



**TOOLKIT
FOR DEVELOPING
A NATIONAL TB
RESEARCH PLAN**

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PREFACE

The global tuberculosis (TB) community has made commendable efforts in the past decade to successfully attain the Millennium Development Goal and other international targets of halting and reversing TB incidence and mortality, respectively. However, despite important achievements to date, the global TB incidence is declining only at the slow rate of 1.5% per year. At the same time, efforts to end TB are experiencing setbacks due to challenges such as that of the cases missing in the reporting system, the association of HIV and TB, and the persisting public health crisis of multidrug-resistant TB.

Recognizing these challenges, the World Health Assembly approved in May 2014 a new End TB Strategy and a set of ambitious targets, later incorporated also within the Sustainable Development Goals for 2030. Targets include the reduction of TB deaths by 90% and of TB incidence by 80% between 2015 and 2030, and the elimination of catastrophic costs due to TB in affected households as of 2020. To achieve these targets, the three-pillar End TB Strategy comprises (i) integrated patient-centred care and prevention; (ii) bold policies and systems, with emphasis on social protection of vulnerable populations; and (iii) intensified research and innovation. The *research and innovation* pillar of the End TB Strategy promotes the need for research along a continuum that links upstream fundamental research to discovery and new tool development, and ultimately to operational and implementation research, allowing innovative strategic approaches to be adapted to specific country needs.

Promotion of intensified research efforts was first detailed in the *Global Action Framework for TB Research*¹ published by WHO in November 2015. It outlines above all the establishment of national TB research networks to drive country-specific efforts and improve the effectiveness of existing tools and systems, as well as action on the development of novel and better interventions. These, associated with a rigorous analysis of the national situation to address weaknesses in the health systems and programmes, could significantly improve TB care and control. The development of national plans for TB research engaging influential actors, such as governmental agencies, donors, policy-makers, academics, and non-governmental and civil society organizations, could result in substantial advances towards ending TB.

In 2016, we are at a delicate juncture of the fight against TB due to plateauing of resources for research and gaps in implementation that remain unfilled. The risk of losing the gains made in the past decade is real and we must take immediate action. WHO is calling upon all Member States to pursue bold actions to effectively tackle TB. The 2030 global targets will not be achieved unless all existing interventions are optimized and implemented, and new transformational tools are developed and put in place everywhere. This may require tough financial choices, with high- and medium-TB burden countries in particular needing to step up their TB response by implementing the Strategy they pledged to support at the World Health Assembly. Now the time to decisively support TB research has come. We must join forces, nationally and internationally, and position the End TB Strategy on a sounder footing so that together we can **End TB**.



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¹ Global action framework for TB research. Geneva: World Health Organization; 2015 [WHO/HTM/TB/2015.2 (<http://www.who.int/tb/publications/global-framework-research/en/>), accessed 14 September 2016].

EXECUTIVE SUMMARY

Tuberculosis (TB) remains an important global health problem. Although a number of important advances have been made to control TB in the past decade, an estimated 10.4 million people fell ill with TB and 1.8 million died from the disease in 2015. WHO's Global TB Programme has identified *research and innovation* as one of the three essential pillars to end TB as a public health threat by 2030. This document provides the structure and tools that enable the necessary actions to be taken to address country-specific TB challenges and ensure that national response activities are supported by evidence to the fullest extent possible.

This document describes how to develop a country-specific approach to utilizing research and innovation to strengthen and improve TB care and control. It provides a series of tools for developing and implementing a national TB research plan that will help in leveraging individual country action to address the global TB burden. These tools will assist a country's national TB control programme or its equivalent to develop an effective *national TB research plan* through a coherent step-by-step process. These tools are described briefly below.

- **Tool 1** (*Establishing a National TB Research Network*) guides countries in establishing a formal network of stakeholders who will drive the development and implementation of the national TB research plan.
- **Tool 2** (*Reviewing national TB control activities and research programmes*) is a self-assessment tool for evaluation of TB control at country level. This includes assessing the characteristics of the TB epidemic, national TB programme, health system and research capacity to inform the development of a national TB research agenda.
- **Tool 3** (*Developing a national TB research plan*) assists with conducting a gap analysis based on the initial situation assessment, and to develop a prioritized national TB research plan and implementation strategy.

These three tools outline the various steps needed to produce a country-specific TB research plan involving all due stakeholders at country level. The national TB research network, described in Tool 1, is an essential first step to identify research priorities from the country-specific situational assessment. It is hoped that funders, researchers and policy-makers will adopt these national priorities and support the drive towards evidence-based TB care and control. We envision that the outcomes of research and innovation will transform policies and practice, which will accelerate progress towards achieving country-specific goals and the End TB strategy by eliminating TB as a public health threat by 2030.



INTRODUCTION

The past decade has seen a significant reduction in the incidence of and mortality due to tuberculosis (TB) (18% lower incidence than in 2000, and half the mortality than in 1990, respectively). Despite these reductions, the global burden of TB disease remains significant, with an estimated 10.4 million TB cases in the world in 2015. Today, TB ranks as the leading infectious disease killer with 1.8 million deaths reported in 2015. Better diagnosis, treatment, vaccines, as well as improved strategies to address the co-drivers of TB (such as HIV, smoking and diabetes) are desperately needed to effectively end TB as a public health threat by 2030, as envisaged by the Sustainable Development Goals (SDGs) and the WHO End TB Strategy.

WHO's End TB Strategy aims to reduce TB deaths by 90% and cut new cases by 80% between 2015

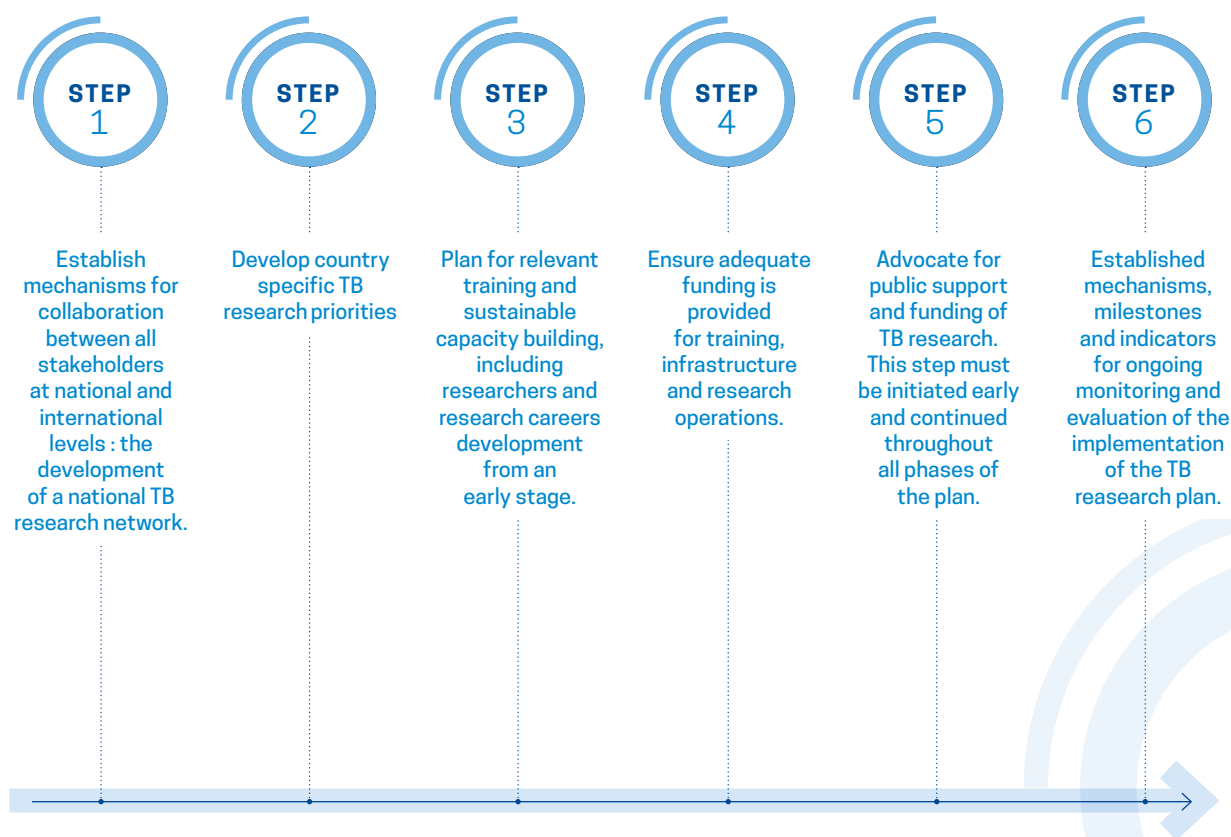
and 2030, and ensure that no family is burdened with catastrophic health expenditure due to TB.¹ “Intensified research and innovation” has been identified as one of the three essential pillars to end the global TB epidemic.

To achieve the goals and milestones of the End TB Strategy, global efforts must be complemented by country efforts. A Global Action Framework for TB Research (GAF)² has been developed by WHO to foster high-quality national and international TB research to end the TB epidemic. A key output at country level is the development of a country-specific TB research strategy (Fig. 1).

¹ Uplekar M, Weil D, Lonnroth K, Jaramillo E, Lienhardt C, Dias HM et al., for WHO's Global TB Programme. WHO's new End TB Strategy. *Lancet*. 2015;385 (9979):1799–801.

² A global action framework for TB research. Geneva: World Health Organization; 2015 (<http://www.who.int/tb/publications/global-framework-research/en/>, accessed 4 September 2016).

Fig. 1. Key steps in developing and implementing a national TB research plan



Source: Adapted from the Global Action Framework for TB Research (GAF)²

This document provides a framework to assist high TB-burden countries in establishing a national TB research network and develop a national TB research plan. The national TB research network will be the key driver for developing and implementing various aspects of the national TB research plan highlighted in Fig. 1.

Aim

The aim of this document is to provide a guide on “how to” develop a national, contextualized, targeted and prioritized TB research plan. It is based on the following tools aimed at guiding the six-step process described above.

Tool 1. *Establishing a national TB research network* that will drive country-level efforts in TB research.

Tool 2. Conducting an initial situational analysis of the country’s strengths and weaknesses to address the TB epidemic using a *self-assessment tool for reviewing national TB control activities and research programmes*

Tool 3. *Developing a national TB research plan* to be used by relevant research stakeholders to address domestic needs.

Audience

This tool-kit is for researchers, national TB programmes (NTPs), government bodies, civil society organizations (CSOs), funders and others interested in TB research. It maps out a set of strategies and activities to link national TB research stakeholders, and promote research as a norm for the evaluation and improvement of TB care and control. This tool-kit will be especially useful for NTPs in establishing a network that will facilitate the development and implementation of a national TB research plan. Additionally, national and international funders

of TB research and capacity-building may benefit from recognizing and understanding local needs and demands, and capitalizing on the network as a platform for innovations and capacity-building initiatives.

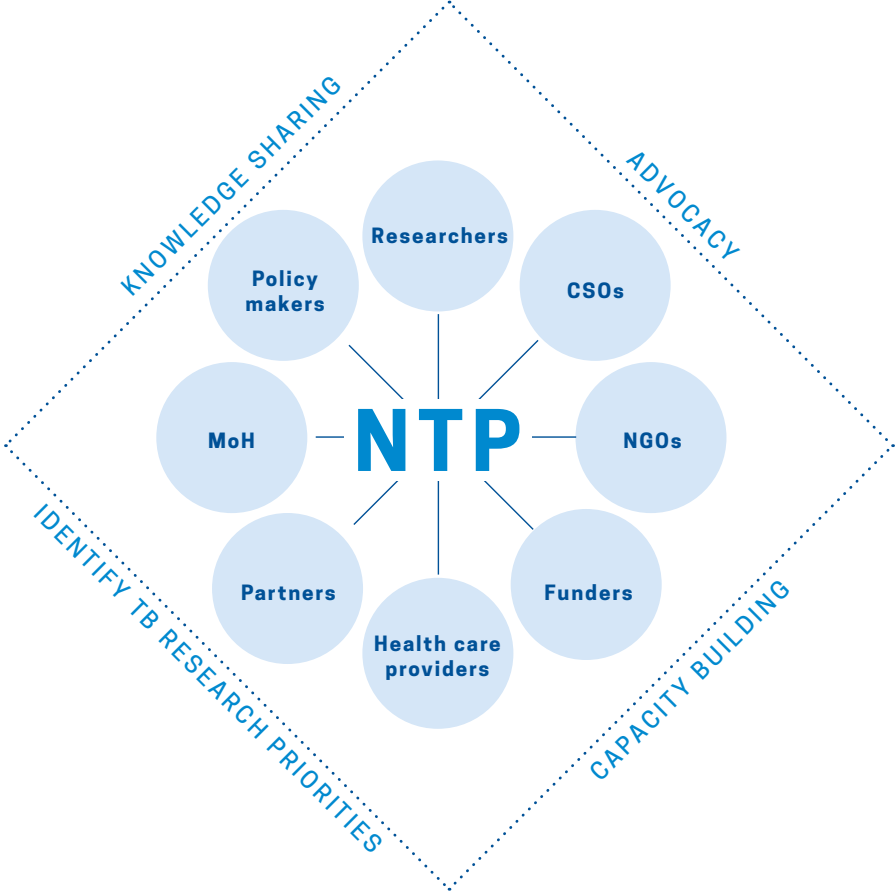
How to develop a national TB research plan

Tool 1. Establishing a national TB research network

A national TB research network (TBRN) is intended to link individuals, organizations and associated systems through a shared concern to address the national TB epidemic. It is intended to connect researchers/ research organizations, universities, government bodies, national and international nongovernmental organizations (NGOs), medical or social associations, CSOs and funders in a common effort to address the national TB epidemic and its control. Some members produce knowledge, others advocate, still others provide funds, engage in capacity-building, develop policy ideas or implement programmes. The network can operate in multiple ways, including exchanging information, collaborating, developing and implementing a research plan, organizing advocacy campaigns, as well as by engaging governments and other funders to support their efforts.

WHO encourages the establishment of a TBRN focusing on knowledge generation through the development and implementation of a national TB research agenda, together with building research capacity and driving research advocacy (Fig. 2). In the following documents, case studies of existing TBRNs are used to demonstrate how a broad partnership of stakeholders can create a platform for development of a successful country-specific research agenda, including the identification of related training needs, with an expected high impact.

Fig. 2. Features of a national TB research network [CSOs (civil society organizations), MoH (ministry of health), NGOs (non-governmental organizations)]

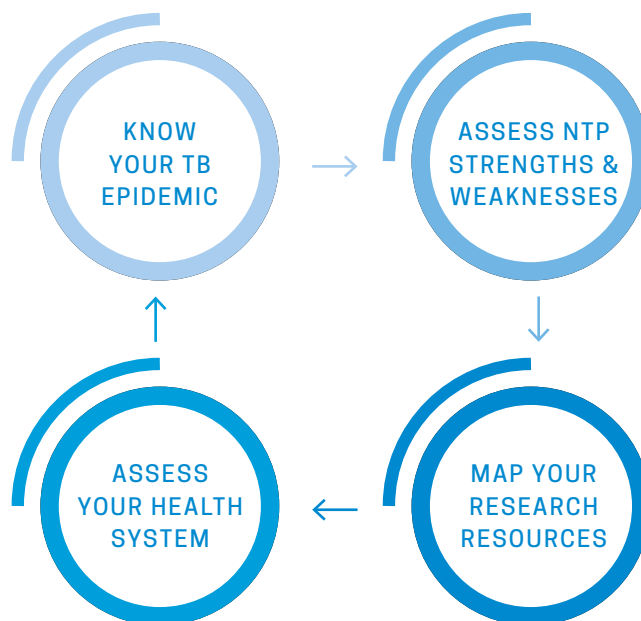


Tool 2. Self-assessment tool for reviewing national TB control activities and research programmes

The TB burden at country level may vary due to local determinants such as socioeconomic status, comorbidities, health-care provision and financing, community engagement, and others. Consequently, similar interventions may not be equally successful in different countries. A situational analysis that provides a deliberate and comprehensive tool to map,

measure and understand the interactions between the national TB epidemic, performance of the NTP, health system, and domestic TB research capacity, is key to understanding the local TB control dynamic (Fig. 3). This tool is useful in helping countries to identify their strengths and weaknesses, as well as the constraints and opportunities with regard to TB care and control. This would lead stakeholders to identify research areas to address country-specific gaps in TB care and control through locally tailored research questions and interventions targeting TB.

Fig. 3. A situational assessment framework



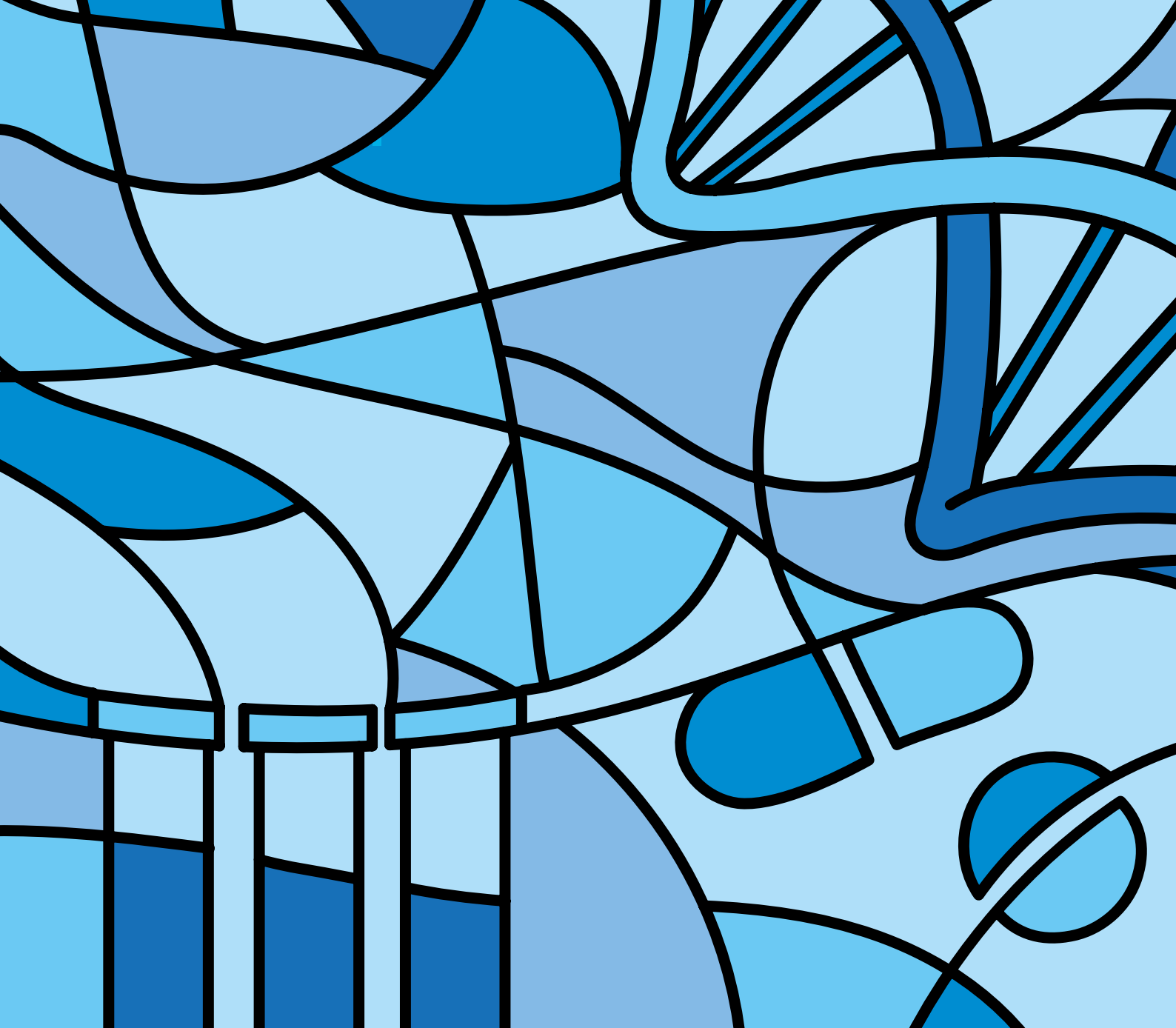
Tool 3. Developing a national TB research plan

This document proposes a logical process for developing a national TB research agenda. The aim is to identify country-specific research questions arising from the situational analysis, to prioritize these questions rigorously and transparently, and disseminate them to all key stakeholders who conduct, support or use TB research. This approach proposes a change from the usual opinion-based *expert consultation* approach to a *full multidisciplinary consultation* of national stakeholders to identify and prioritize the research questions in a systematic way. This process starts with a *gap analysis*, aimed at identifying the research questions from a baseline situational analysis, followed by a *research prioritization exercise*, outlining key TB research needs. The ultimate

outcome is the *development of a national TB research plan* with time-bound deliverables, which will be incorporated into the TB national strategic plan (NSP) for implementation.

More than 85% of the TB burden is concentrated in 30 high-TB burden countries.³ Identifying novel tools and strategies to tackle country-specific TB control issues is expected to have a significant impact on the transmission dynamics of the disease in-country and globally. The present tool-kit provides a comprehensive system to address domestic TB care, and control problems through research. Completion of the three steps outlined in this document will allow for the development of a robust TB research agenda aimed at improving TB care policies and practice through research.

³ Global tuberculosis report 2016, twentieth edition. Geneva: World Health Organization; 2016 (http://www.who.int/tb/publications/global_report/en/, accessed 13 October 2016).



TOOL **1**

Establishing
a National
TB Research Network

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Acronyms

CSO	civil society organization
GAF	Global Action Framework for TB Research
GTB	Global TB Programme
LTBI	latent TB infection
MDR-TB	multidrug-resistant tuberculosis
MoH	Ministry of Health
NGO	nongovernmental organization
NTP	national TB programme
TB	Tuberculosis
TBRN	TB research network
TRAC	Tuberculosis Research Advisory Committee (Ethiopia)
VICTORY	Vietnam Integrated Centre for Tuberculosis and Respiratory Research

1. Introduction

WHO's End TB Strategy¹ aims to reduce, by 2030, the incidence of tuberculosis (TB) by 80% and TB deaths by 90%, as well as achieve 100% protection against catastrophic costs for TB-affected households. To reach these ambitious targets, “intensified research and innovation” has been adopted as one of the three essential pillars of the End TB Strategy. A Global Action Framework for TB Research (GAF)² has been developed by the WHO Global TB Programme (GTB) in collaboration with a wide array of stakeholders to foster the high-quality national and global TB research needed to end the TB epidemic. The GAF outlines the steps and benchmarks to advance research for key stakeholders at global and national levels, particularly in countries with the largest burden of disease.

1.1 Why establish a national TB research network?

A key aspect of the GAF is the development of a country-specific TB research plan that outlines the national TB research needs. The establishment of a national TB research network (TBRN) that links TB control programmes to the national TB research community is the first step in this process. This network aims at developing multi-institutional and multisectoral collaboration across academia, industry, government, private and non-profit organizations to gather evidence and strategize innovations to address country-specific TB control challenges. This document describes the key activities for establishing a multidisciplinary TBRN at country level.

¹ Uplekar M, Weil D, Lonnroth K, Jaramillo E, Lienhardt C, Dias HM et al., for WHO's Global Tb Programme. WHO's new End TB Strategy. *Lancet*. 2015;385 (9979):1799–801.

² A Global Action Framework for TB Research. Geneva: World Health Organization; 2015 (<http://www.who.int/tb/publications/global-framework-research/en/>, accessed 4 September 2016).

1.2 Aim of the TB research network

The aim of the national TBRN is to map available resources for research, and identify and address domestic TB research needs to support programmatic efforts in achieving the End TB Strategy's goals at country level. The national TBRN is key for strategically aligning TB research needs with the available research capacity and research funding. It also links all relevant stakeholders involved in research and induces them to conduct TB research that will inform policy development at the national level, and place the country's research efforts within the larger framework of global TB research efforts. For this purpose, the national TBRN will bring researchers and stakeholders from different institutions and fields together to identify and implement collaborative research projects that address patient needs, and to form a strategic alliance to advocate for greater research funding, infrastructure and training. In promoting and implementing TB research, the national TBRN serves as a focal point for international and domestic research partners, and facilitates TB research throughout the country.

1.3 Objectives of the TB research network

The objectives of the national TBRN are as follows:

1. to establish a platform for knowledge-sharing and collaboration among TB control and research stakeholders at the national level;
2. to develop a country-specific TB research plan based on the characteristics of the TB epidemic and an inventory of resources and activities;
3. to monitor the implementation of the research plan;
4. to develop a plan for funding TB research and capacity-building;
5. to advocate for TB research and funding.

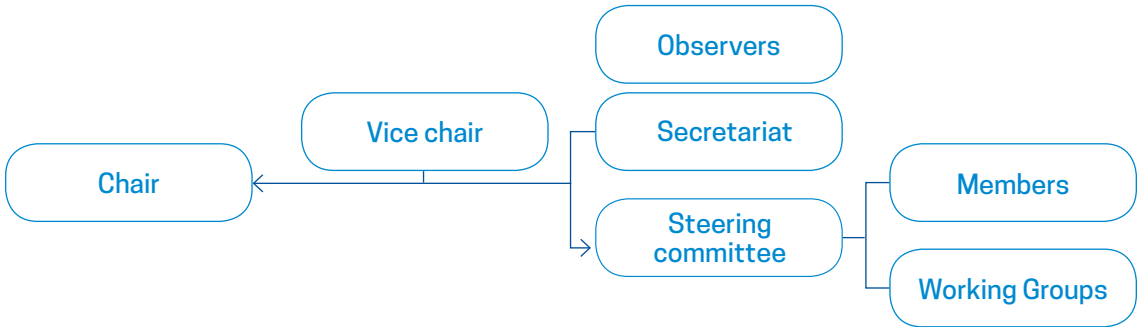
2. Organization of the TB research network

The national TBRN is governed by a *chair* and a *steering committee*, assisted by a *secretariat*. All members of the governing body should be elected by the network (the member profile is described in section 2.4). The suggested responsibilities of the steering committee, chair, vice-chair and secretariat should allow for enough flexibility for country-context adaptation and are outlined below:

- The *steering committee* consists of representatives from the national TB programme (NTP), Ministry of Health (MoH), Ministry of Higher Education, Ministry of Science and Technology, and key national academic and non-academic research institutions, domestic health research funders and health-care providers (public and private). The appropriate number of members will depend on country context, and what is deemed necessary to carry out its mission, as outlined in section 2.3. Members of the steering committee are selected through an open election process for a fixed duration (2–3 years) by the network.
- *The chair* shall preside over all meetings of the committee and network, act as official spokesperson for the network, and perform duties such as scheduling of annual meetings, appointing working groups, holding elections, and so on. *The chair* will also take the lead in setting the mission and vision of the network, by involving all stakeholders. The elected chair should have a term of 2–3 years.

- *The vice-chair* supports the *chair* and represents him/her in case of absence;
- *The secretariat* shall be responsible for executing the network’s administrative operations. These include the following:
 - > organizing meetings of the TBRN, and executing its calendars;
 - > preparing the agenda, taking minutes of the meetings, and organizing the publication of annual reports;
 - > implementing an information and communication strategy, including the maintenance of a website and/or email LISTSERV;
 - > implementing accounting procedures for all funds received by the network;
 - > supporting established working groups, as necessary, by acting as the focal point for collecting and disseminating their reports.
- *Observers* may attend and participate in meetings and deliberations of the steering committee, but do not participate in decision-making. They may consist of representatives from the national ethics committee, WHO and the research funding community (Fig. 1).

Fig. 1. Suggested organogram of the national TB research network



2.1 Activities of the TB research network by objective

The essential activities of the network, in line with the stated objectives, include the following:

Objective 1. To establish a platform for knowledge-sharing and collaboration among TB and other health sectors, as well as research stakeholders at the national level

Activities

- Improve communication and collaboration among various groups of researchers and the NTP by:
 - > establishing thematic working groups within the framework of the TBRN with clearly defined mandates and duration, to assist with research priority-setting and thematic consultations (e.g. by research disciplines, such as clinical/translational research, basic research, implementation research, etc).
 - > establishing subgroups within the network to bring together members who share common interests and wish to explore a special domain or topic, e.g. in infection control, TB comorbidities, diagnostics, etc. These groups will serve as platforms to promote knowledge generation, mutual learning, identification of good practices and knowledge dissemination through debate, advocacy and organization of special events.

Objective 2. To develop a country-specific TB research plan based on the characteristics of the TB epidemic and an inventory of resources and activities

Activities

- Define and compile data that are relevant to the assessment of the national TB epidemic, the strengths/weakness of the NTP, as well as a mapping of the national research capacity using information from:
 - > national health policies and plans, as well as relevant reports on the national health system;
 - > existing TB prevention, care and control policies, the national TB strategic plan, including the annual operational plans; reports from meetings organized by the NTP;

- > findings of previous reviews of the NTP and reports from any previous external assessments, as well as from funding proposals to bilateral or multilateral cooperation mechanisms, and any subsequent reports on implementation and monitoring;
 - > the latest data on financial protection mechanisms established for TB and TB/HIV patients;
 - > any other data from national and international partners involved in TB research, prevention, care and control efforts, including nongovernmental organizations (NGOs) and civil society organizations (CSOs), as well as from national research meeting reports.
- Conduct a situational assessment of the country's TB epidemic, health system, NTP performance and research capacity.
 - Identify gaps in national TB prevention, diagnosis and treatment (including the management of comorbidities).
 - Develop a prioritized national TB research agenda, with a built-in monitoring, implementation and dissemination plan.
 - Integrate the TB research plan within the national strategic plan for TB for implementation.

Objective 3. To monitor implementation of the research plan

Activities

- Regularly monitor implementation of the research plan, from protocol development to completion.
- Monitor dissemination of the outputs of research to policy-makers, programme managers, healthcare providers, as well as to the community at large.

Objective 4. To develop a national TB research capacity-building plan

Activities

- Develop a sustainable plan for research training (e.g. postgraduate training) and research infrastructure based on local capacity by engaging all relevant stakeholders.

Objective 5. To advocate for TB research and funding

Activities

- Advocate for the establishment of a regular and competitive national TB research funding mechanism for implementing the national TB research plan, which can be complemented by grants from international funders as appropriate.
- Involve communities in developing TB research plans, e.g. for capacity-building, policy and programmatic decisions.
- Involve communities in advocacy to increase investments in TB research and capacity-building.

Box 1. Structure and activities of a research network: the example of Ethiopia's TB Research Network

Background and structure

The Ethiopian Tuberculosis Research Advisory Committee (TRAC) was established in 2001 as a voluntary network of the NTP and other relevant MoH departments, public research institutions, major national universities, professional associations and other key TB stakeholders. It is a core technical advisory body to the NTP that sets TB research priorities and builds national capacity to conduct TB research. The NTP acts as the secretariat for TRAC, while once every two years a new chairperson is selected from among members. TRAC has been historically funded by a pooled fundraising mechanism from the MoH, NTP, United States Agency for International Development, Global Fund to Fight AIDS, Tuberculosis and Malaria, Centers for Disease Control and Prevention, and others.

Objectives

(1) Define national TB research priorities; (2) create a conducive environment for TB research; (3) review the current status and challenges of operational and other forms of TB research in the country; (4) recommend effective and efficient mechanisms for coordination, management and evaluation of TB research, as well as dissemination and uptake of results; (5) identify potential funding institutions or organizations for TB research; (6) identify needs for capacity-building to facilitate TB research in Ethiopia; and (7) promote TB research and innovation at all levels of the health system.

Activities and accomplishments

Over the past 14 years, TRAC has been actively engaged in the promotion, conduct and dissemination of operational research on TB control, and has been a forum for dialogue and interaction between researchers and NTP staff in Ethiopia. TRAC organizes annual national research conferences, as well as consultations and side meetings on selected thematic areas of national importance for programmatic design and scale up of services. TRAC also organizes training in operational research methodology. To date, TRAC has organized 12 rounds of such methodology training for 240 experts working at all levels of the health system from across the country. TRAC has also provided operational research training courses and developed an operational research grant mechanism to provide funding for researchers from public institutes and universities, and health-care delivery systems working collaboratively.

As part of ongoing monitoring and evaluation, TRAC, in collaboration with the NTP, has initiated mapping and review of operational research activities and publications on TB in Ethiopia.

2.2 Deliverables of the national TB research network

With the assistance of the steering committee, secretariat and/or other groups and based on activities established for this purpose, the network will deliver the overall action plan for TB research, defining how the main activities will be scheduled and indicate the timing of the deliverables. This national action plan for TB research will include the following:

- a prioritized TB research agenda, and a clear description of the means to implement it;

- an action plan for domestic research capacity-building in TB;
- an action plan for developing/enhancing funding for TB research together with relevant public agencies;
- a set of procedures for monitoring progress, assessing the quality of deliverables, and producing an annual progress report for the public, policy-makers and other relevant stakeholders.

Box 2. REDE-TB: the Brazilian TB Research Network's role in developing a national TB research strategic plan

In 2001, REDE-TB was created as an interdisciplinary group of Brazilian researchers and students with civil society partners, government and health service representatives working on TB and HIV/AIDS from across the country. The common goal was to promote wider discussion among various sectors (government, academia and civil society) on the development and implementation of new technologies and strategies to improve TB care and control. The establishment of REDE-TB helped to build linkages between university and research institution-based researchers, the public health system (particularly the NTP), industry and civil society. The network routinely helps the NTP by conducting studies of strategic importance to the NTP, and through expert guidance committees on specific technical issues (such as the diagnosis and treatment of latent TB infection (LTBI)). In 2015, REDE-TB, in collaboration with Brazil's Oswaldo Cruz Foundation (Fiocruz), and the NTP developed a national TB research strategic plan. Its aim is to produce scientific knowledge that responds to local demands, through implementation and health system research approaches. Among its priorities are: validating the implementation of locally developed TB diagnostics (with a focus on drug-susceptibility testing and detection of latent TB), evaluating the clinical and cost-effectiveness of scaling up existing TB diagnostics and treatment tools, and designing ways to evaluate and implement interventions on vulnerable populations through multidisciplinary approaches (*www.rede.tb.org.br*).

2.3 Activities of the steering committee

These include the following:

A. Administration

- to coordinate open elections for the chair, vice-chair and secretariat positions;
- to propose and agree on new members;
- to organize thematic working groups to drive the performance of target-driven workplans (e.g. to identify and assess new technologies and innovations, develop a national TB research plan), as necessary.

B. Developing a strategy

- to define the scope and content of the network's deliverables;
- to advise on the development of the network's workplans and its relationships with relevant stakeholders, as appropriate;
- to identify and specify how strategic plans for research can be developed and implemented.

C. Creating cohesion and collaboration

- to explore and ensure mechanisms of collaboration with other relevant initiatives nationally and internationally, e.g. by organizing joint research plans and grant applications;

- to ensure the necessary coordination for optimizing the outputs of the national TB research plan within the context of the NSP and meeting the goals of the WHO End TB Strategy;
- to motivate and drive the organization of network meetings to achieve the network's goals (*see* section 2.1).

D. Monitoring, evaluation and reporting

- to follow up on activities of the network, and review its performance against the network's deliverables (*see* section 2.2);
- to identify potential policy issues arising from the research outputs and propose appropriate recommendations to policy-makers (e.g. NTP, MoH, etc.) for implementation;
- in close contact with the secretariat, to develop and implement an efficient communications strategy for the network's missions and goals, and advocate for TB research, capacity-building and funding.

2.4 Member profile

Membership should be inclusive, with representatives of the government sector (Ministry of Science and Technology, MoH, NTP, etc.), and other individuals or organizations that conduct TB research, use TB research outcomes, or support TB research (e.g. through financial support or advocacy). The latter includes representatives from organizations that are in a position to support research in the future, and those that are positioned to become involved in TB research in some capacity (e.g. strategically or financially), and understand the larger national implications of TB research.

Members may represent their organization, or participate in a personal capacity in their field of activity or area of expertise. They should be able to make an active contribution to the network's activities and objectives, and be in a position to influence stakeholders on the planning of research programmes, foster partnerships and leverage resources.

It is essential that the TBRN be multidisciplinary to guarantee a diversity of perspectives, ensure a broad ownership base, and increase the likelihood that evidence generated by the network will be used to inform programmes and policies. The network will be composed of an appropriate number of members, as deemed necessary to carry out its mission. The specific composition of the TBRN will vary according to country-specific settings, but key constituencies need to be represented, such as:

- policy-makers or professionals who are involved in national policy-making; usually this includes representatives from the MoH and Ministry of Science and Technology;
- domestic and international biomedical and social scientists from academic and non-academic research institutions;
- professionals involved in TB control, including clinical, laboratory and logistics professionals, as well as professional health associations;
- professionals or representatives of stakeholders involved in managing the treatment and care of TB comorbidities (e.g. diabetes, HIV, silicosis, etc.);
- institutions that provide training on health care and research;
- NGOs working in the area of health-care support;
- civil society groups, community volunteers and social workers;
- representatives of other stakeholders involved in TB research and control programmes such as the Ministry of Education or Social Welfare;
- international and local funders and philanthropists who fund health research related to TB, as well as poverty alleviation programmes;
- technical agencies such as WHO, which can provide support in research planning and implementation.

3. Establishing the network

3.1 Administrative arrangements

- TBRN meetings are convened at least annually, as well as on an “as needed” basis.
- The steering committee will meet quarterly, in person or virtually. Conflicts of interest must be declared in advance of any discussions, and the chair will decide on a case-by-case basis whether committee members with conflicts of interest should be asked to withdraw from the meeting. A quorum should be set by the network for the steering committee meeting, as well as for general meetings.

3.2 Method of working

The TBRN will maintain the vision outlined in the country’s national strategic plan for TB control, and ensure that it stays in line with WHO’s End TB Strategy. Periodic activity reports together with reports on specific deliverables (*see* section 2.2 above), and recommendations as necessary will be communicated to the network members, and copies of these documents will be made available to the public (e.g. on a website). An annual activity report will be sent to appropriate units at the MoH.

Box 3. Checklist: identification of stakeholders

The involvement of a broad range of stakeholders is essential for establishing or reinforcing an existing national TBRN. The following essential points should be kept in mind.

- Are policy-makers adequately represented?
- Is the private sector and are NGOs adequately represented? It may be necessary to obtain a listing of all private health-care providers and NGOs that currently have dealings with TB, and associated comorbidities.
- Among the researchers, are various disciplines represented, e.g. biomedical sciences, social sciences, education, public health, etc.?
- Is there sufficient community representation?
- Are various districts and regions adequately represented?
- In most countries, parliamentarians, funders and international agencies have an important role in TB care, priority-setting and implementation of major health programmes. Are these entities adequately represented?

3.3 The process of establishing a national TB research network

The successive steps for establishing a national TB research network for the first time are summarized below.

Phase 1. Planning and preparing

- i. The NTP/MoH will appoint a temporary steering committee to organize the initial constitutive meeting. This committee will be replaced by an elected committee during the first meeting.
- ii. The temporary steering committee will set the date, and make the logistical preparations for the initial constitutive meeting that will aim to establish the grounds for the national TBRN, particularly through the development of appropriate terms of reference and structure of the network. This process involves:
 - > identifying and mapping stakeholders for the network's initial membership;
 - > preparing relevant information to disseminate to stakeholders on the purpose and goals of establishing a TBRN and its proposed structure and terms of reference, and sending these materials to stakeholders along with the meeting invitations.
- iii. Budgeting: an initial seed funding is essential to help support the network's activities and set the momentum for a self-sustaining research network. It is ideal if the government, through the NTP /MoH or Ministry of Science and Technology or its equivalent, funds the establishment of the network and the initial workshops to position the network so that it is successful at making bids to and receiving funds from external bodies. To achieve these aims, the temporary steering committee can establish a funding committee from the start. The budget for the first meeting should include the following:
 - logistics, which includes secretariat support, meeting rooms, communication costs, photocopying and printing, as well as press briefing and advocacy materials;
 - travel costs to support relevant stakeholders for travel, at least initially;
 - the steering committee should mobilize funds through the appropriate financial mechanism available at the MoH or similar, or from funders and partners, and/or through channels of bilateral and multilateral corporations.

Is the quality of representation suitable? Usually, the top decision-makers are very busy and may choose to send junior representatives. In such cases, is there a mechanism to ensure satisfactory representation from the top?

Box 4. VICTORY: the example of establishing a national TB research network in Viet Nam

In 2015, Viet Nam's National TB Programme, in collaboration with a range of national partners, set up the Vietnam Integrated Centre for Tuberculosis and Respiratory Research (VICTORY) in line with the country's national End TB Strategy. The Centre brings together government agencies, hospitals, universities, research institutions, the private sector and NGOs. VICTORY is committed to enhancing the capacity of researchers by training and mentoring, contributing to international collaboration on all types of research, and advocating for local investment in TB research. It plans to conduct a number of research studies, starting with a national prevalence survey, and including, among others, clinical trials for novel therapeutics of drug-susceptible and drug-resistant TB.

Phase 2. Initial constitutive meeting

At the initial constitutive meeting, the temporary steering committee will work with stakeholders towards the following outcomes:

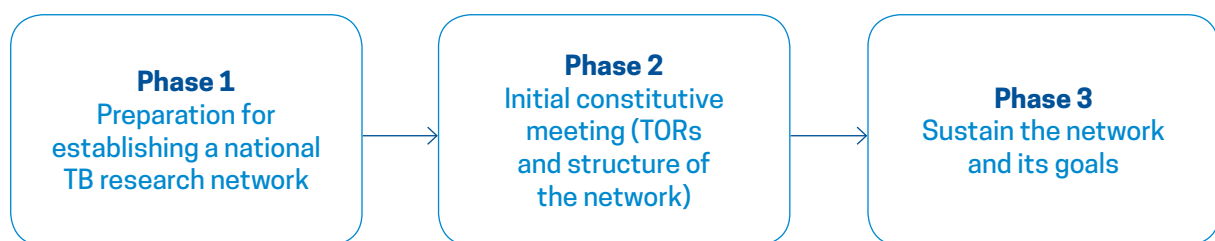
- i. to agree on the mission, objectives and goals of the network;
- ii. to facilitate the transparent election of a steering committee and leadership by all stakeholders, and to agree on their tasks and responsibilities;
- iii. to agree on the terms of reference for the network as outlined in this document, and to engage relevant stakeholders in the process; and

- iv. to appoint individuals/groups in charge of finalizing the terms of reference, and developing a calendar to monitor the deliverables of the network.

Phase 3. Sustain the network and its goals

The newly elected national TBRN leadership will pursue implementation of the network's mission and goals, while engaging in routine review, monitoring and supervision of the network's workplan and efforts.

Fig. 2. The process of establishing a national TB research network

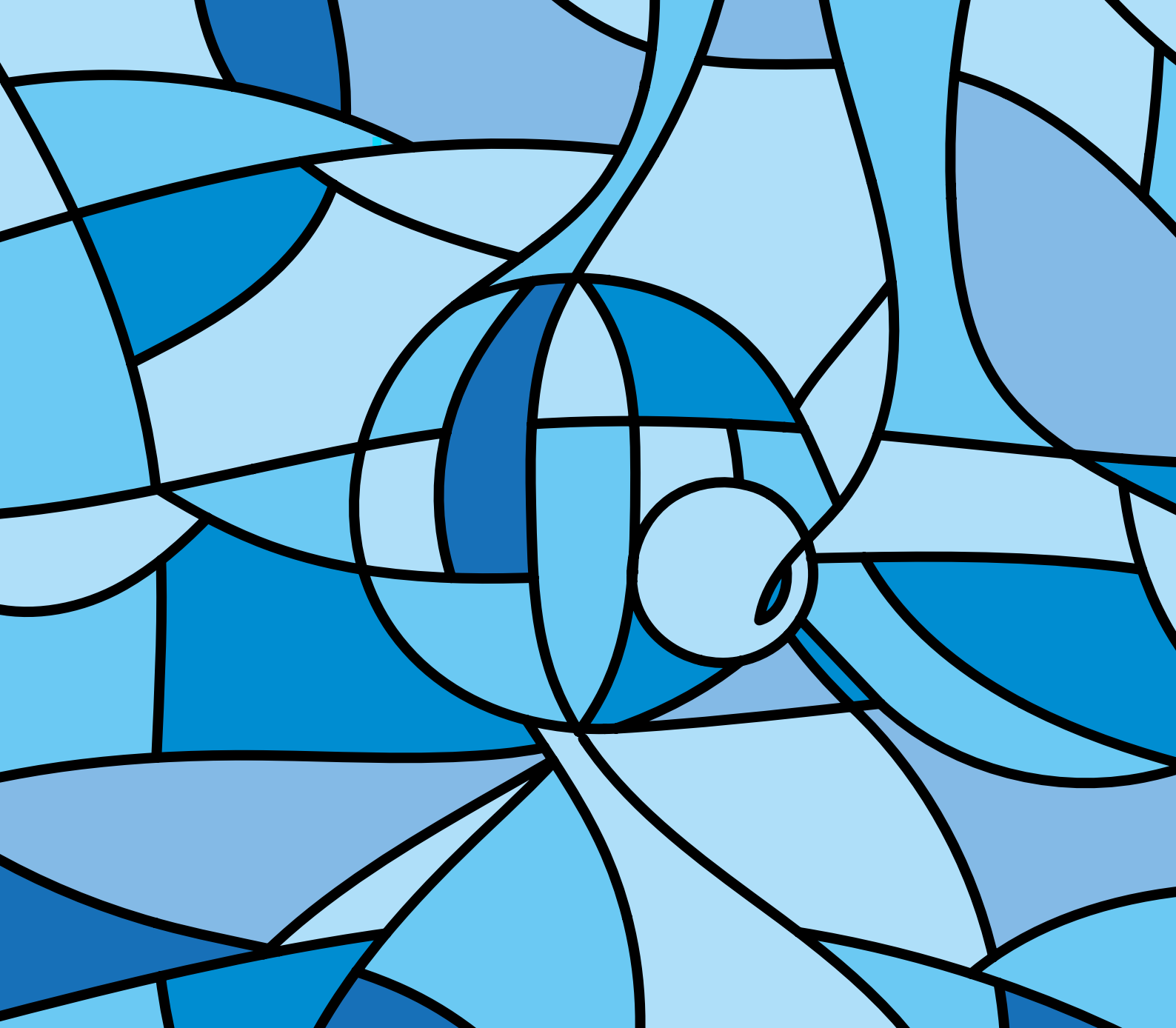


4. Conclusion

The success of the End TB Strategy relies on country-specific adaptation of the GAF to utilize research to curb domestic TB incidence, mortality and morbidity. As an immediate priority, the establishment or reinforcement of a national TBRN is necessary to ensure a common vision for the role of research to end TB. Implementation of the objectives and activities

of the national TBRN requires sustained, coordinated and complementary efforts by the government, researchers, health-care providers, health-care leaders, CSOs, NGOs, policy-makers and patients. The national TBRN is key for leading and mobilizing national TB research initiatives to identify TB research priorities and their implementation strategies.





TOOL **2**

Reviewing national TB
control activities and
research programmes:
a self-assessment tool

THE
END TB
STRATEGY



World Health
Organization

1. Overall aim and rationale

An effective situational assessment is valuable for properly informing a national tuberculosis (TB) research agenda driven by a country-specific TB epidemic. In this context, situational assessment requires a broad, systematic approach, that cuts across the TB epidemic, national TB programme (NTP), health system and research capacity in both the public and the private sectors. The purpose of this tool is to guide stakeholders in assessing the national TB epidemic, performance of the NTP and health system, and the domestic TB research capacity, so that the national TB research network (TBRN) is equipped to develop a research agenda that addresses the needs of all end-users and policy-makers. This is a self-assessment tool that primarily uses existing data to identify and analyse gaps, and develop research questions. Although this tool is not meant to be a data collection exercise, lack of availability of critical data to conduct this assessment may result in the need for data collection to address gaps in TB control. This tool is also intended for routine use to address changing priorities in the field of TB and keep up with new developments.

2. Structure

The situational assessment is intended to broaden the understanding of all participants and provide an oversight of the current state of affairs. It should be performed in a systematic and rigorous way, and aims at assessing the following four areas:

1. *The national TB epidemic* is assessed through the review of data on the epidemiological profiles of various forms of TB. Relevant sources of information for this include national surveillance data, WHO country TB reports and epidemiological reviews, findings of previous reviews of the NTP and reports from any previous external assessment, research publications, as well as funding proposals to bilateral or multilateral cooperation mechanisms (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the World Bank), and any subsequent reports on implementation and monitoring.
2. *The NTP's performance* is assessed for efficiency and effectiveness by using different indicators from relevant data sources from the ministry of health (MoH) and NTP at district, regional and national levels, as well as from other suitable sources.

3. *The national health system* is assessed to evaluate TB care provision at multiple levels to capture where and how patients access care. Here, a health system assessment in addressing TB care and control is conducted using WHO's building blocks of health systems as a guide.¹
4. *The national research landscape* is the overall research environment for conducting TB research. It is evaluated through mapping human resource capacity for conducting TB research, an inventory of countrywide TB research activity and outputs, the role of public and private stakeholders in TB research (e.g. universities, public-private partnerships, etc.), available funding sources as well as the NTP's links to research.

3. Conducting the situational assessment

The situational assessment is a result of teamwork, and requires collaboration among the NTP, MoH, health-care providers, researchers, and other implementers of TB care and control. Different kinds of knowledge, experiences and backgrounds must come together in order to identify and clearly define gaps in controlling domestic TB epidemics, the health system, NTP and research capacity. It is proposed that a working group identified by the national TB research network (TBRN) gathers and inputs the necessary information and data in the situational assessment framework; this will ultimately aid in defining and contextualizing national TB research questions. The working group may include researchers as well as health-care providers, programme managers, policy-makers, representatives of civil society organizations (CSOs) and nongovernmental organizations (NGOs) depending on the context of the country, as described in Tool 1.

The process involves the following steps:

1. defining the scope of the situational assessment (consulting stakeholders, defining deliverables, etc.);
2. establishing working group(s) with the appropriate knowledge and skills from within the national TBRN, and agreeing on their roles and responsibilities for completing the situational assessment. The individuals in these working groups are expected to be knowledgeable about how and where to access information and resources. The TBRN's steering committee will take charge of coordinating this process;

¹ Everybody's business — strengthening health systems to improve health outcomes. WHO's framework for action. Geneva: World Health Organization; 2007 (http://www.who.int/healthsystems/strategy/everybodys_business.pdf, accessed 14 September 2016).

3. articulating an implementation plan for the situational assessment, including defining timelines and frequency of working group meetings, reporting methods, estimating resource needs, etc.;
4. completing the assessment form; and
5. submitting this to the steering committee of the network, which will coordinate the use of this information for developing and prioritizing research questions (see Tool 3 for technical guidance).

Annex 1 provides a template for conducting the situational assessment as envisioned in this tool, and **Annex 2** provides a summary checklist for what is considered in the assessment.

4. Expected outcomes

A situational assessment is part of a continuum of efforts by the national TBRN to develop a country-specific national TB research agenda. The situational assessment is expected to identify needs and gaps that the national TBRN can utilize to formulate research questions. These are summarized below.

1. The extent and severity of the domestic *TB epidemic* (of all forms) is assessed, including in vulnerable populations.
2. *The strengths and needs of the NTP are assessed* to identify the overall preparedness of the programme in terms of policy and regulatory environment. These would include use of diagnostic and treatment algorithms for all forms of TB; availability and implementation

of prevention strategies (e.g. in the context of latent TB infection), as well as treatment and diagnostic coverage, and quality of provision.

3. *The evaluation of TB control within the general health system* includes patients' use of different providers at various levels of the health system, the role of the for-profit and non-profit private sector (and associated treatment delays and costs), as well as how much current TB care provision has been adapted to the poor and vulnerable. The outcome of this assessment also maps the overall governance of TB care structures such as drug management, civil society participation and health system structure, as well as the utilization and structure of the NTP's information management system in the care provision process.
4. *The mapping of the local research landscape* involves assessment of the TB research environment and practices in both the NTP and non-NTP sectors. It includes mapping research resources in terms of human capacity and infrastructure, research outputs and funding sources.

The logical *next steps* are to identify research priorities and draw up health actions to address the gaps identified. Lessons from implementing the outcomes of research and health actions should be incorporated to advise subsequent actions for TB stakeholders.

Once the assessment is complete, **Tool 3** describes how to perform a gap analysis and formulate appropriate research questions that will help to address these gaps.

Annex 1.

1. Know your tuberculosis (TB) epidemic

A. General TB epidemic		
A.1 Estimates of TB burden at national level		
Data year: _____	Number (thousands)	Rate (per 100 000 population)
Prevalence (includes HIV + TB)		
Incidence (includes HIV + TB)		
Incidence (HIV + TB only)		
Mortality (includes HIV + TB)	<i>For new TB cases</i>	
	<i>Among retreatment cases</i>	
Mortality (HIV + TB only)	<i>For new TB cases</i>	
	<i>Among retreatment cases</i>	
Please comment on regional- or district-level differences in TB epidemiology. If possible, please disaggregate the national estimates by district or regional levels.		

A.2 TB case notifications								
Data year: _____								
1. New or previous treatment history unknown		0–4 (N, %)	5–14 (N, %)	15–24 (N, %)	25–34 (N, %)	35–44 (N, %)	44–54 (N, %)	55–64 (N, %)
a. Pulmonary, bacteriologically confirmed	Male							
	Female							
b. Pulmonary, clinically diagnosed	Male							
	Female							
c. Extrapulmonary TB cases, bacteriologically confirmed or clinically diagnosed	Male							
	Female							
Total TB notification, new or previous treatment history unknown (sum a, b, c)	Male							
	Female							
2. Previously treated (all forms)	Male							
	Female							
3. Total TB notification (sum 1,2)	Male							
	Female							
Among the cases reported above, please list total number of TB cases reported among foreign-born individuals (or among non-citizens if that is the criterion used in your country) if known.	Male							
	Female							

A.3 TB Treatment outcome		
Data year: _____		
Cohort size (N=_____)	Success (%) <i>A patient who was cured or who completed treatment</i>	Failed (%)
	Lost to follow up (%)	Not evaluated (%)
	Died (%)	

B. Drug-resistant (DR) TB

B.1 DR-TB burden: demography																	
Data year: _____		Notified MDR-TB cases by age group – n (%) Total N = _____ % of total notified TB: _____								Estimated MDR-TB cases by age group – n (%) Total N = _____ % of total notified TB: _____							
		0–4	5–14	15–24	25–34	35–44	44–54	55–64	>64	0–4	5–14	15–24	25–34	35–44	44–54	55–64	>64
Rifampicin-resistant/ multidrug-resistant TB (RR/MDR -TB) burden	Female																
	Male																
Extensively drug-resistant TB (XDR-TB) burden	Female																
	Male																

Please comment on whether all districts routinely report these data.
If not, please explain why.

B.2 Assessment of DR-TB epidemic	
Data year: _____	
New cases	Previously treated
New TB cases tested for RR/MDR-TB (N, %) _____	Previously treated TB cases tested for RR/MDR-TB (N,%): _____
No. of confirmed RR/MDR-TB cases (N, % notified TB cases) _____	Cases enrolled on MDR-TB treatment (N, % of previously treated TB cases) = _____
Estimated MDR-TB among new TB cases (N, % estimated) = _____	Estimated MDR-TB among previously treated cases (N, % of previously treated TB cases) = _____

B.3 Treatment outcome of DR-TB					
Data year: _____					
Total cohort size N = _____	Success (%)	Failed (%)	Died (%)	Lost to follow up (%)	Not evaluated (%)
Total DR-TB N = _____					
RR/MDR-TB N = _____					
XDR-TB N = _____					

B.4 Additional questions

Is there a “waiting list” for MDR-TB treatment? (Yes/ No)
 If yes, how many patients were waiting for treatment at the time this assessment was conducted?

What are the reasons for the “waiting list”?

What types of care do DR-TB patients receive? Is hospitalization mandatory? Is ambulatory care available?

Please list other comments on DR-TB activities to inform this situational assessment better.

C. Co-epidemics of TB and HIV

C.1 Assessment of TB/HIV care Data year.....

	Number	%
TB patients with known HIV status		<i>per total TB patients</i>
HIV-positive TB patients		<i>per total TB patients</i>
Total HIV-positive TB patients on co-trimoxazole preventive therapy (CPT)		<i>TB/HIV patients on CPT / Total TB/HIV patients</i>
Total HIV-positive TB patients on antiretroviral therapy (ART)		<i>TB/HIV patients on ART / Total TB/HIV patients</i>
Proportion of total HIV-positive patients screened for active TB	N/A	
Proportion of HIV-positive patients screened for latent TB infection	N/A	
Proportion of HIV-positive patients(without TB) provided with isoniazid preventive therapy (IPT)	N/A	

C.2 Treatment outcome in TB/HIV patients

Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

C.3 HIV and DR-TB co-epidemics

	HIV status	
	+	-
% of total DR-TB patients		
% of total RR/MDR-TB patients		
% of total XDR-TB patients		

C.4 Treatment outcome in DR-TB/HIV patients

Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

C.5 Additional questions

Please list any other comments on TB/HIV activities:

D. TB and other co-morbidities

D.1 Assessment of TB among persons with diabetes

Data year :

	Number	%
Number of TB patients screened for diabetes		
Estimated diabetics with TB		<i>per total TB patients</i>
Diabetics screened for active TB		<i>per total diabetics</i>
Diabetics with active pulmonary TB		<i>per total diabetics</i>
Diabetics screened for latent TB infection (LTBI)		<i>per total diabetics</i>
Diabetics treated for LTBI		<i>per total diabetics</i>

D.1a Active TB treatment success rate among diabetic patients

Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.1b Additional questions

Please list other comments on TB management in diabetic people.

D.2 Assessment of TB among inmates (prisoners)

Data year :

Criteria	Number	% (denominator is total inmates)
Estimated inmates with TB		
Inmates screened for active TB		
Inmates with confirmed active pulmonary TB		
Inmates screened for LTBI		
Inmates treated for LTBI		

D.2a Active TB treatment success rate among inmates

Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.2b Additional questions

Please list other comments on TB management among inmates.

D.3 Assessment of TB among mentally ill patients		Data year :
Criteria	Number	% (denominator is total number of mentally ill patients)
Estimated mentally ill patients with TB		
Mentally ill patients screened for active TB		
Mentally ill patients on anti-TB treatment		
Mentally ill TB patients under psychiatric treatment		
Mentally ill patients screened for LTBI		
Mentally ill patients treated for LTBI		

D.3a Active TB treatment success rate among patients with mental illness			
Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.3b Additional questions
Please list other comments on TB in mentally ill people.

D.4 Assessment of TB among people who smoke tobacco								
Data year: _____								
Criteria	15–18 years of age				>18 years of age			
	Male		Female		Male		Female	
	N	%	N	%	N	%	N	%
National smoking prevalence		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Estimated TB patients who smoke tobacco		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Tobacco smokers screened for active TB		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Tobacco smokers on anti-TB treatment		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Tobacco smokers screened for LTBI		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Tobacco smokers treated for LTBI		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>
Tobacco smokers on tobacco cessation treatment		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>		<i>per total population</i>

D.4a Treatment outcomes in TB patients who smoke tobacco			
Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.4b Additional questions

Please list other comments regarding TB management in people who smoke tobacco.

D.5 Assessment of TB among people who use and inject illicit drugs		Data year : _____
Criteria	Number	% (denominator is drug users)
Those who inject illicit drugs (drug users) with TB		
Drug users screened for active TB		
Drug users on anti-TB treatment		
Drug users screened for LTBI		
Drug users treated for LTBI		
Drug user TB patients in drug rehabilitation programmes		

D.5a Treatment outcomes in TB patients who use and inject illicit drugs			
Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.5b Additional questions

Please list other comments regarding TB management in people who use and inject illicit drugs.

D.6 Assessment of TB among vulnerable populations		Data year : _____
Criteria	Number	%
TB prevalence in people with low socioeconomic status (SES) according to national poverty threshold (or other country-specific SES criteria as applicable). For example, SES can be defined as a combination of economic, social and work status, measured by income or wealth, education and occupation, respectively. ²		
TB prevalence in homeless people		
TB prevalence in displaced populations		
TB prevalence in asylum seekers		
TB prevalence in cross-border population		
TB prevalence in patients with chronic obstructive pulmonary disease (COPD)		
TB prevalence in patients with silicosis		

D.6a Treatment outcomes in vulnerable TB patients			
TB patients with low SES according to national poverty threshold (or other SES criteria as applicable) Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
Homeless population with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
Displaced population with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
Asylum seekers with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
Cross-border population with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
COPD patients with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____
Silicosis patients with TB Data year: _____	Cohort number = _____	Success (%) = _____	Failed (%) = _____
	Died (%) = _____	Lost to follow up (%) = _____	Not evaluated (%) = _____

D.6b Additional questions

Please list other comments regarding TB management in vulnerable or key populations.

D.7 Please describe TB epidemiology in key populations other than those described in D6.^a

Data year: _____

Key population description	Number	% of total TB population

2. National TB Programme (NTP) strengths and needs

A. Policy and strategies

Please provide as much information as possible in the context of the questions.

A.1 Disease prevention strategies

What is the current practice regarding contact tracing, including for children under the age of 5 years who live in the household as contacts of TB cases?

What is the current practice regarding contact tracing, including for children above the age of 5 years and adolescents who live in the household as contacts of TB cases?

What is the HIV testing policy for TB cases?

What is the antiretroviral therapy (ART) initiation policy for HIV-positive TB patients?

Does the country have a national plan for programmatic implementation of latent TB infection (LTBI) management, including prioritization of high-risk groups based on the local epidemiological and health-system contexts?

A.2 TB diagnostic algorithms

	Algorithm per the national policy/guideline	Consistency of this algorithm with WHO policy (as relevant)	Comment on challenges in implementing this policy/ guideline	Has impact evaluation been conducted for the last WHO guideline implemented?
New cases				
Retreatment cases				
RR/MDR-TB cases				
TB/HIV coinfection				

A.3 TB Treatment algorithms

	Algorithm per the national policy/guideline	Consistency of this algorithm with WHO policy (as relevant)	Comment on challenges in implementing this policy/ guideline	Has impact evaluation been conducted for the last WHO guideline implemented?
New cases	(Yes/ No), if Yes, attach			
Retreatment cases	(Yes/ No), if Yes, attach			
RR/MDR-TB cases	(Yes/ No), if Yes, attach			
TB/HIV coinfection	(Yes/ No), if Yes, attach			

A.4 Surveys

a) Has a TB prevalence survey been conducted (Yes/No)?

If yes, please state the year: _____

If TB prevalence survey was not performed, please explain why.

b) Has drug resistance survey been conducted (Yes/No)?

If yes, please state the year: _____

If drug resistance survey was not performed, please explain why.

(Here, survey refers to a study using a specially designed sample of patients that is representative of the national or a subnational TB patient population)

B. Diagnosing TB

Please provide as much information as possible in the context of the questions.

B.1 General questions

	NTP	Public non-NTP	Private
What is the main diagnostic approach used in practice for a pulmonary TB suspect? (e.g. triage among those with chronic cough or clinical score, acid-fast-bacilli [AFB], Xpert MTB/RIF, chest X-ray [CXR], antibiotic trial, etc.)			
In which situations is Xpert MTB/RIF prescribed and where is it done?			
What is the average turnaround time for the Xpert MTB/RIF from sputum submission to start of anti-TB treatment?			
What is the average turnaround time for the Xpert MTB/RIF from sputum submission to start of second-line anti-TB treatment?			
In which situation is culture prescribed and where is it done?			
What proportion of TB laboratories that perform culture have external quality control evaluation?			
In which situation is drug susceptibility testing (DST) or rapid test prescribed for diagnosis of drug-resistant TB and where is it done? i) for new cases ii) for retreatment cases			
What is the percentage of notified TB cases tested with a WHO-recommended rapid diagnostic test at the time of TB diagnosis? i) for new cases ii) for retreatment cases			
What is the percentage of notified TB cases tested with a WHO-recommended rapid diagnostic test at the time of diagnosis of drug-resistant TB (DR-TB)? i) for new cases ii) for retreatment cases			
What DST methods are used? (e.g. conventional proportion method, mycobacterial growth indicator tube [MGIT], line probe assay [LPA], Xpert MTB/RIF; if other, please list)			
What is the average turnaround time for the commonly used DST (i.e. time [in days] from sputum submission to receipt of DST results)?			
What is the average turnaround time for the commonly used DST (i.e. time [in days] from sputum submission to start of appropriate anti-TB treatment)?			
Is DST available for second-line drugs?			

B.2 Laboratory assessment				
Category	Assessment criteria	NTP	Public non-NTP	Private
General assessment	Number of smear microscopes (per 100 000 population)			
	Number of culture-equipped labs (per 5 million population)			
	Number of DST facilities (per 5 million population)			
	No. of sites performing Xpert MTB/RIF (per 5 million population)			
Laboratory quality of services	% of smear microscopy sites that are covered by functional external quality assessment (EQA) system?			
	% of first-line DST sites that have demonstrated proficiency by annual EQA panel testing			
	% of second-line DST sites that have demonstrated proficiency by annual EQA panel testing			
	% of Xpert MTB/RIF sites that have demonstrated proficiency by annual EQA panel testing			
	% of labs in which a formal quality management system towards accreditation has been implemented in conducting culture, LPA and/or DST			

B.2 Laboratory assessment				
National TB Reference Laboratory (NTRL)	Is the NTRL in the public sector or the private sector?			
	Are other laboratories carrying out DST linked to the NTRL? If yes, describe the collaboration.			
	What culture methods are used at the NTRL?			
	What is the average turnaround time for the commonly used culture (i.e. time from sputum submission to receipt of culture results)?			
	Does the NTRL have an external control quality assessment, for example by a supranational reference laboratory network (SNRL)? (Yes/No) If yes, please state the responsible SNRL.			

C. Treating TB

Please provide as much information as possible in the context of the questions.

C.1 Treatment approaches for drug-sensitive (DS)-TB

Please describe the regimens commonly used in practice for

- i) bacteriologically confirmed TB patients
- ii) other new patients with a clinical and radiological diagnosis
- iii) retreatment patients

C.2 Treatment approaches for RR/MDR-TB

Where is treatment initiated for laboratory-confirmed RR/MDR-TB patients?

Where is treatment continued for patients (continuation phase)?

Are all MDR-TB patients receiving full treatment? (Yes/No)

If no, please explain why: not _____

Is treatment standardized or individualized?

Please estimate the proportion of patients that receive individualized versus standardized treatment. _____

Does the treatment policy recommend a treatment support framework during the intensive and continuation phases? (Yes/No)

If yes, please identify this framework and the challenges associated with implementing it: _____

Who acts as treatment supporter during the intensive phase and during the continuation phase?

C.3 Current availability and use of second-line drugs (SLDs) in different health sectors

Policy and practice (reality) check:

Can SLDs be bought in pharmacies? (Yes/No)

If yes, is prescription required? (Yes/No)

If yes, is it applied in practice?

If no, please comment: _____

C.4 Use of new drugs/ treatment for MDR TB				
	Proportion of total MDR patients receiving this treatment	NTP	Public non-NTP	Private
Bedaquiline				
Delamanid				
Shorter regimens				

D. Diagnosis and treatment of latent TB infection (LTBI)	
Data year = _____	Total
Proportion of children less than 5 years old who are household TB contacts (according to national guidelines) who have completed TB investigations	<i>Total number of children less than 5 years old who are household TB contacts who have completed TB investigations (according to national guidelines) during the reporting period/total number of children less than 5 years who are household TB contacts (according to national guidelines) during the reporting period</i>
Proportion of children less than 5 years old who are household TB contacts (according to national guidelines) who are eligible for starting on TB preventive therapy and have started treatment	<i>Total number of children less than 5 years who are household TB contacts who have started TB preventive therapy during the reporting period/total number of children less than 5 years who are household contacts of TB and who are eligible for starting on TB preventive therapy during the reporting period</i>
Proportion of children less than 5 years old who are household TB contacts (according to national guidelines) who have completed a course of TB preventive therapy	<i>Number of children less than 5 years old who are household TB contacts (according to national guidelines) who have completed the course of TB preventive therapy during the reporting period/total number of children less than 5 years old who are household TB contacts (according to national guidelines) and who started TB preventive therapy during the reporting period</i>
Proportion of eligible individuals from at-risk populations (according to national guidelines) tested for latent TB infection	<i>Total number of individuals from at-risk populations who have been tested for LTBI during the reporting period/total number of individuals from at-risk populations eligible for testing during the reporting period</i>
Proportion of individuals from at-risk populations (according to national guidelines) with a positive latent TB test who are eligible for starting TB preventive therapy and have started treatment	<i>Total number of individuals from at-risk populations who have started on TB preventive therapy during the reporting period/total number of individuals from at-risk populations who have tested positive for latent TB and who are eligible for starting TB preventive therapy during reporting period</i>
Proportion of individuals from at-risk populations (according to national guidelines) with a positive latent TB test who have completed treatment	<i>Number of individuals from at-risk populations who completed the course of TB preventive therapy during the reporting period/total number of individuals from at-risk populations that started TB preventive therapy during the reporting period</i>
How is LTBI treatment and care financed?	
Is there an electronic or manual monitoring and evaluation system to document and report on the implementation of LTBI management in all high-risk groups?	

E. TB infection control

Please provide as much information as possible in the context of the questions.

(Data year = _____)	NTP	Public non-NTP	Private
Number and percentage of health facilities that had Infection control risk assessment conducted			
Number and percentage of health facilities with functional infection control committees			
Number and percentage of health professionals diagnosed with active TB			
Number and percentage of health professionals diagnosed with latent TB			
Number and percentage of health professionals that started latent TB infection treatment			
Number of training courses provided to health-care professionals on TB infection control			
Please comment on the availability of a coordinating body to develop a national policy, as well as a comprehensive budgeted plan that includes human resource requirements for implementation of TB Infection control at all levels.			

3. Health system assessment for TB care delivery

A. Governance of TB care delivery	
Organization	Please describe the organization of TB control programme, for example, by using an organogram.
	How are the central, regional, district and primary levels of TB control programmes coordinated?
	What kind of technical support do primary levels receive from the NTP?
Management of anti-tuberculosis drug supplies	Please describe briefly the TB drug procurement and distribution system (including registration) that ensures a regular supply of necessary drugs and diagnostic supplies.
	Are all anti-TB medicines officially registered in the country?
	Does the programme encounter shortage of drugs?
	Who is the major purchaser of anti-TB drugs (public, private for profit, private non-profit)?
	What is the existing legal framework for sourcing, importing, registering and distributing drugs?
Civil society participation/patient support	Number and % of new patients with TB (all forms) diagnosed and notified who were referred by community health workers (CHWs) and community volunteers (CVs)
	Number and % of new patients with TB (all forms) successfully treated (cured plus completed treatment) who received support for treatment adherence from CHWs and CVs. Treatment adherence support includes improving/providing access to prevention, diagnosis and treatment, socioeconomic support, as well as activities that reduce stigma and discrimination associated with TB.

B. Information management

Health information system	Please describe the availability of an electronic system (TB cases, MDR-TB cases and mortality) versus manual medical records and health information system (integrated data systems and enterprise architecture) for TB patients.
	Please describe the availability of an electronic system for screening presumed TB cases versus manual medical records.
Laboratory Information System	Please describe the availability of an electronic system (laboratory diagnosed TB and DR/MDR-TB cases) versus manual medical records.
Linking patient information	Please describe on how patient information is linked at all levels of the health-care system.
	Please describe on whether patient information is linked between the NTP, public and private sectors.
Recording	Recording: What kind of information is routinely collected from TB patients: i) DS-TB patients ii) DR-TB patients? iii) TB/HIV patients
Reporting	Who receives the records reports, and how often?
	Please describe the flow of reporting from peripheral to national levels.

C. Human resources					
	No. of health-care staff trained in TB diagnosis and care (physicians, nurses, health extension workers, etc.) per category	No of health-care staff trained in DR-TB management per category	No. of staff trained in TB/HIV or HIV management per category	No. of staff trained in latent TB infection diagnosis and treatment cascade per category	No. of staff trained in TB infection control monitoring and evaluation per category
NTP level					
Central					
Provincial/equivalent					
District/equivalent					
Peripheral/equivalent					
Non-NTP providers					
Public (e.g. hospitals)					
Private (e.g. for profit, or NGOs)					
Is a human resources development (HRD) plan available? If yes, is the plan already funded?					
If yes, does it include capacity-building activities for non-NTP staff?					

D. TB financial indicators (US\$)		
		Data Year: _____
General	National TB programme budget (US\$ millions) per year	
	National TB programme budget as % of total health-care budget per year	
	% Committed funding/actual expenditure	
	% Contribution of the government to the TB budget	
	% Contribution of Global Fund grant(s) to the TB budget	
	% Contribution of other donors to the TB budget	
	% Unfunded	
Public-private mix (PPM)	% Budget dedicated to PPM	
Childhood-TB	% Budget dedicated to childhood TB programme	
DR-TB	% Budget dedicated to DR-TB programme	
	% Budget dedicated to DR-TB drugs	
TB/HIV collaborative activities	% Budget dedicated to TB/HIV activities	
LTBI control	% Budget dedicated to LTBI activities	
Patient support	% Budget dedicated to patient support	
Operational research (OR)/ implementation research (IR) and surveys	% Budget dedicated to OR/IR and surveys	
Basic and clinical research	% Budget dedicated to basic and clinical research	
Perceived gap (Commission on Health Research for Development [CHRD] recommends 10% of total health-care budget – in this case 10% of total TB budget) ^b	Gap in funding for research	

b. Commission on Health Research for Development. Health Research: essential link to equity in development. Cambridge (MA): Oxford University Press; 1990

E. Service delivery

Please provide as much information as possible in the context of the questions.

E. 1 Overview of private sector in the country

Do TB patients get treatment services in the private sector?

What is the extent of the private health sector in the country in general?
Please comment on both the for-profit and non-profit private sectors.

If known, please provide health expenditure per capita of the public versus private sector.

Describe the health insurance scheme in the country in relation to TB, as well as the population coverage.

What is the nature of the private health sector, and how does it vary across urban, rural and special (e.g. slum) populations?

What is the presence of the private sector in geographical areas with low outreach of public services for TB (evidenced by low case notifications)?

Describe the corporate health sector in the country, and its perceived role in DS-TB and DR-TB management.

E. 2 Existing links between the NTP and private providers of TB care

Is there a public-private mix (PPM) programme? (Yes/No)
If yes, please describe the areas of collaboration or collaborative activities.

Describe the links between the NTP and each of the main private TB care providers that are in some kind of collaboration with the NTP.

Describe the role of the NTP and private sector or their collaboration in social support for DS-TB patients (e.g. psychological support, material support, etc.) or treatment education for patients.

For DR-TB, please comment on the role of the NTP in supporting DR-TB management training, coordinating social support, drug supply and management, and treatment supervision for rational use of anti-TB drugs by the private sector.

E.3 Treatment outcomes according to the type of health-care provider

NTP Cohort size (N = _____)		Public (non-NTP) Cohort size (N = _____)		Private for-profit Cohort size (N = _____)		Private non-profit Cohort size (N = _____)	
Success (%)=_____	Failed (%) =_____	Success (%)=_____	Failed (%) =_____	Success (%)=_____	Failed (%) =_____	Success (%) =_____	Failed (%)=_____
Lost to follow up (%)=_____	Not evaluated (%)=_____	Lost to follow up (%)=_____	Not evaluated (%)=_____	Lost to follow up (%)=_____	Not evaluated (%)=_____	Lost to follow up (%) =_____	Not evaluated (%) =_____
Died (%)=_____		Died (%)=_____		Died (%)=_____		Died (%)=_____	

E.4 TB diagnosis services offered by all health-care providers

Number of laboratories providing:	NTP	Non-NTP public	Private for-profit	Private non-profit
Microscopic diagnosis				
Xpert MTB/RIF test				
Rapid DR-TB diagnosis (please state the methods)				
Number of laboratories doing solid/liquid culture				
DST for first-line drugs (FLDs) using solid/liquid culture				
DST for second-line drugs (SLDs) using phenotypic method				
Line probe assay (LPA) test for FLDs				
LPA test for SLDs				

E.5 Treatment outcomes according to health-care level

Data year=.....

Community level Cohort size (N = _____)		Primary level Cohort size (N = _____)		Secondary level Cohort size (N = _____)		Tertiary level Cohort size (N = _____)	
Success (%)=_____	Failed (%) =_____	Success (%) =_____	Failed (%)=_____	Success (%) =_____	Failed (%)=_____	Success (%)=_____	Failed (%)=_____
Lost to follow up (%)=_____	Not evaluated (%)=_____	Lost to follow up (%) =_____	Not evaluated (%) =_____	Lost to follow up (%) =_____	Not evaluated (%) =_____	Lost to follow up (%) =_____	Not evaluated (%) =_____
Died (%) =_____		Died (%) =_____		Died (%) =_____		Died (%) =_____	

E.6 Approach to vulnerable populations

What kind of social support is offered to the patients while on treatment? Please list below.

<p>Social protection programmes <i>Social protection programmes in this context comprise all public and private initiatives that aim at removing financial barriers that prevent TB patients from accessing health services. They aim to advance TB prevention, treatment, care and support by protecting patients from the impoverishing effects of medical expenditures, for example, by providing indemnities, nutrition support, etc.</i></p>	<p>Type of support provided</p>	<p>Geographical coverage</p>	<p>Percentage of total TB patients benefiting (total patients benefiting/total TB patients notified) Data year: _____</p>
1			
2			
3			
4			

4. Research resource mapping

A. Human resource mapping in TB research

Total number of researchers engaged in TB research in the country	N = _____
--	------------------

Of the total researchers enumerated, please identify them by qualification and research discipline.

	Total number	Highest qualifications, by number				Type of employment, by number	
		Diploma	BSc	MSc	PhD	Permanent	Contractual/ project based
Basic, translational and preclinical research							
Clinical research							
Operations/implementation research							
Health system and policy							
Epidemiology							

B. TB research activity mapping

Numbers of TB research projects in the past 5 years	Basic research	Clinical research	Operations/ implementation research	Health system and policy	Epidemiology
Total projects planned					
Projects completed					
Projects in progress					
Articles published in local peer-reviewed journals					
Articles published in international peer-reviewed journals					

C. TB research actors and their funding sources

Inventory of key institutions involved in TB research	List number of institutions per category	List numbers of institutions that have worked with NTP in the past 5 years	Range of average annual budget for research per institution (US\$)	Lists of main funding sources for the past 5 years (% private fund, etc.)	Range of average annual budget for capacity-building per institution (US\$)
Public research institutes					
Public universities					
Private research institutes					
Private universities					
NGOs					
Other					

D. Assessment of enabling environment for research

Please provide as much information as possible in the context of the questions.

Individual	Is there access to training/funding for continued application of skills, e.g. training grants, fellowships, etc.?
	Please comment on the availability of research capacity-building systems for degree and training programmes in various research disciplines, e.g. public or private universities, research Institutes, etc. Please also comment on the sufficiency of these capacity-building systems.
	Is there a career growth plan for individual researchers? If so, where? (For example, in universities, research institutes, governmental bodies, private sector, others)
Organizational	Do academic/research institutions have access to regular domestic funding to conduct research? Please describe.
	Do academic/research institutions have access to regular international funding to conduct research?
	Is there adequate physical infrastructure for conducting research? You may use section C as a reference.
Supra-organizational (networks and support units)	Is there a national and regional ethics bureau ? (Yes/No) If yes, please comment on the efficiency of the system in the context of research.
	Please comment on the existence and efficiency of national regulatory agency (similar to the European Medicines Agency [EMA] and the United States Food and Drug Administration [FDA]).
	Please comment on the existence and efficiency of national and regional public and private partnerships focusing on research.
	Are there legislations and policies supportive of research and innovation?
	Does the country have a national health research agenda?
	Does the country have a national TB research agenda?
	Are there national research grants available at the national, regional and/or district levels?

E. Assessment of NTP's link to research

Please provide as much information as possible in the context of the questions.

Is there a research focal person(s) in the NTP? (Yes/No). If yes, how many? Please describe his/her role.

Is there a research focal person in the laboratory coordination unit? (Yes/No). If yes, please describe his/her role.

Does the NTP conduct operations/implementation research? (Yes/No). If yes, please describe the NTP's current research activities.

Does the NTP receive local funding to do operations/implementation research? (Yes/No). If yes, please list average annual funding per funder.

Does the NTP receive external funding to do operations/implementation research? (Yes/No). If yes, please list average annual funding per funder.

Please comment on the availability of training for programme and laboratory staff to conduct operations or implementation research (please identify type and frequency of training).

Is there opportunity for programme and laboratory staff to link with other government blocks beyond MoH (e.g. Ministry of Science and Technology, Ministry of Education, Ministry of Social Development, Ministry of Justice, etc.) to meet, design, implement and interpret research outcomes relevant to ending TB at country level?

Is there opportunity for programme and laboratory staff to link with researchers to identify research priorities, design, implement and interpret research outcomes relevant to the programme?

Is there opportunity for the NTP to regularly link with and discuss current research outcomes with practitioners, policy-makers and other disease programmes or control partners (please identify interaction media and frequency)?

F. Assessment of national policy framework for uptake of the outputs of TB research for policy actions

Please provide as much information as possible in the context of the questions.

Is there a mechanism/framework in place for systematic evaluation of the outputs of TB research for policy actions at country level? Please describe.

What are the steps followed at country level for making policy/strategic actions based on evidence generated through research?

Annex 2. Summary of the situational assessment tool for developing a TB research plan

Know your TB epidemic

Assessment of the national TB epidemic landscape by gender, age and various forms of TB, and their treatment outcomes

Assessment of management frameworks for the TB/HIV co-epidemic and their effectiveness

Assessment of the TB epidemic in vulnerable populations such as those with diabetes and incarcerated individuals, and assessment of their treatment outcomes

NTP strengths and weaknesses

Assessment of the preparedness and practices of the NTP in preventing new TB cases in contacts of patients with TB and HIV, and implementation of management programmes for latent TB infection

Assessment of the consistency of national TB diagnostic and treatment algorithms with WHO's policy, and impact evaluations of the adopted diagnostic and treatment algorithms

Assessment of recent surveys for drug-sensitive and/or drug-resistant TB

Assessment of the availability, coverage and quality of laboratory services

Assessment of the availability and coverage of second-line drugs (including new drugs), infection control, as well as treatment for latent TB infection

Health system assessment for TB care delivery

Assessment of the organization of the TB control programme at central, regional and peripheral levels

Assessment of the national TB drug registration, procurement and supply system

Assessment of the existing TB patient information management system (electronic versus manual), linkage of information between different levels of health care, as well as recording and reporting practices

Assessment of TB management in health-care workers and staff at all levels of the health-care system

Assessment of financial costs for TB management, funding sources, and availability and lack of funding

Assessment of the availability and utilization of health services at various levels, and their quality in terms of treatment outcomes

Assessment of links and collaboration between the NTP and private care providers in terms of care and support to TB patients

Assessment of the health system's approach to vulnerable populations with regard to TB treatment and support

Assessment of diagnostic service delivery by the NTP, and public and private sectors

Assessment of CSO engagement in identifying and supporting TB patients of all types

Mapping resources for TB research

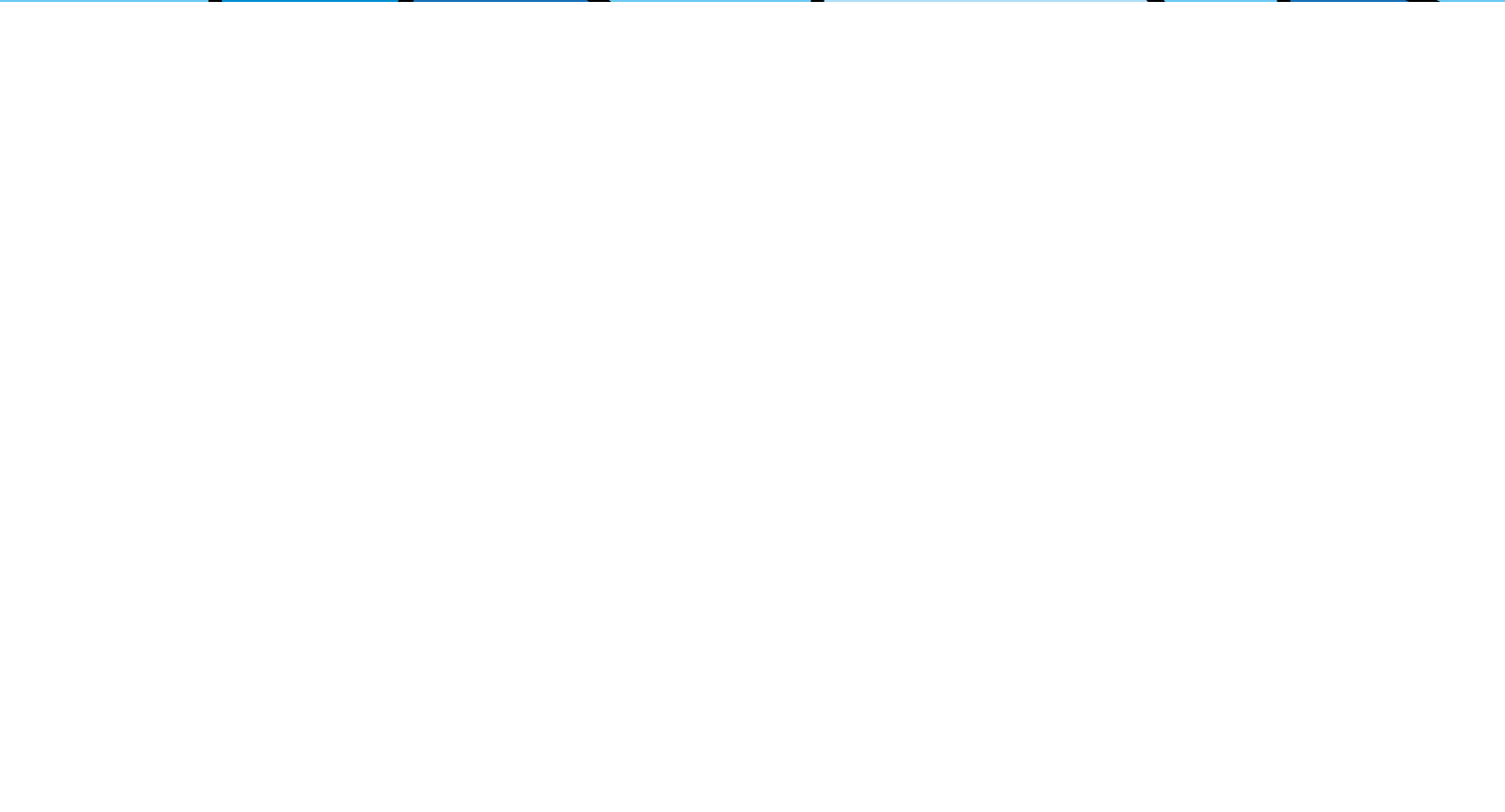
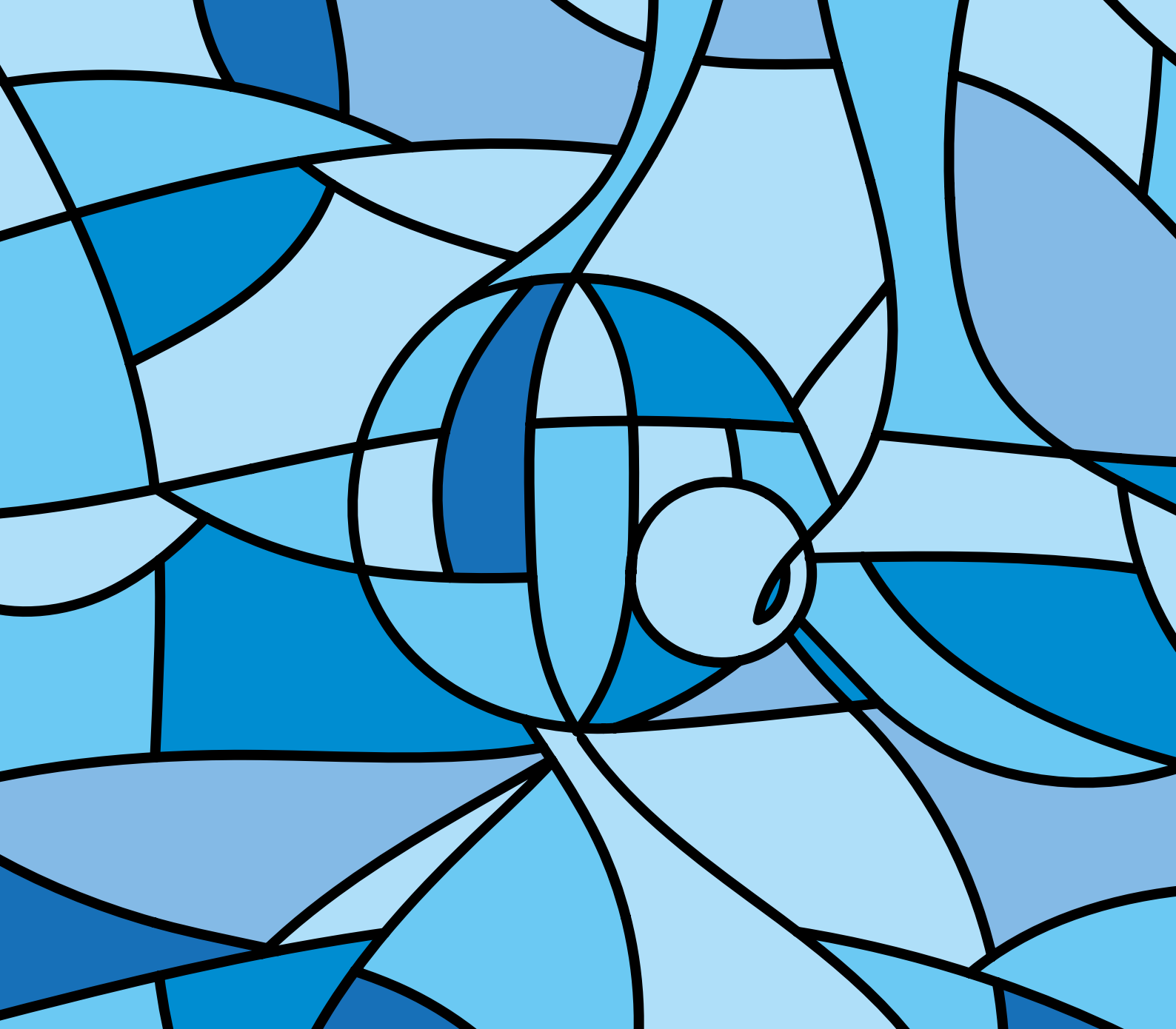
Mapping of TB researchers in various disciplines

Mapping of TB research activity by organizations

Mapping of TB research funding sources for existing research institutions/universities or their equivalent

Assessment of an enabling environment for research in terms of availability of opportunities for individuals, and convenient systems (e.g. legal, ethical, financial, etc.) for research organizations/universities in conducting and scaling up research

Assessment of the NTP's link to researchers and research activities, as well as assessment of the national framework for uptake of the outputs of TB research for policy actions





TOOL **3**

Developing
a National TB Research Plan

Contents

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Abbreviations

CHNRI	Child Health and Nutrition Research Initiative
CSO	civil society organization
MoH	Ministry of Health
NGO	nongovernmental organisation
NSP	national (TB) strategic plan
NTP	national tuberculosis programme
SWOT	strengths, weaknesses, opportunities and threats
TB	tuberculosis
TBRN	TB research network

Introduction

Priority-driven research in tuberculosis (TB) with a clearly defined purpose and emphasis on answering questions of importance is likely to have a significant impact on improving knowledge and practice of TB prevention and control. The overall objective of this exercise is to identify a list of country-relevant research questions for the various research disciplines and stakeholders to work on collaboratively to address domestic TB control issues. TB research questions are identified from gaps in the country's TB situational assessment conducted by the national TB research network (TBRN). This allows the process of prioritizing research to be achieved in consensus.

Country-specific research priorities can be identified by undertaking the following key activities:

- establishment of a TBRN – *see Tool 1*;
- situational assessment of the national TB epidemics, strengths/weaknesses of the national tuberculosis programme (NTP), health system and research capacity – *see Tool 2*; and
- gap analysis of the outcomes of the situational assessment – *the present Tool 3*.

Approach and process

Developing a research plan encompasses three essential processes:

1. *identifying research questions* in the context of country-specific needs and targets for TB control;
2. *prioritizing the research questions* using a transparent and systematic methodology to identify high-quality questions with the greatest public health benefit, while maximizing return on investments;
3. *composing the final TB research plan* to strategically include the prioritized list of research areas with directions on how TB stakeholders can contribute to the implementation and monitoring of the research plan.

Who should be involved?

The national TBRN's steering committee should establish a dedicated team from within the network to undertake the process.

Target audience

The target audience for developing and utilizing a national TB research plan comprises the NTP, Ministry of Health (MoH), Ministry of Research, Science and Technology, development and funding agencies, research institutions, universities, policy-makers, the research community, health professionals, nongovernmental organizations (NGOs) and civil society organizations (CSOs).

1. Identifying the TB research questions

Identifying research questions is one of the most critical aspects of developing the research plan. The process entails conducting a strengths, weaknesses, opportunities and threats (SWOT) analysis of the outcomes of the situational assessment (Tool 2) to identify TB control challenges, followed by a gap analysis to refine and formulate the research questions. These two processes are described below.

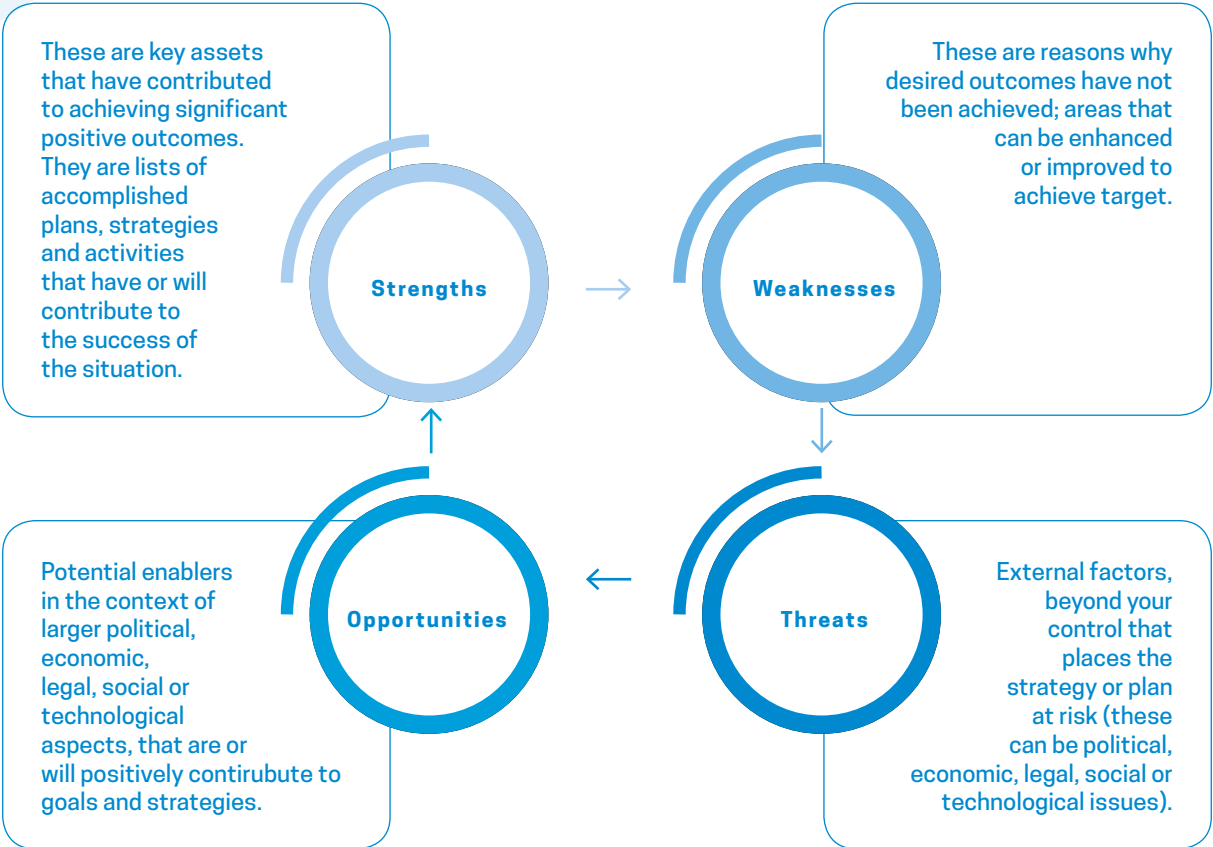
1.1 Strengths, weaknesses, opportunities and threats (SWOT) analysis

The SWOT matrix is a management tool that uses an inventory of internal strengths and weaknesses, mapped against external threats and opportunities to identify gaps and facilitate decision-making (Fig. 1). In the context of development of research questions, SWOT facilitates gap identification by enabling analysis of the respective strengths and weaknesses of,

opportunities for and threats to TB control. Being in essence an assessment technique, SWOT offers the opportunity to fully understand and appropriately describe specific problems or gaps within a country-specific context. Strengths and weaknesses refer to the factors that are internally related to the situation being assessed, while opportunities and threats refer to the factors that are beyond the scope of TB programmes but have significant influence on its performance and outcome. The gaps identified through this process should then be analysed carefully so as to inform the development of a national TB research plan.

A properly conducted and fully completed SWOT analysis requires a rigorous and transparent approach, based on identification of strong assets that contributed to achieving appropriate results so that the reasons for non-achievement of expected results are fully identified and understood; and the potential opportunities have been fully considered while addressing the potential or actual threats.

Fig. 1. SWOT analysis framework



1.2 Gap analysis

Analysing the gaps identified from the SWOT analysis will help measure the difference between the current situation and the ideal state that the country wants to reach. Once gaps have been identified, the aim is to develop tasks that need to be completed to close these gaps.

The gap analysis should describe the constraints and insufficiencies that can explain the current and expected weaknesses in the context of the TB epidemic. It is not a description of components that have not yet been implemented, neither is it a list of strategic interventions or activities to be implemented. In other words, it should describe what has been lacking, missed or not achieved through the implementation of an ongoing policy or strategy.

Upon completion of the gap analysis, there should be:

- a. a common understanding of the differences between *current* and *best* practices (Table 1 gives a format of a gap analysis chart for this purpose);
- b. an assessment of the barriers that need to be addressed for successful implementation of best practices. These should be considered in three important categories:
 - c. **people** (e.g. lack of human resources in numbers and skill sets);
 - d. **processes** (e.g. inexistent or inefficient processes);
 - e. **technology/resources** (e.g. missing, insufficient or inefficient technological capability or resources);
- discussion on how best to address the identified gaps: if the outcome yields *a case for research*, a research question or statement will be formulated. The research questions will subsequently be organized and prioritized (*see* the section below).

Table 1. Gap analysis chart

	Best practice (target)	Best practice strategies	How current situation differs from best practice	Barriers to best practice implementation	Identify how to bridge the gap (for e.g. operations/ implementation research, clinical research, budget scale up, etc.)
1					
2					
3					
4					

2. Prioritizing the research questions

2.1 Introduction

Establishing an order of priority for the research questions identified as a result of the gap analysis is essential, as specific gaps or particular constraints may have a much greater impact on the improvement of TB control than others. The context and criteria for priority-setting are based primarily on the value that a scientific question contributes to closing the identified gaps, but priority-setting is also expected to address what questions will have most impact on morbidity and mortality, with due consideration

for ethical and equity implications. In the end, this process will support with advocating for and assisting with the allocation of resources for research, while simultaneously identifying areas for strengthening research capacity, and promoting social accountability, ownership and shared responsibility in implementing the research plan. Ultimately, development and implementation of a national research plan will foster demand-driven research to address domestic TB control needs and enhance national contribution to global research needs.

Box 1. Checklist: preparatory work by the team convening the priority-setting exercise (1)

1. Is the research priority-setting process and method adequately understood?
2. Have the key groups that will be involved been identified and contacted? How many people/groups will be involved, and from how many institutions?
3. Is there enough support from political decision-makers, government bodies and/or NGOs? If so, in what form?
4. Are there adequate resources to convene meetings needed for the exercise?
5. Has the situational assessment tool been completed using available background documents on health statistics, socioeconomic profile and prior research information?
6. Have appropriate research questions been identified by conducting a gap analysis using the situational assessment tool?
7. Is there credible leadership in the national TBRN that will facilitate the establishment of working groups to assume roles and responsibilities, and reach agreement on a workplan for research priority-setting?

A method for systematic and transparent prioritization adapted from the Child Health and Nutrition Research Initiative (CHNRI) methodology (2) and the *International roadmap for tuberculosis research* (3) is used to rank research questions using five categories (Table

2). This methodology is based on participants taking decisions by consensus at each step of the process in a transparent and accountable way. It is intended to provide assistance for planning a high-quality research priority-setting exercise at national (and subnational) levels.

Table 2. Criteria used to prioritize research questions

Criteria	Definition	Grading scale
Effectiveness	Will answers to the research question provide knowledge, evidence and strategic directions for reducing the disease burden most effectively?	Strongly disagree, 0 Disagree, 1 Agree, 2 Strongly agree, 3
Equitability	Will answers to the research question provide suitable data, knowledge, evidence and strategies to improve equity in disease burden distribution?	Strongly disagree, 0 Disagree, 1 Agree, 2 Strongly agree, 3
Answerability	Based on (1) the level of existing evidence and knowledge, and (2) the size of the gap from the current level of knowledge to the proposed end-point, would you say that a study can be designed to answer the research question and to reach the proposed end-point?	Strongly disagree, 0 Disagree, 1 Agree, 2 Strongly agree, 3
Deliverability	Taking into account government capacity and partnership requirements, as well as the resources needed to implement this research proposal, would you say that desired end-points of the research are achievable?	Strongly disagree, 0 Disagree, 1 Agree, 2 Strongly agree, 3
Ethical aspect	Will answers to the research question provide knowledge, evidence and strategies in an <i>ethical way</i> , i.e. protecting the rights of patients, avoiding harm and maximizing well-being? <i>Research areas scored “disagree” or “strongly disagree” in this section should not be considered further</i>	Strongly disagree, 0 Disagree, 1 Agree, 2 Strongly agree, 3

2.2 Prioritization steps

The first step is to organize the research questions: the list of research questions identified from the SWOT and gap analyses need to be compiled and divided into various research categories: basic, clinical/translational, operations/implementation, health systems and policy, and epidemiology (see **Annex I** for definitions of the various research disciplines). Working groups should be established to prioritize the questions within these five research areas in their specific areas of expertise.

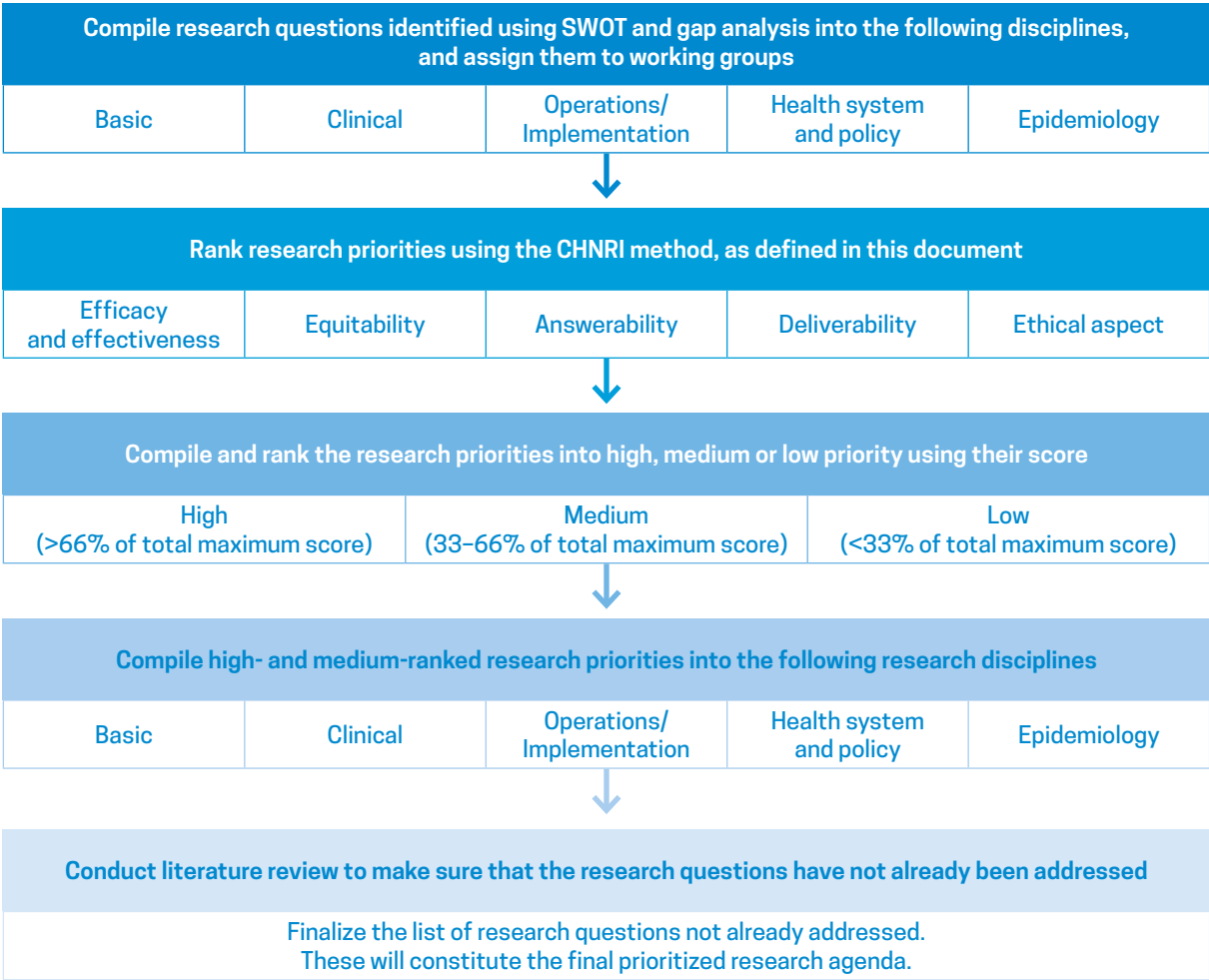
Specific activities of these working groups are described below and summarized in Fig. 2.

1. *Scoring the research questions* – the working groups will score all the research questions according to the criteria outlined in Table 2.
2. *Ranking the research questions* – prioritization of the research questions is based on the total score calculated to assess the importance of the question. Based on this, the research questions are categorized as follows:
 - a. **high**-priority (>66 percentile of the maximum score achieved for a research question). For example, if the highest score achieved during the prioritization exercise is 12, research questions with a score of >8 (= 66% of 12) are considered high-priority.
 - b. **medium**-priority (between 33 and 66 percentile of the maximum score). For example, if the highest score achieved during the prioritization exercise was 12, 66% of 12 (which in this case is = 8) and 33% of 12 (which in this case is = 4) are the high and low boundaries for medium-priority score.
 - c. **low**-priority (<33% of the maximum score). For example, if the highest score achieved during the prioritization exercise is 12, research questions that scored <4 (33% of 12) are considered low priority and will be dropped from the national TB research agenda.
3. *Reviewing the literature* – a literature search is needed to make sure that the prioritized research questions have not already been addressed domestically or internationally as applicable. Conducting a thorough search to identify relevant studies is a key factor in minimizing research duplication. The process and outcomes of the literature search should be documented in a way that enables it to be evaluated and reproduced.
4. *Finalizing the list* – the working groups consolidate the research priorities, and formalize a final draft that is reviewed by the TBRN steering committee. Only research priorities with high and medium priority are integrated into the final national TB research agenda (4).

Box 2. Multidisciplinary research agenda

TB-endemic countries are encouraged to prioritize and invest in research (across all spectrums from “benchside” to “bedside”) that will lead to an improved TB control programme, according to available resources and capacity. The objective is to broaden the research focus to multiple research disciplines that can positively add to local care and control efforts, as any gaps in the continuum of research from bench to bedside will result in gaps in TB care and control. To develop research questions in all aspects of research, it is important to analyse the identified gaps from all angles (basic, clinical/translational, health system, policy, operations/implementation and epidemiological research). The national TBRN is encouraged to think about the various ways the country can address global TB research priorities in basic and clinical/translational research, in addition to operations research. WHO has also developed *an International roadmap for tuberculosis research* (3), with a list of global TB research priorities in various disciplines. Countries with the capacity to conduct multidisciplinary research are encouraged to use the priorities identified in this roadmap to contribute to global needs.

Fig. 2. Research priority-setting process



2.3 Expected outcomes

The outcome of this exercise is a comprehensive list of country-specific TB research questions, with competing priorities ranked according to potential impact on disease burden, equity, as well as general feasibility of conducting the research with available resources. Such a list will be very helpful for researchers to direct their work at the most needed areas of investigation. It will be also useful for policy-makers because it provides an overview of the strengths and weaknesses of competing investment options, based on the collective input of national TB stakeholders.

TB research with the goal of improving public health needs to consider the priorities of relevant

stakeholders who are best positioned to act on new findings. There are a number of stakeholder groups whose perspectives should be incorporated into research priority-setting. Undertaking a consultation process using the above approach is one way to generate research priorities that are relevant, usable and contextually appropriate, which can be formally integrated into the country’s national TB strategic plan (NSP). Integrating research questions into the NSP submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria is beneficial to help ensure implementation of prioritized research questions. It is expected that addressing research questions prepared in this manner will help bridge knowledge gaps, so as to best prevent, detect and treat TB in a country.

3. Developing a national TB research plan

3.1 Introduction

The goal of developing a national TB research plan is to stimulate research activities that will generate evidence on country-relevant TB research priorities. The research plan is expected to create a consensus between the national TB programme, national research community, TB research funders and other relevant stakeholders on research priorities relevant to TB control in the country.

A national TB research plan has two main goals:

1. to list the research areas that require new knowledge in the immediate to medium term, and will strategically contribute to improving TB control nationally; and
2. to provide guidance to researchers, research institutions, funders and other relevant stakeholders on how they can contribute to country need-based TB research.

3.2 The content of the national TB research plan

The recommended format for composing the national TB research plan is described below. A general outline is shown in Fig. 3.

1. Introduction. The purpose and rationale for a national TB research plan, as well as its aims and objectives should be described. In the introduction, the lifespan of the research agenda, as well as the target audience should be specified.

2. Methodology. This section describes the methodology used to develop the research agenda. Essential components of this section are listed below.

- 2.1 *Data collection and tools:* the data collection instrument (e.g. situational assessment tool used), as well as SWOT and gap analyses used to formulate research questions or statements should be summarized.
- 2.2 *Stakeholder engagement mechanisms:* mechanisms and structures by which stakeholders were engaged to identify and prioritize research questions should be described. This includes the list of members of the working groups,

their selection process, and the process by and frequency with which they met and produced the document.

3. Research priorities. Report the research questions categorized by research discipline (e.g. operations, epidemiology, health systems, etc.) and by the order of priority.

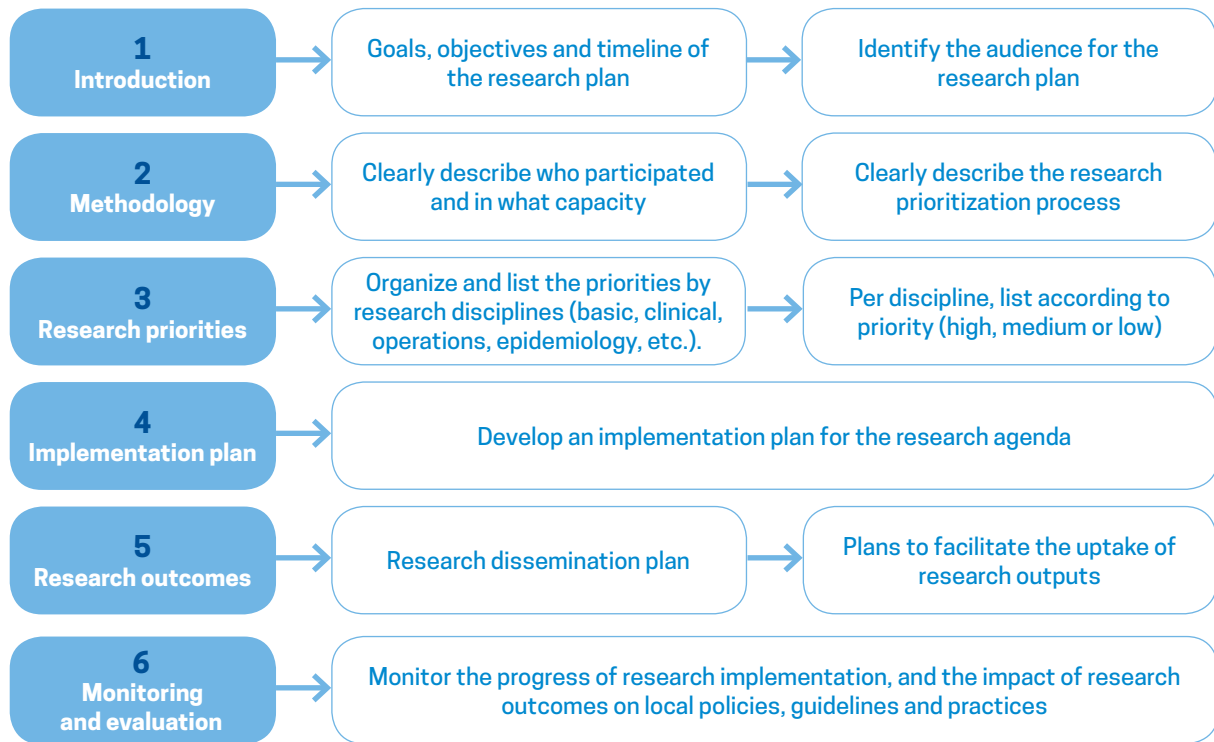
4. Implementation plan. Describe how the present plan should be implemented. This requires the following components:

- 4.1 *Describe the role of stakeholders.* The national TBRN, with the support of relevant government bodies such as the MoH, should ensure that national research activities are geared towards addressing the identified priorities. Encouraging or incentivizing stakeholders to make deliberate efforts to conduct and support the prioritized TB research agenda can facilitate this.
- 4.2 *Emphasize the need for collaboration.* The research priorities identified using this tool will most likely be multidisciplinary and cannot be addressed without close coordination and collaboration among various stakeholders. A statement describing the need for collaboration, and mechanisms to facilitate and encourage this should be described in the document, for example, by incentivizing research grant applications that involve multidisciplinary investigators, as applicable.
- 4.3 *Identify funding resources.* There are various approaches to mobilizing resources to fund the research agenda, but the most successful approach entails pooling resources from multiple sources. Countries can create a research budget in the MoH and/or Ministry of Science and Technology, allocate funding from the regular TB control budget, encourage PhD and MSc researchers to adopt priorities from the national research agenda for their thesis projects, organize side meetings with domestic and international funders to discuss the implementation plan, etc.

4.4 *Research protocol development.* To secure competitive domestic and international health research grants and improve the quality of research outcomes, the national TBRN

should solicit the necessary technical support for protocol development, for example, by establishing a peer-review process.

Fig. 3. Outline of a national TB research plan



5. Research outcomes. The TBRN is encouraged to establish a strategy for communicating the outcomes of the national TB research plan through policy briefs, newsletters, seminars, etc. The reporting of research outcomes is also the responsibility of every researcher and research institution, to ensure that evidence reaches end-users. The MoH and other coordinating institutions also have a role in ensuring that the research outcomes are available for utilization at the national level by policy-makers, communities, target populations, and all other relevant stakeholders, for example, by requesting all approved research studies to have a component on research dissemination.

6. Monitoring and evaluation. Once the research priorities and the implementation plan have been devised, the next step is to decide on appropriate indicators to monitor their implementation and evaluate their impact. For example, the national TBRN can use the following indicators for tracking the implementation and impact of the research priorities over time.

6.1 Quantitative indicators:

- i. the proportion of research studies from the research plan that have been conducted;
- ii. the proportion of research outcomes that have been published in peer-reviewed journals;
- iii. the number of research priorities whose implementation has led to change or update in policy or practice.

6.2 Qualitative indicators:

- i. Has the outcome of the research been validated internally, for example, through rigorous and transparent quality assessment of the design, execution and interpretation of the research outcome?
- ii. Has the generalizability of the research outcome been adequately addressed, e.g. through external validation methodologies such as statistical or mathematical modelling?
- iii. Does the research outcome have the potential to address or inform national TB control policies and practice?

Conclusion

TB research concordant with the priorities established in a national TB research plan, produced in the manner described here, will have maximal utility for country-specific TB control. The situational assessment and gap analysis exercises provide an excellent opportunity to bring up issues relevant to and in line with country needs in a continuum that extends from bench to bedside. The final document should be a harmonized, multidisciplinary research agenda that has been validated through a multistakeholder process in order to enable an enhanced sense of ownership and improved collaboration. The value of a research agenda depends

on there being a solid investment in infrastructure and people: increasing the capacity of national stakeholders to analyse their needs, set priorities, generate resources, and participate nationally in the design, implementation and evaluation of research and health programmes. Ultimately, viable and applicable TB control strategies will emerge if this research agenda is supported with good national research planning that includes a relevant funding strategy, along with dedicated leadership, and a system of monitoring and evaluation that promotes both learning and implementation.

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Annex 1.

Definitions of research areas

Basic/Fundamental research. “Experimental or theoretical work that aims to acquire new knowledge of the underlying phenomena and observable facts without any particular application or use in view” (5). Basic research is needed to keep the product pipeline filled, and to ensure that a sufficient number of new product candidates and strategies enter clinical development.

Clinical or patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies (6).

Epidemiology

The National Center for Biotechnology Information (NCBI) defines epidemiology as “the field of medicine concerned with the determination of causes, incidence, and characteristic behaviour of disease outbreaks affecting human populations”. It includes the interrelationships of host agent, and environment as related to the distribution and control of disease (7).

Health systems and policy

Health system and policy research is an emerging field that seeks to understand and improve how societies organize themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes. By nature, it is inter-disciplinary, a blend of economics, sociology, anthropology, political science, public health and epidemiology that together draw a comprehensive picture of how

health systems respond and adapt to health policies, and how health policies can shape – and be shaped by – health systems and the broader determinants of health (8).

Operations research

Operational research aims to develop solutions to current operational problems of specific health programmes or specific service delivery components of the health system, e.g. a health district or a hospital. This research is characterized by a strong problem-solving focus and an urgency to find solutions. Its demand-driven nature and close association with health-care delivery and routine health-care operations ensure operational relevance of the research activities, and rapid uptake and local utilization of research findings. The operational problems are often identified through routine monitoring and evaluation activities for which this research, where it exists, can be an important complement that allows a health programme to explore new ideas and experiment with potentially more effective approaches to its operations.

A wide range of study designs and research methods are used, ranging from descriptive and analytical studies to operational experiments and the use of mathematical modelling. The research often starts with exploratory studies to better define the problem and its determinants, and to identify potential solutions that can subsequently be tested under operational conditions (9).

Translational research

Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory and in preclinical studies to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science (6).



CONCLUSION

Research along its full spectrum, from basic to implementation, is critical to develop new tools and strategies for better TB care and control and provide scientific evidence for programmes practitioners and policy makers to alleviate morbidity and mortality from TB. In aligning country specific goals to the End TB Strategy, developing a *national TB research plan* endorsed and recognized by the wider TB care and control community as a commonly-used instrument for improving TB control is a critical initial step. In practice this relies on using a multi-stakeholder and multidisciplinary TB research network to develop a prioritized national TB research agenda based on a rigorous situational assessment of the TB epidemic, NTP performance, health system context and research resources.

The sustainable transition of this national TB research plan to implementation requires the establishment of domestic mechanisms of TB research funding that can be complemented by international financing when necessary, as well as for investments on targeted capacity-building and institution strengthening activities.

TB research is chronically underfunded. In 2014, there was a 1.3 billion USD global gap in TB research funding¹. The national network of experts and policy makers are key in making the case for TB research investment by highlighting the potential economic, social and health impacts. As such, the network is strategically positioned to advocate for and inform the debate on the need for more domestic health research funding for TB.

Overall, developing a national TB research plan using a network of TB research stakeholders presents a new paradigm for enhancing the practice of national research prioritization & implementation, as well as for advocating for TB research funding and capacity building. National TB Programmes or their equivalents are encouraged to develop and implement a national TB research plan with the view of operationalizing an evidence-based and cost-effective strategies needed for an effective country-specific response to end the TB epidemic.

¹ Treatment Action Group. 2016. http://www.treatmentactiongroup.org/sites/default/files/201511/TB_FUNDING_2015_WEB.pdf New York, NY. Accessed September 28, 2016



A Toolkit for Developing a National TB Research Plan

The goal of this toolkit is to assist a country's national TB control programme or its equivalent to develop an effective national TB research plan through a coherent step-by-step process. It provides a series of tools that will help in leveraging individual country action to address the global TB burden.



Establishing a
national TB research
network



Reviewing national
TB control activities
and research
programmes: *a self-
assessment tool*



Developing a
national TB
research plan

