THE END TB STRATEGY

World Health Organization

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**.

Dr Mario Raviglione
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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.

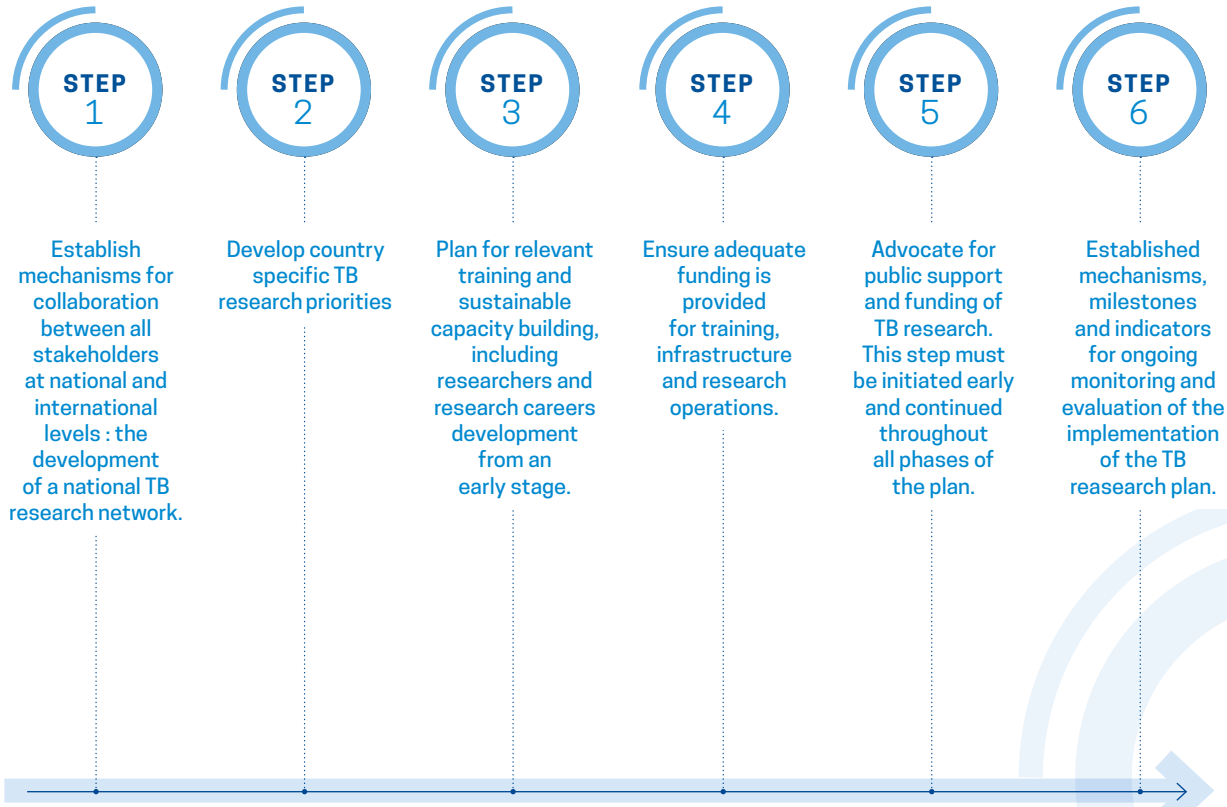
WHO's End TB Strategy aims to reduce TB deaths by 90% and cut new cases by 80% between 2015 and 2030, and ensure that no family is burdened with catastrophic health expenditure due to TB.[1] "Intensified research and innovation" has been identified as one of the three essential pillars to end the global 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.

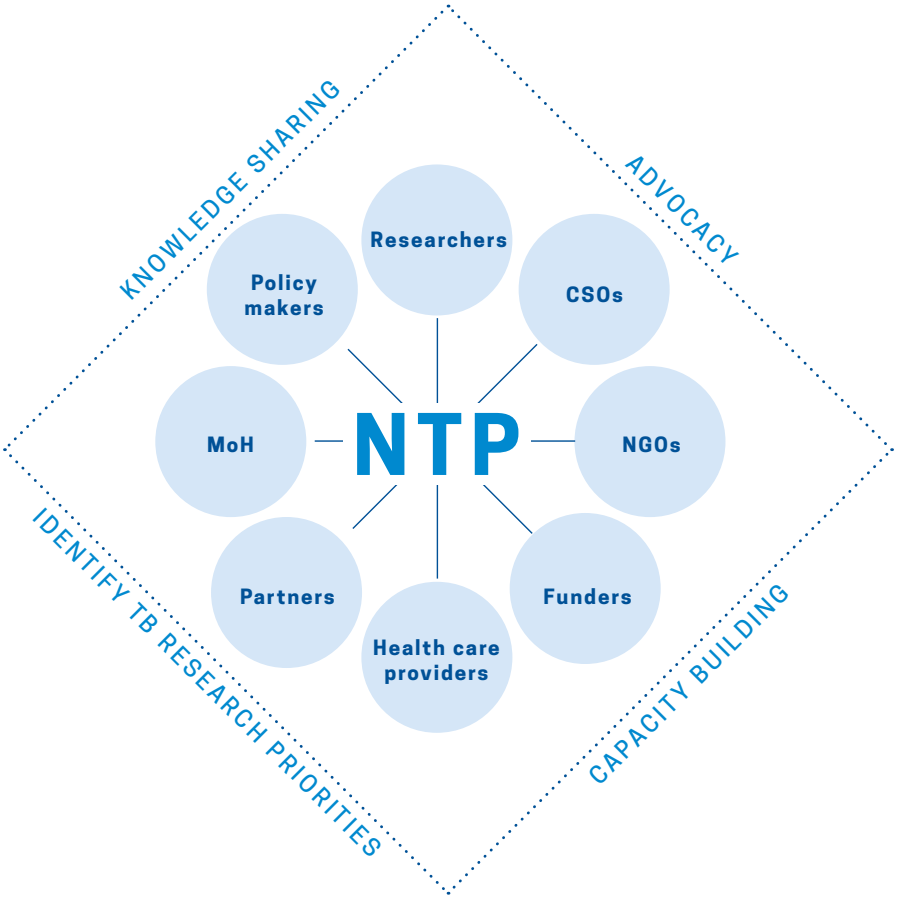
How to develop a national TB research plan

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.

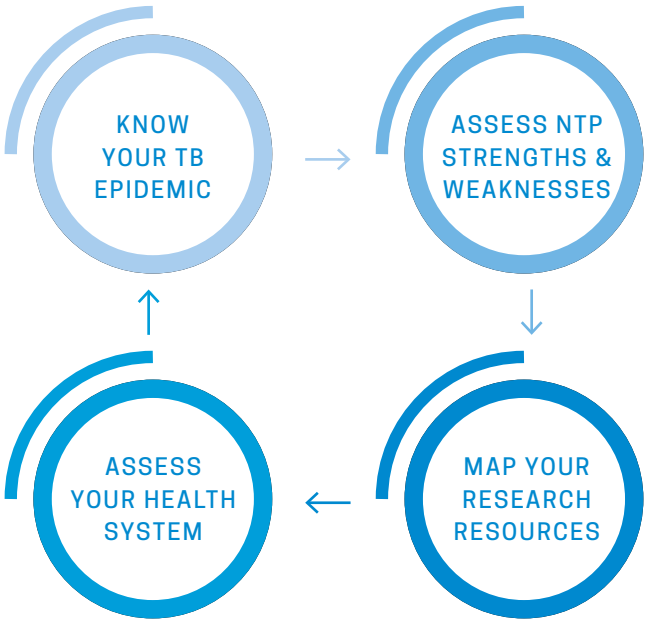
Fig. 2. Features of a national TB research network
[CSOs (civil society organizations), MoH (ministry of health), NGOs (non-governmental organizations)]



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

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