it comes to priority-setting. Consensus is facilitated by ensuring stakeholder engagement and involvement during the process of developing the plan, with clear communication and discussion of the criteria used to make decisions at every stage. Regular updates to the senior management in the MOH and other key sectors should be included as part of the roadmap for developing the plan. The following aspects can assist with facilitating consensus and buy-in by both government and nongovernmental stakeholders:

- ▶ Ensuring that stakeholders are adequately engaged and have their contributions and perspectives acknowledged and reflected in the strategic plan.
- ▶ Scheduling regular updates to senior management in the MOH as well as in other key sectors throughout the planning process, thereby ensuring that senior management provides strategic guidance to shape successive versions of the draft plan.
- ▶ Dissemination of the draft versions of the strategic plan to all stakeholders for input, including targeted outreach to key sectors that are not part of mainstream TB programming.
- ▶ Openly acknowledging all key suggestions received and indicating how and where these have been considered in the draft plan, and providing feedback for those suggestions that are not included.

MOH: ministry of health; TB: tuberculosis.

port resource mobilization as well as implementation of interventions by all relevant sectors.

2.7.2 Dissemination and advocacy

Dissemination and advocacy are integral aspects of the strategic planning process, which will also facilitate implementation. These aspects need to be considered during NSP development and throughout the implementation period. The main objectives of dissemination are to ensure buy-in, awareness and understanding of the strategic focus and targets by key stakeholders, which will strengthen collective ownership and facilitate implementation. Communicating the plan to key decision-makers will also facilitate allocation of the required human, financial and material resources.

A dissemination and advocacy plan will facilitate a structured and systematic approach to the dissemination. The relevant activities for NSP dissemination and communication should form part of the plan, and should use existing platforms, events and initiatives where possible. Ultimately, the most powerful advocacy tool for the NSP is meaningful involvement and ensuring that the voices, needs, perspectives and interests of the relevant stakeholders are considered throughout the planning process.

The identification of key stakeholders to target for dissemination is informed by the interventions and activities included in the strategic plan, and the approach will need to be customized to the target audience. [Table 2.3](#) gives an example of how an advocacy plan can be structured.

2.7.3 Resource mobilization

As highlighted above (Section 2.6.2), resource mobilization for the NSP starts with the planning and preparatory phase of the NSP development process, to ensure that all key stakeholders, partners and potential funders are well engaged in the process. Ensuring the involvement of high-level government leadership is also crucial, to garner political commitment and facilitate domestic resource mobilization for the NSP.

To supplement the resources available from existing partners and stakeholders, it is usually necessary to mobilize additional resources from new sources (e.g. innovative financing mechanisms) to meet the funding needs for the NSP. This process involves using relevant aspects of the NSP to apply for funding from potential funders, and ongoing advocacy with existing partners for increased (or sustained) support. This may require additional steps to select the activities to be prioritized for funding, in line with donor requirements and expectations.

Table 2.3 Example of aspects to include in the communication, advocacy and resource mobilization plan for the NSP

Stakeholder	Expected role	Dissemination approach and platforms
Senior MOH leadership	Resource allocation Stewardship of NSP implementation	Formal updates during NSP development Formal ministerial endorsement of the NSP Regular (e.g. quarterly) presentation to ministerial management meetings
Other government ministries	Implementation of relevant strategic plan activities Resource allocation	Involvement in the strategic planning process Formal ministerial endorsement of relevant interventions in the NSP (and inclusion in the sector strategic plan) Inclusion in the multisectoral coordinating body for overseeing implementation of the NSP Support for and integration of TB activities in relevant events in the respective sectors
Technical and funding partners	Resource allocation Technical and implementation support	Involvement in the strategic planning process Inclusion in the coordinating body for overseeing multisectoral and multistakeholder implementation of the NSP Formal presentation of the strategic plan at key platforms (e.g. UN country team meetings and Global Fund country coordinating mechanisms) Funding proposals
Media (conventional media, social media and influencers)	Communication to the public and affected communities	Customized brief for the media Targeted sessions for the media and other influencers, highlighting relevant aspects of the strategic plan
Affected communities	Support NSP implementation Resource mobilization	Involvement of representatives in the strategic planning process Regular updates to affected communities using appropriate communication platforms Communication and engagement through representatives of affected communities

Global Fund: Global Fund to Fight AIDS, Tuberculosis and Malaria; MOH: ministry of health; NSP: national strategic plan; TB: tuberculosis; UN: United Nations.

CHAPTER 3

Structure and components of a TB NSP

3.1 Overview

This section presents the proposed structure of the national TB strategic plan. If the country has a standard format for NSPs, it is recommended to use that format, to ensure alignment with other health sector plans as far as possible. The proposed content of the respective sections and subsections of the strategic plan are presented below.

It is important to maintain coherence and consistency across different sections and components of the NSP, and a standardized numbering system can help to facilitate this. A numbering system will also help with cross-referencing and linkages of the elements throughout the plan, including the linkage of goals, objectives and strategic interventions with their inherent activities and subactivities and indicators. An example of a numbering system is presented in [Box 3.1](#).

Box 3.1 Example of a numbering system for the strategic plan

Goal: Reduce the incidence of TB to less than 55 per 100 000 per year by 2025

Objective 1: Increase TB treatment coverage from 50% in 2020 to 90% in 2025

Strategic intervention 1.1 Scale-up WRD as an initial diagnostic test for TB and detection of rifampicin resistance, including in children with signs and symptoms of TB

Activity 1.1.1 Develop a costed implementation plan to improve the specimen transportation system

Subactivity 1.1.1.1 Assess the capacity of the programme's diagnostic network relative to testing demand to meet the country's TB targets

Subactivity 1.1.1.2 Develop a costed implementation plan for expansion of the specimen transport system

Subactivity 1.1.1.3 Establish agreements with local courier service providers for the transport of specimens

Activity 1.1.2 Accelerate expansion of rapid molecular diagnostic equipment

Subactivity 1.1.2.1 Conduct a readiness assessment at new targeted health facilities or testing sites

Subactivity 1.1.2.2 Organize training for health workers at new targeted health facilities or testing sites on the use of rapid molecular diagnostics

Strategic intervention 1.2 Introduce and scale up targeted measures to find and treat people with TB among high-risk groups

Activity 1.2.1 [Specify first activity]

Activity 1.2.2 [Specify second activity]

Objective 2: [Specify second objective]

Strategic intervention 2.1 [Specify first strategic intervention for Objective 2]

Activity 2.1.1 [Specify first activity]

Activity 2.1.2 [Specify second activity]

If subactivities are needed, use the same numbering system

Subactivity 2.1.2.1 [Specify first subactivity of second activity]

Subactivity 2.1.2.2 [Specify second subactivity of second activity]

Subactivity 2.1.2.3 [Specify third subactivity of second activity]

3.2 Summary of the findings from the situation analysis

The situation analysis outlines the country context and profile; it covers demographic information as well as key cultural, social, economic and political characteristics that are relevant for the health status of the population or have implications for the delivery of health services. The analysis also includes a brief description of the structure of the health system and its referral system, the TB epidemiological profile, the TB social determinants and multisectoral elements (e.g. social protection and legislation) relevant to the TB response. The degree of detail included for each of these aspects will depend on the local situation and each aspect's relevance to the national TB response. This section outlines elements to be considered for the situation analysis; the content included in the analysis should be informed by relevant guidelines and other guidance documents referenced here.

Note: The situation analysis should be succinct and focused, and only include information that is directly relevant to the interventions in the NSP, or to the implementation modalities for those interventions. The suggested content given here is indicative – some aspects may not be relevant in specific country contexts.

3.2.1 The country context (indicative length: 3 pages)

The country context includes a brief description of relevant aspects relating to:

- ▶ geographical and demographic characteristics;
- ▶ political and socioeconomic context;
- ▶ vulnerable populations; and
- ▶ ethics, equity and human rights.

These aspects are discussed below.

Geographical and demographic characteristics

Some of the key aspects to include in this section are:

- ▶ information on, for example, population size, age and sex distribution and life expectancy; and population distribution by geographical areas (e.g. urban versus rural), ethnic or cultural groups, and hard-to-reach populations; and
- ▶ information on potential threats to TB services, such as natural disasters and relevant environmental conditions.

Political and socioeconomic context

This section should provide a relevant description of the country's political and administrative system, including the levels at which key decisions are made. Some of the key elements to be considered are:

- ▶ government and administrative system, and the structure of the subnational levels;
- ▶ the linkage of the MOH with other ministries and sectors;
- ▶ key political developments that may have implications for the implementation of the strategic plan (e.g. anticipated changes in political decision-makers, governance structures, and mid- and long-term policies under development);
- ▶ key economic indices such as gross domestic product (GDP), gross national income and income distribution, and recent trends and projections for these indices over the strategic plan period; and
- ▶ key economic activities, levels of employment and income distribution, including a description of populations and communities that are economically disadvantaged.

Vulnerable populations

This section should describe populations that are vulnerable in the context of health and are affected by health inequities, with a focus on TB (e.g. increased risk of developing TB, reduced access to TB services, increased risk of poor treatment outcomes, increased risk of TB-associated disability or increased risk of facing costs greater than 20% of household income or expenditure). Examples of such groups are migrants, refugees, internally displaced populations, prisoners, children, people aged over 65 years, ethnic minorities, pastoralists and miners.

Ethics, equity and human rights

This section should describe relevant human rights considerations that have implications for universal access to TB services. Examples of elements that may be included are:

- ▶ legislation and instruments on ethics, equity, human rights and gender related to access to health and social protection services, including description of populations that are excluded from relevant essential services, or have special conditions to access those services;
- ▶ the availability and nature of engagement of TB stakeholders in the promotion and protection of human rights, particularly for marginalized pop-

ulations such as ethnic minorities, prisoners and migrants;

- ▶ stigma and discrimination, and their implications for the TB response and access to TB services;
- ▶ gender norms and stereotypes that limit access to health and social services; and
- ▶ ethics standards applied in the provision of TB services, including the measures in place for ethical management of special situations.

3.2.2 The national health and social care system *(indicative length: 3–5 pages)*

This section should briefly describe relevant aspects of the health and social care system as it relates to the provision of TB services. This description can include the elements below, with the nature and the content being informed by the country context; other elements can be included where relevant.

Organization of the health and social care delivery system

This section should describe the architecture of the system for delivering the relevant health and social protection services. It should also indicate how referral works across the system, highlighting the roles of communities, civil society and the non-state sector (including the private sector) in providing health and social services. Some of the elements to be included in this section are outlined below.

Health and social protection governance

This section should describe the governance structures for health and social protection in the country at national and subnational levels. Where relevant services are not under the MOH, the linkage and referral system should also be described. Elements to be considered include:

- ▶ an overview of how health and social protection services are organized in the country, including the role of the public sector, private sector, faith-based organizations, NGOs and other providers; and
- ▶ the institutional arrangements for provision of health and social protection services.

Health and social service providers

This section should describe the structure of the health system and system for the provision of social services at national and subnational levels; for example:

- ▶ the hierarchy of the health and social protection system, including the referral system across the various levels and services;

- ▶ distribution of health facilities at national and subnational levels, including their accessibility in both rural and urban settings, and highlighting any significant issues with distribution and access to health facilities;
- ▶ health care providers beyond the public sector, with a focus on TB services (e.g. private providers, faith-based organizations, and health services run by NGOs and others);
- ▶ the community system network for TB services, and its role in providing quality TB services;
- ▶ mechanisms for the provision of quality TB services across all levels of the health system, including the private sector; and
- ▶ mechanisms for the provision of social services for the general population and people affected by TB.

Other sectors

This section should describe linkages with services provided to potentially vulnerable populations (e.g. miners, internally displaced populations and prisoners), who may receive health services through services run by other ministries or agencies.

Financing for health and TB services

This section should describe the health financing landscapes, including key UHC and health financing indicators; for example:

- ▶ government funding for health and social services, highlighting any peculiarities of TB services, and including funding through other sectors (e.g. local government and municipalities);
- ▶ funding from the local non-state sector (e.g. private sector and philanthropic organizations);
- ▶ external funding; and
- ▶ mechanisms for covering health and social protection expenditure with a focus on TB services (e.g. health insurance and out-of-pocket payments).

Human resources for health

This section should describe human resources at each level of the health system as well as human resources gaps and any plans to address them, highlighting aspects specific to TB services. It should also cover human resources in other government departments, the private sector and civil society organizations.

Pharmaceuticals and other medical products

This section should describe the system for procurement and delivery of drugs and supplies (e.g. national drug authority requirements, supply chain management, information tracking and quality assurance), with focus on commodities required for TB services, including TB infection control and tests for screening and diagnostics.

Infrastructure and health technologies

This section should describe the physical infrastructure for the provision of TB services, the diagnostic network and the status of relevant health technologies, as outlined below.

Physical infrastructure

Infrastructure in place at all levels of the health care network at national and subnational levels (including the non-state sector) should be summarized here. This section should also include a brief overview of the essential infrastructure for airborne infection control, to protect patients, health care workers, visitors and others in this environment, including the provisions for separation and isolation of people with known or suspected infectious diseases.

Diagnostic network

This section should give a brief overview of the national laboratory network across all sectors, with a focus on TB services. It could include availability, capacity and coverage (at geographical and people level) of the recommended screening and diagnostics for TB, as well as the referral system across the laboratory network and laboratory information system.

The description should also cover other relevant diagnostics, such as radiology and other imaging technologies.

Health technologies

This section should describe relevant health technologies in the country, and the related capacities for their introduction and scale-up. Examples to consider in this section include digital treatment adherence support technologies, digital tools for social support and social protection services, and geographical information system (GIS) technologies.

Surveillance system for TB

This section should describe the national health information system, including its coverage across the hierarchy of the health system and across different pro-

viders of health services. It should also outline the TB surveillance system and its linkage with the national health information system and other relevant information systems (e.g. laboratory information systems and pharmaceutical management information systems) as well as the vital registration system. The WHO checklist of standards and benchmarks for TB surveillance (18) includes aspects to be considered in this section.

Social protection

This section should describe the country's social protection floor (57), existing government-administered and nongovernmental social protection schemes (e.g. social assistance, social insurance and social support services) and the eligibility criteria for these schemes. It should also outline the linkages and eligibility of people affected by TB to access this support, and how the implementation and coverage are coordinated and monitored across various sectors.

Research and innovation

Elements that could be described in this section include:

- ▶ the institutional capacity for research, including research institutions and resource availability;
- ▶ the national system for coordination and oversight of research, including the role of academia, civil society or community organizations in generating field evidence and any policies that inform the translation of research into national policy and practice; and
- ▶ specific provisions for research on priority infectious diseases, with a focus on TB research.

3.2.3 Epidemiology of tuberculosis

(indicative length: 3–5 pages)

This section should provide an overview of the epidemiology of TB in the country, based on the latest available data. The data should be disaggregated as much as possible – for example, by gender, age, areas (e.g. states, provinces, regions or districts) – to facilitate the identification of populations and population groups requiring focus.¹ It is recommended to present the most relevant information using appropriate graphics.

¹ Identify the geographical areas with the highest TB burden; compare TB occurrence between rural and urban settings; determine, within the geographical areas, the regions or districts with the highest numbers and notification rates of TB.

National and subnational burden of TB and drug-resistant TB

This section should give an overview of the national burden and recent trends of TB, including drug-resistant TB. It should include the status regarding key impact indicators from the End TB Strategy, such as estimated incidence, mortality and level of TB-related costs greater than 20% of household income or expenditure.

TB/HIV and other determinants, risk factors and comorbidities

This section should describe known key determinants, risk factors and comorbidities relevant to the national TB epidemic; it could include, for example, HIV, under-nutrition, alcohol use disorders, diabetes and smoking. It should include the estimated burden of the risk factors in the general population and among TB patients, and the burden in relevant key populations, and it should summarize relevant subnational and subpopulation data.

TB burden in key vulnerable populations

This section should describe the burden of TB in relevant vulnerable populations. Examples of such populations include children and adolescents, urban poor (including residents of informal settlements), indigenous populations and ethnic minorities, migrants and internally displaced populations, prisoners, and miners and residents of mining and permining communities.

For each vulnerable population, the estimated magnitude of the population and the estimated burden of TB (including drug-resistant TB), and the treatment coverage (including recent trends), should be described. As far as possible, the summary should include relevant disaggregation of the data; for example, by age group, gender or site of TB (pulmonary versus extrapulmonary TB).

3.2.4 The national TB programme (indicative length: 3–5 pages)

This section should describe the core elements of the country's TB programme; that is:

- ▶ *organization of the NTP* – this section should describe the NTP at all levels (including national and subnational structures) and should focus on aspects relevant to the key interventions in the strategic plan; and
- ▶ *organization of services along the TB care cascade* – this section should summarize the system for the

provision of TB services along the continuum of care, including services for TB prevention, and for screening, diagnosis, treatment, support and care for people affected by TB.

Note: Relevant technical guidelines along the continuum of care can be accessed on the WHO's TB knowledge sharing platform (58), which brings together all WHO TB guidelines, operational handbooks and training material. The content is available via the website and on applications for smartphones and tablet computers. The rest of this section focuses on the content of the section on organization of services along the TB care cascade.

TB infection prevention and control (IPC)

This section should describe the following aspects, as they relate to airborne infection control:

- ▶ guidelines and institutional arrangements for IPC, with a focus on measures for airborne infection control;
- ▶ coordination and implementation of IPC at various levels of the health system, and in relevant community and congregate settings, including:
 - infection control risk assessments and plans for selected high-risk settings;
 - overall responsibility for health facility maintenance and renovation, and consideration for airborne infection control in health facility standards;
 - mechanisms and resources for supplies and consumables for airborne infection control;
 - status of implementation of airborne infection control in TB high-risk health facilities and departments; and
 - adequacy of infrastructure of health care facilities for implementation of TB IPC.

TB preventive treatment (TPT)

This section should summarize the following:

- ▶ national policy on TPT, including TPT regimens and the status regarding testing for TB infection;
- ▶ target populations for TPT, and coverage and uptake of TPT in the target populations, including people living with HIV;
- ▶ mechanisms to support adherence to TPT; and

- ▶ M&E of TPT, including adverse drug events and treatment completion.

TB screening and diagnosis

This section should describe:

- ▶ current national policy on TB screening and active TB case finding, including target populations for screening;
- ▶ diagnostic algorithms for drug-susceptible and drug-resistant TB;
- ▶ alignment of the algorithms with available diagnostics at various levels of the health system;
- ▶ the responsibilities of different categories of health workers in TB screening and diagnosis;
- ▶ the status and coverage of TB screening and diagnosis services; and
- ▶ M&E of TB screening for the respective target populations and across relevant sectors (e.g. community, clinics, occupational health services, prisons and immigration services).

TB treatment and care

This section should outline the approaches to treatment of TB, with an emphasis on quality care, including:

- ▶ treatment modalities for drug-susceptible and drug-resistant TB (including the role of hospitalization and ambulatory treatment);
- ▶ follow-up and monitoring system for people on treatment for TB;
- ▶ active drug safety monitoring and management (aDSM);
- ▶ treatment outcomes, including relevant disaggregation (e.g. by case category, drug resistance, TB/HIV, gender and age groups);
- ▶ modalities for facilitating adherence to treatment, and for providing psychological and social support for people on treatment for TB;
- ▶ mechanisms for ensuring health literacy; and
- ▶ provisions for palliative care, including end-of-life care.

Screening and management of comorbidities

This subsection should describe the structure and location of, and linkages with, respective programmes or departments responsible for addressing relevant comorbidities (e.g. HIV, diabetes, tobacco cessation,

Box 3.2 Management of TB/HIV

This section of the NSP should include:

- ▶ a summary of the coordination mechanism for TB/HIV, including data systems and systems for the procurement and supply of relevant drugs and supplies;
- ▶ national guidelines for screening, diagnosis and prevention of HIV-associated TB;
- ▶ service coverage and treatment outcomes for HIV-associated TB; and
- ▶ level of decentralization of and integration of TB and HIV services.

HIV: human immunodeficiency virus; NSP: national strategic plan; TB: tuberculosis.

mental health, undernutrition, alcohol and drug use disorders and silicosis).

HIV is used in **Box 3.2** as an example, but the description in the NSP should include all comorbidities relevant to the country context.

Addressing TB-related disability during and after TB treatment

This subsection should describe services available for people to prevent and manage TB-associated disability during and after TB treatment. It should also outline the provision of and linkage to services for mitigation of TB risk and social protection.

Addressing TB in vulnerable populations

This subsection should describe health and social services for locally relevant population groups with a significantly higher TB incidence than the general population, those with reduced access to appropriate TB services, or those at risk of poorer outcomes of TB treatment. Vulnerable populations will be context specific; examples include children and adolescents, people living in informal settlements, prisoners, indigenous populations and ethnic minorities, miners, migrants, internally displaced people, refugees and hard-to-reach populations.

Children and adolescents are included in **Box 3.3** as an example, but the description in the NSP should include all vulnerable populations relevant to the country context.

Box 3.3 Management of TB in children and adolescents

This section of the NSP should describe institutional arrangements for providing health services for children and adolescents along the continuum of care, highlighting aspects with implications for TB services. Other relevant information includes:

- ▶ services and coverage of contact investigation and TPT;
- ▶ availability of child-friendly formulations for anti-TB drugs;
- ▶ models of care;
- ▶ nutritional and social support for children with TB; and
- ▶ M&E.

M&E: monitoring and evaluation; NSP: national strategic plan; TB: tuberculosis; TPT: TB preventive treatment.

3.2.5 Summary of the review of implementation of the previous TB strategic plan

This section should summarize progress made in implementing the interventions and activities of the previous strategic plan, including key achievements and enabling factors, and challenges and recommendations. More information on the review of implementation of national TB strategic plans can be found in WHO guidance for reviews of TB programmes (59). The enabling factors can inform the implementation modalities for the subsequent NSP, whereas the gaps and challenges should be considered as part of the programmatic gap analysis.

3.2.6 Programmatic gaps analysis

This section should describe the key gaps and challenges to be addressed by the strategic plan, based on the findings presented in [Sections 3.2.1–3.2.5](#) above, and on the outputs of the process described in [Section 2.3.4](#), in [Chapter 2](#). It should include gaps in TB service delivery across the care cascade, and in the delivery and coordination of these services within the health sector and in other relevant sectors.

The outline presented for [Sections 3.2.1–3.2.5](#) above can be used to structure the programmatic gap analysis. [Table 3.1](#) provides an example of programmatic gap analysis of a TB NSP.

Table 3.1 Example of an outline for summarizing the programmatic gap analysis

Programme area	Key gaps (to be quantified where possible, with appropriate references for the data sources)	Identified root or contributory causes
<p>The national health and social care system (Section 3.2.2)</p>	<p>Health and social protection governance</p> <p>TB is not included among the criteria for social assistance grants</p>	<p>Inadequate awareness of the social consequences of TB</p> <p>Disproportionate focus on biomedical interventions in the TB training curricula and other strategic documents</p>
	<p>50% of people with TB who are eligible for social assistance for other conditions do not access social assistance</p>	<p>10% of people with TB do not have national identification documents required to access social services</p>
<p>Health and social service providers</p>	<p>30% of public sector health facilities do not provide TB services</p>	<p>Historical designation of sites as DOTS centres with inadequate decentralization</p> <p>Inadequate health worker capacity to manage TB</p>
	<p>60% of health facilities operated by mining companies do not provide TB diagnostic services</p>	<p>Inadequate awareness of senior management in mining companies regarding the local TB situation and required services</p>
<p>Financing for health and TB services</p>	<p>30% of the national TB budget required to implement the TB NSP was unfunded</p> <p>TB was not included in the district action plan in 7 of the 24 districts</p>	<p>Low awareness of TB among key decision-makers at national and subnational levels</p>
<p>Human resources for health</p>	<p>The share for health in some of the district budgets is very low (<5%)</p>	<p>Overreliance on external funding to address TB</p>
	<p>Insufficient programmatic and clinical staff for the management of TB</p>	<p>TB-related stigma and fear of infection among health workers</p> <p>Inadequate incentives and infection control provisions for health workers</p> <p>Insufficient opportunities, including training for staff at all levels</p>
<p>Pharmaceuticals and other medical products</p>	<p>Inadequate supplies of ancillary medicines for people with TB</p> <p>Frequent stock-outs of anti-TB medicines at facility level</p>	<p>Ancillary medicines not included in the procurement for anti-TB medicines</p> <p>Inadequate monitoring and reporting of stock status at facility level</p>

Programme area	Infrastructure and health technologies		Key gaps (to be quantified where possible, with appropriate references for the data sources)	Identified root or contributory causes
	Physical infrastructure	Inadequate airborne infection control in health facilities	Infrastructure design and renovations not in line with infection control standards	
		Diagnostic network	Health facility infrastructure not adequately maintained	
		Health technologies	Limited funding for expansion of laboratory diagnostics	
Surveillance system for TB		30% of health facilities do not have reliable internet access	Frequent machine breakdown Frequent power outages	
		High (41%) level of TB underreporting as reported by the TB inventory study	Low penetration of internet services outside urban centres	
Social protection		Unknown coverage of social assistance services for TB-affected families	Private sector facilities and some hospitals are not linked to the national TB surveillance system High workload and reporting burden on staff Multiple systems in place (paper-based and electronic), making harmonization of data difficult	
Research and innovation		National research agenda does not include TB-specific research	Unclear eligibility of people with TB for social assistance grants No systematic social needs assessment of people with TB Recording and reporting system does not include social protection indicators	
The NTP (Section 3.2.4)	Organization of the NTP	Inadequate staff for coordination of TB services at national and subnational levels	Inadequate engagement of researchers in the national TB response Key staff positions for the TB programme are not filled Inadequate funding for human resources for the TB programme	
	Organization of services along the TB care cascade	Low coverage of core elements of airborne infection control (focal person, infection control committee and infection control plans)	Perception among key decision-makers that TB is no longer a major problem in the country Low awareness of infection control among facility managers No national guidelines or SOPs for airborne infection control	

Programme area	Key gaps (to be quantified where possible, with appropriate references for the data sources)	Identified root or contributory causes
	Low (25%) coverage of TPT among eligible household contacts of people with TB	Health worker reluctance to provide TPT (concerns about resistance, side-effects, effectiveness and workload) Inadequate supplies of TPT medicines (funding, TPT perceived as low priority)
	Only 63% of people with DR-TB had second-line DST	Second-line DST is only performed at the national reference laboratory There is no nationwide specimen transport system to facilitate second-line DST
TB screening and diagnosis	24% of people diagnosed with MDR/RR-TB were not started on treatment	Limited number of health facilities providing DR-TB treatment Long waiting time for results of baseline examinations required before DR-TB treatment initiation
TB treatment and care	Low (20%) coverage of nutrition assessment among people with TB	Inadequate health worker capacity and tools on nutrition assessment No system in place for addressing nutrition needs of TB patients
Screening and management of comorbidities	No data on TB burden in key vulnerable populations	Recording and reporting system does not collect key data on vulnerability No targeted interventions for TB vulnerable populations in the previous NSP
Addressing TB in vulnerable populations	Inadequate awareness of the NSP at district level Inadequate engagement of other sectors in strategic plan implementation	Inadequate involvement of the district level staff in the development of the NSP Suboptimal engagement of leadership in key sectors for the TB response
Implementation of previous strategic plan		

DOTS: directly observed treatment short course; DR-TB: drug-resistant TB; DST: drug susceptibility testing; MDR/RR-TB: multidrug-resistant or rifampicin-resistant TB; NSP: national strategic plan; NTP: national TB programme; SOP: standard operating procedure; TB: tuberculosis; TPT: TB preventive treatment.

3.3 Goals, objectives and interventions

This section presents the goals, objectives and interventions for the NSP.

3.3.1 Goals

A strategic plan should have one or more specific goals. Usually, these goals will have a broad perspective and will be defined within the national vision for ending TB, aligned with the End TB Strategy and in the context of the national development and health sector plans. It is recommended that each goal be defined in line with SMART (specific, measurable, attainable, realistic and time-bound) criteria. The achievement of goals may be measured using impact indicators.

3.3.2 Objectives and strategic interventions

Each objective is a clear statement that is logically related to the goals and rationally linked to one or more gaps that are to be addressed through the implementation of the strategic interventions specified in the plan. As with the goals, the strategic objectives should also be SMART, as far as possible. Each objective will be reached through the implementation of a set of the respective strategic interventions (see [Box 3.4](#) for an example). Achievement of objectives may be measured through outcome indicators.

3.4 Activities and subactivities

Activities and subactivities to be implemented for each intervention to achieve the objectives and goals of the strategic plan should be itemized. This will facilitate appropriate costing (especially if the bottom-up costing approach is used), and inform implementation of the plan. The activities and subactivities should be listed by year, with quarterly breakdown for at least the first 2 years, and clear assignment of responsibilities among all key actors (see [Table 3.2](#) for an example). Following annual reviews, the activities and subactivities should be updated to ensure that they remain relevant and responsive to the prevailing situation.

3.4.1 Key elements to include in the activities (and subactivities)

The key elements to be included are:

- ▶ clear time frame, with a quarterly breakdown at least for the first 2 years of the plan;
- ▶ indication of how the activities (and subactivities) will be carried out, and who will do this, and itemization of the information needed to make their implementation successful (e.g. time, location and geographical priorities, responsible implementer, provider types, costs and process indicator);
- ▶ known or potential sources of funding for the implementation; and
- ▶ any additional needs for successful implementation, such as technical assistance.

Box 3.4 Example of strategic plan goals, objectives and interventions

Goal:

Reduce the incidence of TB to less than 77 per 100 000 per year by 2025

Objective 1

Increase TB treatment coverage from 50% in 2020 to 75% in 2025

Interventions

- 1.1 Scale up WRD as an initial diagnostic test for TB and detection of rifampicin resistance in all people with signs and symptoms of TB
- 1.2 Introduce and scale up targeted measures to find and treat people with TB among high-risk groups
- 1.3 Strengthen systematic engagement of private and other unlinked public health care providers in the delivery of TB services
- 1.4 Expand free-of-charge or highly subsidized TB service packages, including diagnosis of TB, and provision of all TB medicines and ancillary drugs

Objective 2

Increase coverage of social support for eligible people with TB to 90% by 2025

Interventions

- 2.1 Define a social support package and eligibility criteria for people with TB
- 2.2 Strengthen engagement and collaboration with relevant stakeholders for the provision of social protection for people with TB
- 2.3 Conduct advocacy for social protection for people with TB
- 2.4 Define the M&E indicators for social protection measures for people with TB

Objective 3

Increase the coverage of the TB surveillance system to 100% by 2025 for the recording and reporting of TB data that are of high quality and reliable for decision-making

Interventions

- 3.1 Establish a link between the national TB surveillance system and facilities that were identified as sources of underreporting (private sector facilities and some hospitals)
- 3.2 Transition from paper to digital case-based surveillance systems
- 3.3 Implement routine monitoring and improve the quality and validity of routine TB surveillance data (e.g. monitoring visits, health facility assessments and DQA app)
- 3.4 Hold training workshops on routine data analysis and use for policy, planning and programmatic action

DQA: data quality assurance; WRD: WHO-recommended rapid diagnostic test; M&E: monitoring and evaluation; TB: tuberculosis.

Table 3.2 Example of a strategic plan matrix for one goal, outlining the objectives, strategic interventions, activities and subactivities¹

Goal: Accelerate reduction of TB incidence to 10% per year by 2025 and then to an average of 17% per year from 2025 onwards						
Date	Location	Implementer	Costs in US\$	Source of funding	Process indicator	Additional technical assistance needs
Objective 1: Increase the proportion of people with presumptive TB tested with rapid diagnostics at diagnosis from 50% in 2020 to 90% in 2025						
Strategic intervention 1.1 Scale-up WRD as an initial diagnostic test for TB and detection of rifampicin resistance, including in children with signs and symptoms of TB						
Activity 1.1.1 Develop a costed implementation plan to improve the specimen transportation system						
Subactivity 1.1.1.1	National and subnational levels	NTP	80 000	MOH	Assessment report available	Diagnostic network assessment
Assess the capacity of the programme's diagnostic network relative to testing demand to meet the country's TB targets						
Subactivity 1.1.1.2	National and subnational levels	NTP		MOH	Costed plan for specimen transport system available	Costing of the plan for the specimen transport system
Develop a costed implementation plan for expansion of the specimen transport system						
Subactivity 1.1.1.3	Subnational level	NTP		MOH		
Establish agreements with local courier service providers for the transport of specimens						
Activity 1.1.2 Accelerate expansion of rapid molecular diagnostic testing for TB						
Subactivity 1.1.2.1	Subnational level	NTP		MOH	Report of readiness assessment available	
Conduct a readiness assessment at new targeted health facilities or testing sites						
Subactivity 1.1.2.2	Subnational level	NTP		MOH	Number and proportion of health facilities or laboratories with trained health workers	
Organize training for health workers at new targeted health facilities or testing sites on the use of rapid molecular diagnostics						
Subactivity 1.1.2.3	National level	NTP	12 500	MOH	Number of health facilities or laboratories with capacity for rapid molecular diagnosis of TB	
Procure additional equipment for rapid molecular diagnostic testing (based on assessment of diagnostic network [subactivity 1.1.1.1])						

¹ This is indicative only, not exhaustive.

	Date	Location	Implementer	Costs in US\$	Source of funding	Process indicator	Additional technical assistance needs
Objective 2: Increase coverage of social support for eligible people with TB to 90% by 2025							
Strategic intervention 2.1 Define social support package and eligibility criteria for people with TB							
Activity 2.1.1 Develop a package of evidence-based interventions to protect vulnerable populations through social protection meeting defined eligibility criteria	Q1/Y1	National level	NTP and the ministry of social protection		MOH, ministry of social protection	Package of social protection interventions defined	Technical assistance to define social protection package
Strategic intervention 2.2 Strengthen engagement and collaboration with relevant stakeholders for the provision of social protection for people with TB							
Activity 2.2.1 Establish a national multisectoral and multistakeholder working group for social protection for people with TB	Q1/Y1	National level	NTP		MOH	Minutes of quarterly meetings of the social protection working group	
Objective 3: Increase the coverage of the TB surveillance system to 100% by 2025 for the recording and reporting of TB data that are of high quality and reliable for decision-making							
Strategic intervention 3.1 Establish a link between the national TB surveillance system and facilities that were identified as sources of underreporting (private sector facilities and some hospitals)							
Activity 3.1.1 Visit private sector facilities and hospitals to retrospectively notify underreported cases and update the national TB database	Q1/Y1	Subnational level	NTP		MOH	Number of health facilities visited	
Activity 3.1.2 Conduct regular record linkage between the database of the NTP and other databases of TB cases (e.g. laboratories and national health insurance databases)	Q1/annually	National and subnational levels	NTP and other sectors		MOH	Record linkage completed	
Activity 3.1.3 Develop a simplified recording and reporting tool that facilitates private sector facilities and hospitals to notify future TB cases	Q1-4/Y1	National level	NTP, HMIS and IT developers		MOH	Tool developed and ready for piloting	Technical assistance to support the development of a tool and integration to the TB national surveillance system

	Date	Location	Implementer	Costs in US\$	Source of funding	Process indicator	Additional technical assistance needs
Strategic intervention 3.2 Transition from paper to digital case-based surveillance systems							
Activity 3.2.1 Prepare for the transition to a digital case-based surveillance system							
Subactivity 3.2.1.1.1 Conduct a readiness assessment for the implementation of a digital case-based surveillance system, with identification of gaps to be strengthened	Q1/Y1	National and subnational levels	NTP, HMIS and external partners		MOH	Report of readiness assessment available	
Subactivity 3.2.1.1.2 Develop a TB digital strategic plan (ensuring alignment with the national digital health strategic plan) informed by readiness assessment	Q2-3/Y1	National level	NTP, HMIS with support from partners		MOH	Strategic plan for TB digital health available	
Subactivity 3.2.1.1.3 Develop an implementation plan for scale-up of the digital case-based surveillance system	Q4/Y1	National level	NTP, HMIS, with support from partners		MOH	Implementation plan for digital case-based surveillance system available	
Strategic intervention 3.3 Implement routine monitoring and improve the quality and validity of routine TB surveillance data							
Activity 3.3.1 Develop SOPs and tools to support routine quality checks and data validation at all administrative levels	Q2/Y1	National level	NTP		MOH	SOPs and tools available	Consultant to support SOPs and tools development
Activity 3.3.2 Train staff on recording and reporting procedures and new data quality SOPs	Q3/Y1	National and subnational levels	NTP		MOH	Training conducted	
Activity 3.3.3 Update the digital package to include automated data quality checks and validation rules	Q4/Y1	National and subnational levels	NTP		MOH	Automated data quality checks and validation rules integrated	IT support to code automated checks and validation rules within the digital package
Strategic intervention 3.4 Hold training workshops on routine data analysis and use for policy, planning and programmatic action							
Activity 3.4.1 Conduct workshops on data analysis and use at provincial level	Q2/Y2	Provincial level	NTP with support from partners		MOH	Number of workshops conducted	Facilitation of the workshops

HMIS: health management information system; IT: information technology; MOH: ministry of health; WRD: WHO-recommended rapid diagnostic test; NTP: national TB programme; Q: quarter; SOP: standard operating procedure; TB: tuberculosis; Y: year.

3.5 M&E component of the NSP

The M&E component outlines the indicators to track progress of implementation of the NSP and the achievement of the targets, and the coordination of M&E activities included in the NSP. This should include both continuous M&E and periodic reviews.

Table 3.3 provides selected examples of indicators and elements that should be specified.

3.5.1 Continuous M&E

The NSP should include a description of the frequency of regular review meetings (e.g. quarterly, semesterly or annually) at various levels, and which stakeholders should be involved in the collection, analysis, sharing and discussion of data. These review meetings enable early identification of implementation challenges and bottlenecks, which in turn can facilitate timely intervention to improve programme implementation. Data should be analysed and presented in a way that facilitates appropriate interpretation by all relevant stakeholders in these meetings.

3.5.2 Mid-term strategic plan review

In addition to the regular review meetings, it is recommended that a comprehensive mid-term review of the implementation of the strategic plan be implemented; this is particularly relevant for strategic plans covering periods of about 5 years or more. The mid-term review should be included in the strategic plan, and the required resources should be included in the budget. The objectives of this review are to:

- ▶ determine whether the country is on track to achieve the strategic plan targets;
- ▶ identify bottlenecks to implementation that should be addressed to accelerate progress towards targets;
- ▶ identify good practices that could be scaled up; and
- ▶ identify emerging challenges, threats and opportunities and, if necessary, update the strategic plan accordingly.

Where there are significant modifications to the NSP based on the mid-term review, this can be reflected as an addendum to the strategic plan, which should also be formally endorsed by the relevant government offices where possible.

3.5.3 End-term strategic plan review

An end-term review is performed during the final year of implementation of the strategic plan, primarily to serve as a baseline for the preparation of the successor strategic plan. This is a comprehensive exercise that should be conducted with the participation of all stakeholders involved in the implementation of the plan, and it should be planned, costed and budgeted for as part of the strategic plan. It is also good practice for end-term reviews to include external experts who can provide an independent perspective on the country's progress with implementing the NSP.

Table 3.3 Sample M&E component for the NSP

Item	Indicator	Purpose	Calculation ^a	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline (2020)	Target (2025)
Goal	TB incidence	Impact	WHO estimates	Global TB report (baseline); Modelling (target)	Annually; once	NA	NA	100 per 100 000	77 per 100 000 ^b
Goal	Number of TB deaths	Impact	WHO estimates	Global TB report; modelling	Annually; once	NA	NA	1 000	680 ^c
Goal	TB-affected families facing costs >20% of household income or expenditure due to TB (%)	Impact	Survey results	TB patient cost survey	At the end of the NSP period	M&E focal point	National	47%	10%
	Proportion of annual budget defined in TB strategic plan that is funded	Input	Available domestic and international funding each year divided by the estimated NSP funding needs for the same year	NTP, finance department	Annually	Finance focal point	National	75%	100%
Objective 1	TB treatment coverage	Outcomes	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	Surveillance system	Quarterly	M&E focal point at relevant levels	Facility, district, province, national	50%	75% ^d
	Number of people diagnosed with TB	Outputs	Number of new and relapse cases that were notified and treated	Surveillance system	Quarterly	M&E focal point at relevant levels	Facility, district, province, national	5 000	6 380
	Costed implementation plan to improve specimen transportation system	Process	NA	NTP	Once off (2023)	NA	NA	Implementation plan not available	Implementation plan developed and costed

Item	Indicator	Purpose	Calculation ^a	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline (2020)	Target (2025)
	Proportion of health facilities or testing sites with trained health workers	Process	Number of health facilities or laboratories with trained health workers on the use of rapid molecular diagnostic testing for TB, divided by total number of health facilities or laboratories that are equipped with rapid molecular diagnostic tools for TB	NTP and laboratory system	Annually	TB and laboratory focal points at relevant levels	Facility, district, province, national	35%	80%
	Number of health facilities with access to rapid molecular diagnostic testing	Process	Number of health facilities or laboratories with capacity for rapid molecular diagnosis of TB	NTP and laboratory system	Annually	TB and laboratory focal points at relevant levels	National	10	100
	Package of social protection interventions for people with TB defined and published	Process	NA	NTP	Once off (2023)	M&E focal point	National	Not available	Available
Objective 2	Number of social protection working group meetings held	Process	Number of meetings	NTP	Quarterly	M&E focal point	National	0	4 times per year
	Report of readiness assessment for implementation of digital case-based surveillance system available	Process	NA	NTP	Once off (2023)	M&E focal point	National	Not available	Available
Objective 3									

Item	Indicator	Purpose	Calculation ^a	Source of information	Periodicity	Who will collect the information	Level of information collection	Baseline (2020)	Target (2025)
	SOPs and tools to support routine quality checks and data validation at all administrative levels published	Process	NA	NTP	Once-off (2023)	M&E focal point	National	Not available	Available
	Number of data analysis and use workshops conducted at provincial level	Process	NTP	NTP	Annually	M&E focal point	National and subnational TB programme	0	15

M&E: monitoring and evaluation; NA: not applicable; NSP: national strategic plan; NTP: national TB programme; SOP: standard operating procedure; TB: tuberculosis; WHO/GTB: World Health Organization Global TB Programme.

^a For more detailed information on the calculation of standard TB indicators, please refer to the online annex of the definition and reporting framework for tuberculosis (40) and guidance on tuberculosis surveillance (39).

^b Assumption: The national population was 10 million in 2020, and increases to 11 million in 2025, i.e. 10 000 incident cases at baseline and ~8 500 six years later.

^c Assumption: Case Fatality Rate (approximated as mortality as a proportion of incidence) drops from 10% in 2020 to 8% in 2025 as a result of better quality of care.

^d Assumption: There are 20% of detected cases who were not officially notified in 2020. The problem of under-reporting is fully addressed by 2025 and an additional 5% improvement is made in treatment coverage as a result of improved case detection.

3.6 Costing

This section presents the resource needs for the implementation of the strategic plan. For each year of the plan, the costing should identify:

- ▶ the estimated total funding needed for implementation of the plan;
- ▶ the source or sources of funding for each intervention (i.e. the funding contributions of the government, including loans, and of each international partner); and
- ▶ the funding gap, calculated as the difference between the amount of funds needed and the expected funds from all sources.

The output formats for the costing will be determined by the purpose of the costing and will continue to evolve because requirements from stakeholders and funding partners are dynamic. Hence, this section does not provide a “standard” format for presenting the costing; rather, the output of the costing should be flexible enough to be customized for the different uses.

3.7 Contingency measures

The contingency planning identifies, plans for and summarizes potential risks or events that may adversely affect access to and availability of TB care and prevention services along the continuum of care. [Table 3.4](#) can be used to summarize contingency measures.

Table 3.4 Example of a contingency planning

Stages of care continuum	Consequences for care continuum	Description	Countermeasures (interventions)	Location	Implementer	Other stakeholders to be engaged
Vulnerable groups with TB infection	Reduced access to preventive treatment for vulnerable groups (e.g. high-risk contacts of people with TB, homeless people and people living with HIV)	Health care workers responsible for TB and contact tracing are deployed to the emergency response	Engagement of community health workers to support contact screening and investigation Use of digital technologies to support contact tracing and referral	Subnational level (health facility and community)	Staff at health facility and community health workers	Relevant technical and funding partners, civil society organizations, community health workers, service providers for digital health technologies
Symptomatic disease, not yet in care	Reduced access to TB diagnosis	Reduced access to health facilities due to the impact of the emergency (e.g. damaged roads and security concerns) Closure or repurposing of health infrastructure to respond to the emergency	Engagement of community health workers to support TB screening and sputum collection Redirection of the specimen transportation system to facilities that are still operational Use of digital technologies to support screening and delivery of laboratory results Ensure inclusion of TB in relevant community outreach activities as part of the emergency response	National and subnational level (health facility and community)	Staff at national and subnational level (health facility) and community health workers	Relevant technical and funding partners, civil society organizations, community health workers, specimen courier service, and service providers for digital health technologies
Symptomatic disease, in care	Treatment interruption due to interruption of supplies of TB medicines and other health commodities	Reassignment of health workers and other resources to the emergency response Disruption of the supply chain system due to the emergency Loss of records of people in care	Ensure inclusion of TB in the package of essential services to be maintained during the emergency response Close monitoring of supplies, with redistribution to sites with inadequate stock Multi-month dispensing of anti-TB treatment drugs Use of digital technologies to support treatment adherence Public outreach to people on treatment whose records have been lost (to be completed as locally relevant)	National and subnational levels	Staff at national and subnational level (health facility)	Relevant technical and funding partners, civil society organizations, community health workers, supply chain management team, and service providers for digital health technologies
Others as locally relevant	(to be completed as locally relevant)	(to be completed as locally relevant)	(to be completed as locally relevant)	(to be completed as locally relevant)	(to be completed as locally relevant)	(to be completed as locally relevant)

HIV: human immunodeficiency virus; TB: tuberculosis.

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