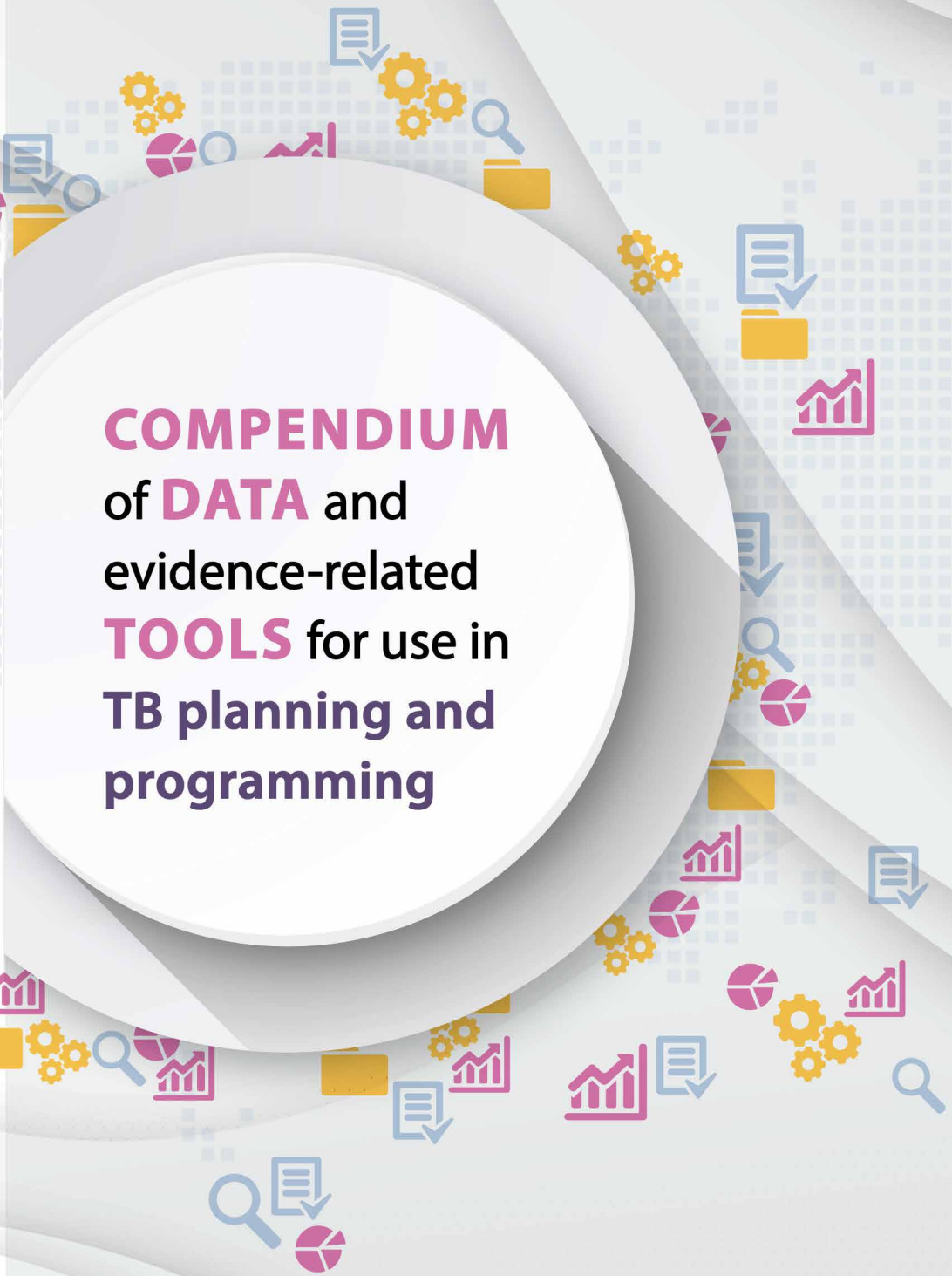
World Health Organization

# COMPENDIUM of DATA and evidence-related TOOLS for use in TB planning and programming



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# Contents

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The *Compendium of data and evidence-related tools for use in TB planning and programming* was developed as a companion document to the *People-centred framework for tuberculosis programme planning and prioritization – user guide*, published by the World Health Organization (WHO) in 2019. The compendium is intended to support implementation of the people-centred framework user guide. It can also be used independently to inform decisions taken by national tuberculosis (TB) programmes about the implementation of the tools included in this document.

This compendium was developed through a collaborative partnership between WHO and various partners. The following institutions contributed to the tools included in Chapter 3 of this compendium: the Bill & Melinda Gates Foundation, the Foundation for Innovative New Diagnostics, the TB Modelling Analysis Consortium, the Special Programme for Research and Training in Tropical Diseases, the Royal Tropical Institute Netherlands, the KNCV Tuberculosis Foundation, Linksbridge and the United States Agency for International Development. The development of the document also benefited from inputs from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Stop TB Partnership and the United States Centers for Disease Control and Prevention.

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# Abbreviations

| | |
|---|---|
| ACF | active case finding |
| AIDS | acquired immunodeficiency syndrome |
| CI | confidence interval |
| DHS | demographic and health survey |
| DNA | deoxyribonucleic acid |
| DOT | directly observed treatment |
| DR-TB | drug-resistant TB |
| DS-TB | drug-susceptible TB |
| DST | drug-susceptibility testing |
| FIND | Foundation for Innovative New Diagnostics |
| GHCC | Global Health Cost Consortium |
| Global Fund | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GP | general practitioner |
| HEUS | health expenditure and utilization survey |
| HIV | human immunodeficiency virus |
| KNCV | KNCV Tuberculosis Foundation |
| LSHTM | London School of Hygiene & Tropical Medicine |
| M&E | monitoring and evaluation |
| MATCH | mapping and analysis for tailored disease control and health system strengthening |
| MDR-TB | multidrug-resistant TB |
| MFL | master facility list |
| MoH | ministry of health |
| N/A | not applicable |
| NGO | nongovernmental organization |
| NHIF | National Health Insurance Fund (Kenya) |
| NTLCP | National Tuberculosis and Leprosy Control Programme (Ethiopia) |
| NTLD | National Tuberculosis, Leprosy and Lung Disease Programme (Kenya) |
| NTP | national TB programme |
| NSP | national strategic plan |
| OHT | OneHealth tool |
| OR/IR | operational research and implementation research |
| PhilHealth | Philippine Health Insurance Corporation |
| PPA | patient pathway analysis |
| PPM | public–private mix |
| RR-TB | rifampicin-resistant TB |
| SITT | Sistem Informasi Tuberkulosis Terpadu (Indonesia) |
| SRL | supranational reference laboratory |
| TB | tuberculosis |
| TB MAC | TB Modelling and Analysis Consortium |
| TIME | tuberculosis impact module and estimates |
| UCT | University of Cape Town |
| UN | United Nations |
| US CDC | United States Centers for Disease Control and Prevention |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

CHAPTER 1

# Introduction

# 1. Introduction

Globally, tuberculosis (TB) is a major cause of ill health and one of the leading causes of death worldwide. In 2019, about 10 million people fell ill with TB and 1.4 million people died from the disease *(1)*. The World Health Organization (WHO) End TB Strategy, adopted by all Member States at the World Health Assembly in 2014, includes ambitious milestones and targets for reductions in this burden *(2)*. The 2030 targets are a 90% reduction in TB deaths and an 80% reduction in the TB incidence rate (new cases per 100 000 population per year), compared with 2015. Global commitment to achieving the milestones and targets was reaffirmed at the first-ever United Nations (UN) high-level meeting on TB, held in September 2018 *(3)*.

Achieving national targets and ending TB will require national TB programmes (NTPs) to make efficient use of available resources by prioritizing high-impact interventions that are designed to address programmatic gaps. Also needed will be broader efforts to progress towards universal health coverage, multisectoral action to address broader determinants of the TB epidemic (e.g. poverty, undernutrition) and technological breakthroughs (e.g. a new vaccine) that can substantially accelerate declines in TB incidence.

Over the past 2 decades, there has been a considerable increase in the number of tools to generate, analyse and use data and evidence, to support discussion and decision-making by NTPs. Increasingly, countries are developing more robust national surveillance systems; implementing multiple health surveys; and using data analysis and visualization tools in policy, planning, programming and investment decisions. However, as more data are generated and data analysis tools evolve and increase in number, it can be challenging to understand how, why and when these tools should be implemented.

This compendium is designed to help NTPs to make best use of the available tools for policy, planning and programming. The document summarizes information about the key tools related to data and evidence that are available for use in TB planning and programming, and how they can be applied.

The tools that are profiled are described in terms of how they fit within the *People-centred framework for tuberculosis programme planning and prioritization (4)*. The framework was developed to help NTPs to leverage relevant in-country data and evidence in an organized manner that feeds into planning and programming decisions. More information about the framework and how it can be used is available in the user guide *(4)*.[1]

Together with the people-centred framework, this compendium aims to enable better use of data and evidence for TB programme planning at both the national and subnational levels. It is expected to help NTPs and their national stakeholders to understand how and when different data and evidence-related tools could be used. As the global community of users grows, the compendium itself will evolve as existing material is improved or new material is added. Ultimately, the data and evidence tools highlighted in the compendium are only useful where they support the needs of NTPs during the development and implementation cycles of their national strategic plans (NSPs) for TB.

The compendium is organized into four sections. Following this introductory section, Chapter 2 provides an overview of the different types of tools that are profiled in the document, outlines the standard content of each tool profile, and explains how each tool fits within the people-centred framework and what to consider when implementing each tool. Chapter 3 comprises profiles for individual tools. Each profile includes a case study to illustrate how the tool can be used at country level, and a set of "mini-profiles" for tools that are complementary but not critical. Chapter 4 shows the global status of implementation for each of the tools, as of August 2020.

[1] An overview is provided in Annex.

CHAPTER 2

# Overview of data and evidence-related tools

# 2. Overview of data and evidence-related tools

## 2.1 Types of tools

The data and evidence-related tools profiled in this compendium serve a variety of functions, as illustrated in Table 2.1.

**Table 2.1. Functions of tools to support discussion and decision-making of NTPs**

| Function | Brief description of the function and corresponding examples of tools |
|---|---|
| Primary data generation | Tools that include a primary data collection/generation component<br><br>Examples: TB drug-resistance surveys, national TB prevalence surveys, TB inventory studies, TB patient cost surveys and TB service delivery costing studies |
| Data review processes | Processes to review existing data sources and analyses for the purposes of improving the TB programme<br><br>Examples: standards and benchmarks assessments |
| Data analysis | Tools that apply an analytical method to primary data sources<br><br>Examples: care cascade analysis, diagnostic network optimization, TB inventory studies, MATCH, PPA, private sector drug sales analysis, and the OneHealth tool for TB budgeting and epidemiological modelling |
| Data visualization | Tools that have a primarily visual communication output and also apply an analytical method to primary data sources<br><br>Examples: care cascade analysis, diagnostic network optimization, MATCH and PPA |

MATCH: mapping and analysis for tailored disease control and health system strengthening; NTP: national tuberculosis programme; PPA: patient pathway analysis.

In some cases, one tool may serve several functions. For example, tools that are used for both data analysis and visualization include care cascade analysis, diagnostic network optimization, mapping and analysis for tailored disease control and health system strengthening (MATCH) and patient pathway analysis (PPA). Similarly, depending on the design, an inventory study may serve as both a data generation tool (prospective design) and a data analysis tool (retrospective design).

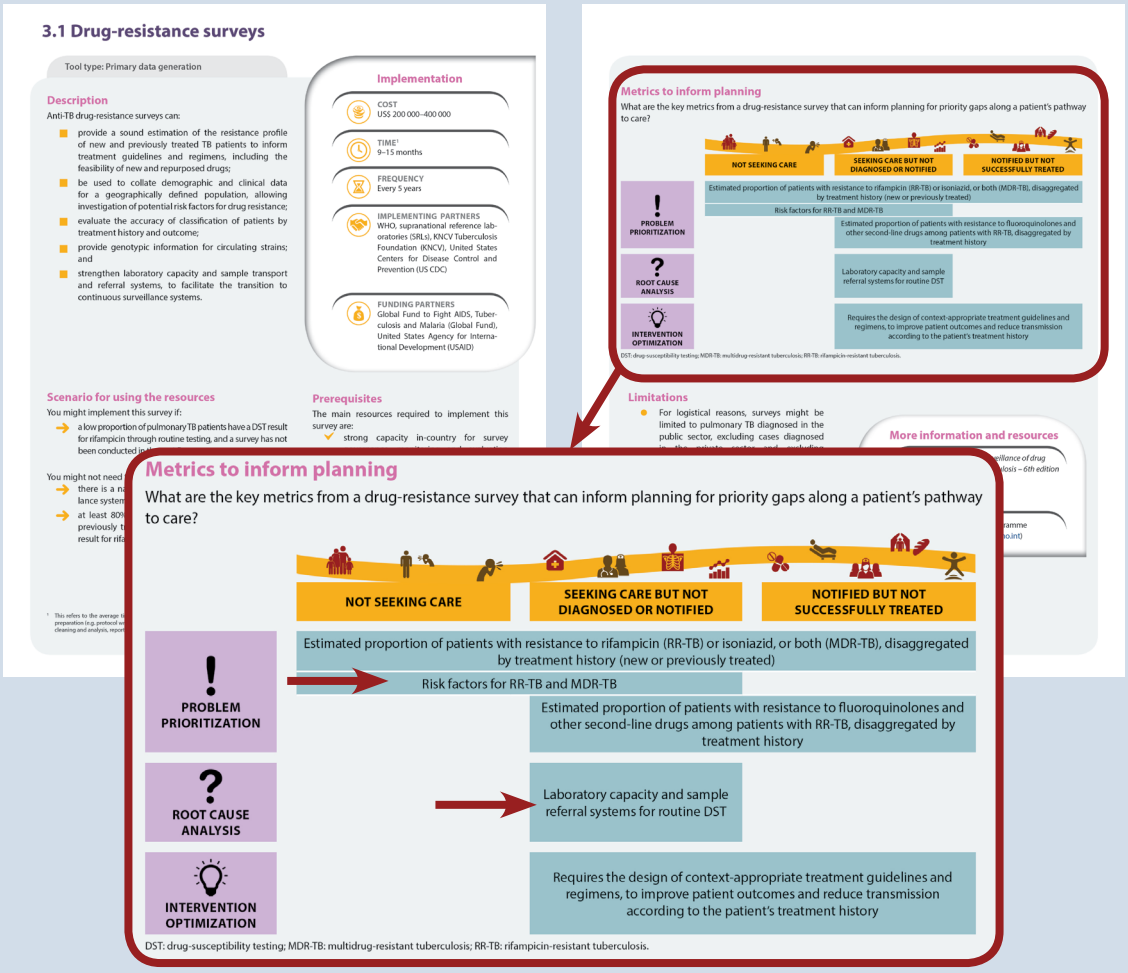
# 2.2 Contents of tool profiles

Each profile contains standardized information to give potential users a clear and concise understanding of the tool and its implementation. For most of the tools included in the compendium, more detailed user guidance and implementation documents are available; links to and references for these documents can be found in the respective profiles.

Each profile includes the following elements:

- **Description** – Brief description of the tool, which may include definition, objectives, methodology, rationale and implications for TB programmes.
- **Implementation cost** – Approximate cost to implement the tool.
- **Implementation time** – Approximate number of months it would take to implement the tool.
- **Implementation frequency** – The frequency with which implementation of the tool needs to be repeated in a country.
- **Implementation partners** – Examples of partners who are or have been involved in either the development or the implementation of the tool (or both).
- **Funding partners** – Examples of institutions or agencies that may be able to provide financial support for the implementation of the tool.
- **Scenario for using the resources** – Typical scenarios in which a country might consider implementing the tool.
- **Prerequisites** – Data (or non-data) resources that are required for implementing the tool; for example, the PPA requires both of the following:
    - some type of care-seeking data, such as from a demographic and health survey (DHS), prevalence survey, or health expenditure and utilization survey (HEUS); and
    - some type of service availability data, such as from a service provision assessment, or a service availability and readiness assessment (SARA).
- **Metrics to inform planning** – Key metrics or outputs of the tool that can inform policy and programming for priority gaps along the care continuum (Box 2.1 describes how to interpret this section in the tool profile).
- **Limitations** – Any aspects (including methodological limitations) that require attention when interpreting and using the results of the tool.
- **More information and resources** – Further information on the implementation and use of the tool, and resources that provide more detail about the tool.
- **Contact** – Institutions to contact for further information.
- **Case study of country use** – An example of how the tool has been used successfully in a country setting. The case study includes information on the key inputs to the tool and the key outputs from the tool; it also explains how those outputs inform programming and priority setting in the country.

## Box 2.1. How to read the "metrics to inform planning" section in the individual tool profile




The illustration above shows an example of a two-page individual tool profile that contains the standardized information described earlier. The section "metrics to inform planning" outlines potential key metrics or outputs that could be obtained from the tool.

The potential key metrics from each tool are mapped according to:

- where they are relevant along the continuum of care; and
- where they can be used to support discussions during a country planning process.

### Examples:

Key metric "Risk factors for RR-TB and MDR-TB" is located in the first and second part of the continuum of care and within the problem prioritization category. Thus, this particular indicator can be used to inform discussion on identification and prioritization of programmatic gaps (problem prioritization exercise) in the first two areas of the continuum of care.

Key metric "Laboratory capacity and sample referral systems for routine DST" is located in the second part of the continuum of care and within the root cause analysis category. Thus, this particular indicator can be used to inform discussion during root cause analysis; for example, it may suggest why people seek care but fail to be diagnosed or notified.

## 2.3 How to use the compendium

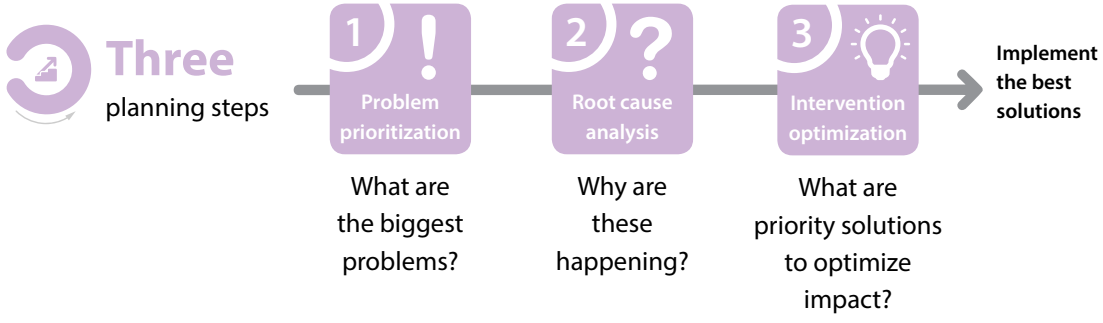
This compendium has been developed in alignment with the people-centred framework, a conceptual framework that promotes the use of data and evidence in TB programme planning and prioritization *(4)*. The framework has three main components as shown in Fig. 2.1 (and summarized in Annex).

**Fig. 2.1. Three components of the people-centred framework**

People-centred framework components

**1-3-3**





The following steps are suggested for using the compendium to inform discussion and decision-making in TB programmes, particularly in conjunction with the application of the people-centred framework:

1. List essential information required to enable TB programmes to identify and prioritize programmatic gaps, determinants and causes of the programmatic gaps, and the potential interventions along the continuum of care.

   The following questions may be considered to ensure that essential information required for planning and programming of the TB programmes is included:

   - What is the burden and the rate of notification of TB disease, including its distribution (e.g. by age and sex) and trends, for drug-susceptible TB (DS-TB), drug-resistant TB (DR-TB) and TB/HIV?
   - What are the barriers to accessing care, TB diagnosis, notifications and adherence to treatment?
   - Why do people with TB or at risk of developing TB not access the health system, why are those who have sought care not diagnosed or notified, and why are those who have started on treatment not successfully treated?
   - What factors should be considered (e.g. recommendations, best practices and lessons learned) to improve access to care, diagnostic capacity, surveillance systems and treatment success?

2. Conduct an inventory of the existing evidence within the country.

   Guided by the above questions, NTPs should identify relevant available data and evidence within the country. As highlighted in the people-centred framework, NTPs should consider the inclusion of epidemiological, people-centred and system-related data. More information on the potential in-country data sources according to the types of data is available in Chapter 2 of the people-centred framework user guide *(4)*.

3. Using the people-centred framework, TB programmes can map the existing data sources and their relevant key metrics, and can identify potential data gaps along the care continuum, to assist in determining which tools should be implemented for better decision-making.

   Table 2.2 summarizes how different tools included in this compendium may provide relevant key metrics for the identification of programmatic gaps and the prioritization of corresponding interventions.

## Table 2.2. Mapping of relevant resources by potential key metrics along the care continuum

**TB burden**

**Prevalence survey:** Estimated burden of disease caused by TB
**Drug-resistance survey:** Estimated proportion of patients with resistance to rifampicin (RR-TB) or isoniazid, or both (MDR-TB)

<table>
<tr><th colspan="3">People not accessing the health system</th><th colspan="3">People with TB seeking care but either not diagnosed or not notified</th><th colspan="3">People notified as a TB case but not successfully treated</th></tr>
<tr><td>People with TB infection, high-risk for disease</td><td>Asymptomatic disease, not seeking care</td><td>Symptomatic disease, not seeking care</td><td>Presenting to health facilities, not diagnosed</td><td>Diagnosed by non-NTP, not notified</td><td>Diagnosed by NTP, not notified</td><td>Diagnosed, not started on treatment</td><td>Notified, not successfully treated</td><td>Successfully treated, not relapse free</td></tr>
<tr><td colspan="9">Care cascade analysis: Estimated losses (or attrition) along the care continuum</td></tr>
<tr><td colspan="9">Operational/implementation research: Programmatic gaps and their solutions identified by specific studies</td></tr>
<tr><td colspan="9">Epidemiological modelling: Estimated trends in notifications, incidence, mortality and other key surveillance indicators</td></tr>
<tr><td colspan="9">TB service delivery costing study: Estimated cost of delivering TB services at the facility level</td></tr>
<tr><td colspan="9">OneHealth tool for TB budgeting: Estimated costs and health impacts associated with investments in the health system</td></tr>
<tr><td colspan="9">PPA: Alignment of care seeking with service availability</td></tr>
<tr><td colspan="3"></td><td colspan="6">MATCH analysis: Spatial analysis of TB burden and programmatic indicators</td></tr>
<tr><td colspan="3"></td><td colspan="2">Diagnostic network optimization: Distribution of diagnostic capacity and its alignment with demand</td><td colspan="2">Inventory study: Level of underreporting of TB</td><td colspan="3">Patient cost survey: Economic burden incurred by TB affected households</td></tr>
<tr><td colspan="3"></td><td colspan="2">ScreenTB: Estimated yield and cost-effectiveness of different screening methods</td><td colspan="2">Standards and benchmarks: Capacity and quality of surveillance systems</td><td></td><td></td><td></td></tr>
<tr><td colspan="3"></td><td></td><td colspan="2">Private drug sales: Volume of TB patients in private sector</td><td></td><td></td><td></td></tr>
</table>

MATCH: mapping and analysis for tailored disease control and health system strengthening; MDR-TB: multidrug-resistant tuberculosis; NTP: national tuberculosis programme; PPA: patient pathway analysis; RR-TB: rifampicin-resistant tuberculosis.

To keep the table concise, the mapping of the tools in Table 2.2 is purposely constructed based on the main key metrics (or outputs) of the tools. Some tools may provide other relevant key metrics for other areas but are not listed above. For example:

- a national TB prevalence survey may provide information on barriers to accessing care (e.g. the proportion of symptom-screen positive survey participants who did not seek care) and data relevant to TB surveillance (e.g. the proportion of survey participants with previous TB treatment who were not registered with the NTP);
- inventory studies may provide evidence related to the adherence of the non-NTP sector on diagnostic and treatment guidelines, and successful models of engagement with different types of health care providers for diagnosis and treatment; and
- a diagnostic network optimization offers solutions for improving diagnostic capacities (e.g. developing models to inform optimized placement and use of existing equipment, sample referral network design and investment in new products or services).

The individual profiles of resources included in Section 3 show more detailed key metrics that NTPs can obtain from each tool. Closely examining the profiles of the tools that have already been implemented in the country will allow NTPs to be familiar with the list of key metrics (or outputs), and therefore facilitates the use of the data to inform TB programme planning and programming activities.

## 2.4 Considerations for tool implementation

The following are some considerations for the implementation of tools included in this compendium:

- Different tools may provide information within the same areas of the care continuum; for example, inventory studies, MATCH, private drugs sales, and standards and benchmarks assessments provide metrics that can be used to inform issues around TB surveillance from different perspectives. Each tool has specific key metrics to inform TB programme planning; therefore, NTPs are advised to critically review and complement findings from different tools, to help in a comprehensive assessment of the situation.

- **NTPs are not expected to implement all tools included in this compendium.** For better decision-making, different countries may need to implement different tools based on the estimated burden of TB disease in the country, country context, existing data gaps, programmatic needs, and availability of human and financial resources to implement the tools. For example, countries with a good surveillance system of high coverage and a small private sector may not need to implement an inventory study or private drug sales analysis; similarly, countries with a drug-susceptibility testing (DST) coverage of more than 80% among bacteriologically confirmed new and previously treated pulmonary TB patients may not need to implement a drug-resistance survey. In addition, countries that wish to implement the MATCH approach are likely to need the following in a digital format: TB programme data, laboratory results and spatial data corresponding to subnational reporting units.

- Factors to consider before implementing a tool include the availability of funding and implementing partners, potential outputs and how they address important evidence gaps in a given setting, and limitations of the tool.

- Implementing the tools listed in this compendium requires strong commitment by and leadership from the NTP, and sufficient funding. This is particularly true for the implementation of national studies such as national TB prevalence surveys, drug-resistance surveys, inventory studies, catastrophic TB patient cost surveys and TB service delivery costing studies. Expert review and protocol clearance are prerequisites for implementing such studies.

CHAPTER 3

# Tool profiles

# 3.1 Drug-resistance surveys

Tool type: Primary data generation

## Description

Anti-TB drug-resistance surveys can:

- provide a sound estimation of the resistance profile of new and previously treated TB patients to inform treatment guidelines and regimens, including the feasibility of new and repurposed drugs;
- be used to collate demographic and clinical data for a geographically defined population, allowing investigation of potential risk factors for drug resistance;
- evaluate the accuracy of classification of patients by treatment history and outcome;
- provide genotypic information for circulating strains; and
- strengthen laboratory capacity and sample transport and referral systems, to facilitate the transition to continuous surveillance systems.

## Implementation

**COST**
US$ 200 000–400 000

**TIME**[1]
9–15 months

**FREQUENCY**
Every 5 years

**IMPLEMENTING PARTNERS**
WHO, supranational reference laboratories (SRLs), KNCV Tuberculosis Foundation (KNCV), United States Centers for Disease Control and Prevention (US CDC)

**FUNDING PARTNERS**
Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), United States Agency for International Development (USAID)

## Scenario for using the resources

You might implement this survey if:

- a low proportion of pulmonary TB patients have a DST result for rifampicin through routine testing, and a survey has not been conducted in the past 5 years.

You might not need to implement this survey if:

- there is a national quality-assured continuous surveillance system; and
- at least 80% of bacteriologically confirmed new and previously treated pulmonary TB patients have a DST result for rifampicin.

## Prerequisites

The main resources required to implement this survey are:

- strong capacity in-country for survey governance, monitoring and evaluation (M&E), and communications;
- good logistics, including reliable procurement and distribution of supplies of equipment and rapid networks for sample referral; and
- adequate laboratory capacity for processing and testing samples for TB and drug susceptibility, and external quality assurance by SRLs.

[1] This refers to the average time required for data collection or field operations, and the time needed for completion of all laboratory testing. The average time required for study preparation (e.g. protocol writing, obtaining ethical approval, logistical arrangement, training and piloting) is 6–9 months. For post-field operations, the average time to complete data cleaning and analysis, report writing, results dissemination and policy translation is 6 months.

## Metrics to inform planning

What are the key metrics from a drug-resistance survey that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | Estimated proportion of patients with resistance to rifampicin (RR-TB) or isoniazid, or both (MDR-TB), disaggregated by treatment history (new or previously treated)<br>Risk factors for RR-TB and MDR-TB | Estimated proportion of patients with resistance to fluoroquinolones and other second-line drugs among patients with RR-TB, disaggregated by treatment history | |
| ROOT CAUSE ANALYSIS | | Laboratory capacity and sample referral systems for routine DST | |
| INTERVENTION OPTIMIZATION | | Requires the design of context-appropriate treatment guidelines and regimens, to improve patient outcomes and reduce transmission according to the patient's treatment history | |

DST: drug-susceptibility testing; MDR-TB: multidrug-resistant tuberculosis; RR-TB: rifampicin-resistant tuberculosis.

## Limitations

- For logistical reasons, surveys might be limited to pulmonary TB diagnosed in the public sector, excluding cases diagnosed in the private sector and excluding extrapulmonary TB.
- Surveys are facility based, meaning that people with TB who do not have access to health care will be missed.
- Surveys are a snapshot of the current situation. They cannot provide information about changes over time unless they are repeated. In contrast, continuous surveillance systems allow monitoring and response in real time.

## More information and resources

*Guidelines for surveillance of drug resistance in tuberculosis – 6th edition (5)*

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

## Eswatini anti-TB drug-resistance survey – 2018

### Introduction

This case study is based on material from the 2019 global TB report *(6)*. Next-generation sequencing is a valuable tool for the surveillance of DR-TB, and is increasingly being integrated into drug-resistance surveys. Compared with conventional phenotypic DST, next-generation sequencing provides accurate and more rapid results for both first-line and second-line anti-TB drugs, including identification of the specific mutations conferring drug resistance. It can also offer valuable insights into molecular epidemiology, including phylogenetics, strain evolution and transmission.

### Implementation

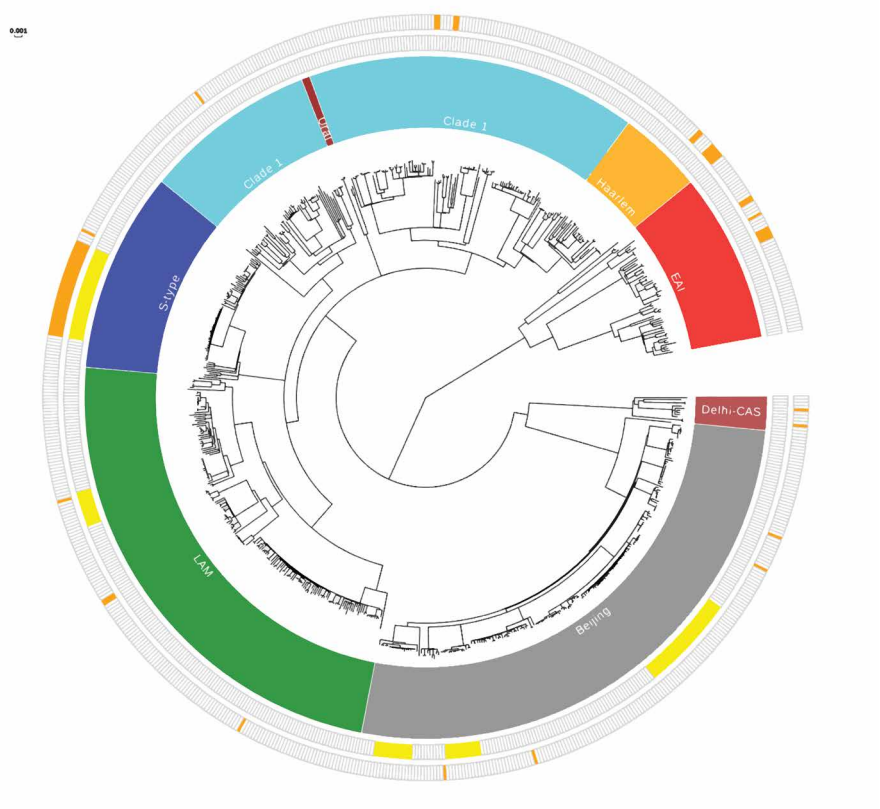
A national drug-resistance survey was undertaken in Eswatini in 2017–2018, enrolling people with presumptive TB from all diagnostic centres across the country. Sputum samples were tested using the GeneXpert MTB/RIF assay, of which 1443 were positive for *Mycobacterium tuberculosis* complex. These 1443 samples were cultured in liquid media using the BD BACTEC MGIT 960 system, followed by extraction of genomic DNA and whole genome sequencing at San Raffaele Scientific Institute, Italy (WHO TB SRL). Data from whole genome sequencing were available for 735 patients.

### Results

The national prevalence of rifampicin resistance was 8.6% (95% confidence interval [CI]: 6.7–11%) among new TB patients and 17.5% (95% CI: 11–25%) among previously treated TB patients, comparable with levels observed in the previous survey in 2009. However, 56% of these cases harboured the Ile491Phe mutation in the *rpoB* gene, which is missed by the GeneXpert MTB/RIF test. Although the presence of this clone was detected among 30% of cases of rifampicin-resistant TB (RR-TB) in the previous survey, ongoing transmission is evident.

The results of this survey have important policy implications for Eswatini. Whole genome sequencing has demonstrated that GeneXpert MTB/RIF cannot be relied on for the diagnosis of rifampicin resistance in the country, because some people with RR-TB will be missed. The national diagnostic algorithm is being modified accordingly, to integrate sequencing technologies. This will improve the detection of people with RR-TB and ensure access to appropriate treatment and care.

## Fig. 3.1. A phylogenetic tree of 727 *M. tuberculosis* strains from the national anti-TB drug-resistance survey in Eswatini




Notes for figure:
This circular phylogram was created using EvolView 3. Eight samples were excluded due to mixed TB infections. The clustering of rifampicin-resistant strains is evident.

Inner layer: strains are grouped by *M. tuberculosis* lineage.

Middle layer: transmission clusters are shown as yellow strips (the upper bound 12 single-nucleotide polymorphism cut-off was used to define a cluster).

Outer layer: rifampicin-resistant strains (as determined by genetic investigation) are shown as orange strips.

*M. tuberculosis*: *Mycobacterium tuberculosis*.

## Democratic Republic of the Congo anti-TB drug-resistance survey – 2017

### Implementation

This case study is based on material from a paper by Kayomo et al. (2020) *(7)*. The first national survey was completed in the Democratic Republic of the Congo in 2017, using a clustered design. Sputum samples from 1732 smear-positive pulmonary TB patients were tested by the GeneXpert MTB/RIF assay. If the sample was positive for *M. tuberculosis* complex, targeted gene sequencing was performed directly on sputum preserved in ethanol at the Institute for Tropical Medicine, Belgium (WHO TB SRL), using the Deeplex Myc-TB assay (GenoScreen, Lille, France).

### Results

The prevalence of rifampicin resistance was low, at 1.8% (95% CI: 1.0–3.2%) among new patients and 17.3% (95% CI: 11.9–24.4%) among previously treated patients. Resistance to pyrazinamide, fluoroquinolones and second-line injectable drugs was also low. The prevalence of resistance to isoniazid among rifampicin-susceptible patients was higher, at 6.6% (95% CI: 4.4–9.8%) among new patients and 8.7% (95%: 3.2–21.2%) among previously treated patients. Diagnosing and treating isoniazid-resistant patients remains a challenge, given that many will be missed by the current national diagnostic algorithm that is driven by detecting rifampicin resistance using GeneXpert MTB/RIF.

This is the first nationwide survey to incorporate targeted sequencing directly on sputum. It serves as a proof-of-concept for other settings that do not yet have rapid specimen transport networks or the capacity to conduct culture. Table 3.1 shows the prevalence of resistance among pulmonary TB patients.

**Table 3.1. Prevalence of resistance to first- and second-line drugs among pulmonary TB patients in the Democratic Republic of the Congo *(7)***

| | New patients | | | Previously treated patients | | | Rifampicin-susceptible patients | | | Rifampicin-resistant patients | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Resistance to selected drugs and drug combinations | n | % | 95% CI | n | % | 95% CI | n | % | 95% CI | n | % | 95% CI |
| Rifampicin | 1485 | 1.8 | 1.0– 3.2 | 149 | 17.3 | 11.9–24.4 | - | - | - | - | - | - |
| Isoniazid (all) | 1158 | 7.2 | 4.8–10.7 | 102 | 23.0 | 14.5–34.5 | 1213 | 6.7 | 4.6–9.9 | 38 | 71.5 | 43.3–89.2 |
| Isoniazid (Hr-TB) | 1112 | 6.6 | 4.4–9.8 | 84 | 8.7 | 3.2–21.2 | 1213 | 6.7 | 4.6–9.9 | - | - | - |
| Rifampicin and isoniazid (MDR-TB) | 1133 | 0.9 | 0.4–1.8 | 102 | 15.8 | 9.0–26.3 | - | - | - | 37 | 73.7 | 42.8–91.2 |
| Pyrazinamide | 1175 | 1.1 | 0.6–2.1 | 104 | 1.8 | 0.5–6.7 | 1217 | 0.3 | 0.1–0.8 | 38 | 21.6 | 9.0–43.2 |
| Fluoroquinolone | 1042 | 0.1 | 0–0.7 | 93 | 0 | 0–3.9 | 1095 | 0 | 0–0.7 | 35 | 0 | 0–10.0 |
| Injectable | 1128 | 0.3 | 0.1–1.2 | 100 | 0.8 | 0.1–5.3 | 1176 | 0.3 | 0.1–1.2 | 38 | 0 | 0–9.3 |
| Fluoroquinolone or injectable | 983 | 0.4 | 0.1–1.4 | 88 | 1.0 | 0.1–5.9 | 1034 | 0.5 | 0.1–1.4 | 35 | 0 | 0–10.0 |
| MDR-TB and fluoroquinolone or injectable | 983 | 0 | - | 88 | 0 | 0–4.1 | - | - | - | 35 | 0 | 0–10.0 |

CI: confidence interval; Hr-TB: rifampicin-susceptible, isoniazid-resistant tuberculosis; MDR-TB: multidrug-resistant tuberculosis; n: number with results.

# 3.2 Inventory studies

Tool type: Primary data generation

## Description

An inventory study provides a direct measurement of the level of underreporting of diagnosed TB cases into the national TB surveillance system. TB inventory studies link records of TB patients (using standard case definitions) from the national surveillance system with other available case-based databases (e.g. from public or private health facilities, laboratories or health insurance records). If such databases already exist, the study will be retrospective in design and will only require desk review and analysis. If databases need to be established, the study will involve field operations and will be prospective in design. Under certain circumstances, capture–recapture modelling of inventory study data also allows for the indirect estimation of TB incidence.

## Implementation

**COST**
Prospective US$ 200 000–500 000
Retrospective US$ 25 000–50 000

**TIME**[1]
Prospective 6–12 months
Retrospective 3–6 months

**FREQUENCY**
Every 3 years

**IMPLEMENTING PARTNERS**
WHO, US CDC, KIT Royal Tropical Institute, independent consultants

**FUNDING PARTNERS**
Global Fund, USAID, Unitaid

## Scenario for using the resources

You might implement this study if:

- national health authorities require a formal evaluation of the coverage of the national TB surveillance system;
- a large proportion of diagnosed TB cases are thought to not be reported to the NTP from other health sectors (public or private);
- much of the health care provided to TB patients in the country is outside the remit of the NTP; or
- the conditions for estimating TB incidence – see *(8)* for a list of conditions – using at least three lists (e.g. national TB surveillance, claims from health insurance, medical records in hospitals and clinics) are potentially met.

You might not need to implement this study if:

- there is little evidence that a sizable proportion of health care providers operate outside the remit of the NTP (e.g. if the private sector is small, or if existing regulations limit access to TB drugs to officially reported cases).

## Prerequisites

The main resources required to implement this survey are expertise in:

- the implementation of health facility based surveys;
- data management;
- probabilistic record linkage;
- complex sampling designs;
- engagement with different types of health care providers; and
- capture–recapture modelling methods.

[1] This refers to the average time required for data collection or field operations (for prospective design) or for desk review (for retrospective design). The average time required for study preparation (protocol writing, obtaining ethical approval, logistical arrangement, training and piloting) is 1–2 years (for prospective design) and 3–6 months (for retrospective design). For post-field operations, the average time to complete data cleaning and analysis, report writing, results dissemination and policy translation is 3–4 months.

## Metrics to inform planning

What are the key metrics from an inventory study that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| | Incidence estimation | | |
| **PROBLEM PRIORITIZATION** | | Exhaustive and up-to-date master list of health facilities (public and private) | |
| | | Proportion of people with TB who are diagnosed by public and private providers, but not notified to the NTP | |
| **ROOT CAUSE ANALYSIS** | | Factors associated with underreporting | Adherence to national treatment guidelines from the non-NTP sector |
| | | Adherence to national diagnostic guidelines from the non-NTP sector | |
| **INTERVENTION OPTIMIZATION** | | Successful models of engagement with different types of health care providers for diagnosis | Successful models of engagement with different types of health care providers for treatment |

NTP: national tuberculosis programme.

## Limitations

- Difficulties with case ascertainment, particularly for clinically diagnosed TB.
- Imperfect record linkage due to probabilistic matching.
- Resulting changes of reporting practices of health care providers as a direct effect of study implementation.
- Unmet conditions for capture–recapture that render this analysis unusable.

## More information and resources

*Assessing tuberculosis under-reporting through inventory studies (8)*

This guide explains how to design, implement and analyse an inventory study.

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

## National TB inventory study of Indonesia, 2017

### Background

This case study is based on material from the 2018 global TB report *(9)*. Indonesia has a large private health sector that is not yet firmly linked to the reporting network of the NTP. Also, some of the secondary and tertiary level facilities of the public health sector do not have functioning and sustained reporting links with the NTP.

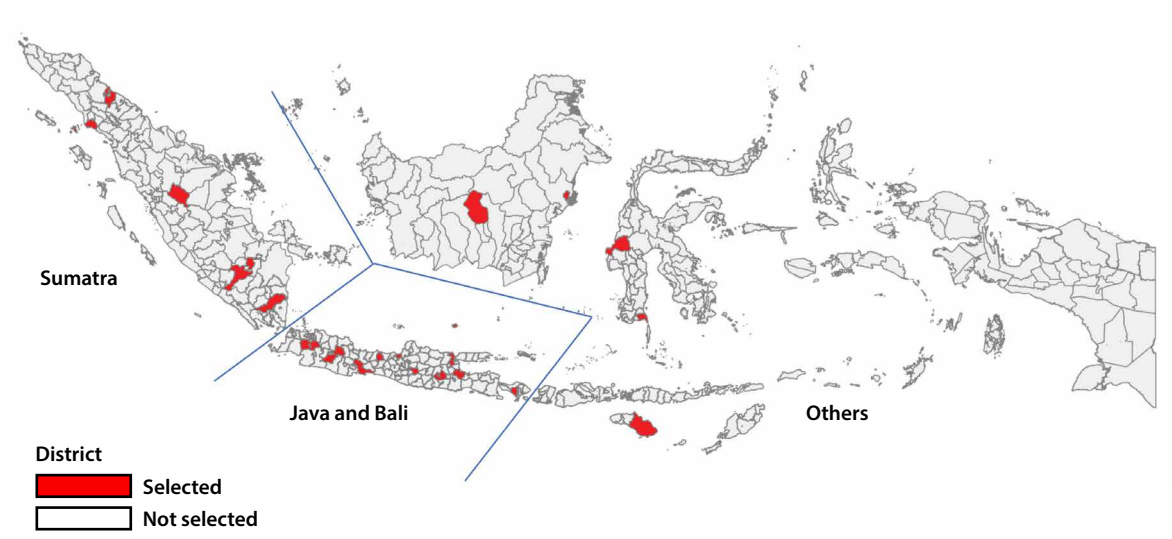
In 2016, a total of 360 565 TB cases were notified to national authorities, while the estimated TB incidence was 1 020 000 (95% CI: 660 000–1 460 000). To address underreporting, a Health Ministerial Decree was enacted in 2017, making notification of TB mandatory nationwide.

A national TB inventory study was implemented in 2017 under the leadership of the NTP and the National Institute of Health Research and Development. The aims were to directly measure the level of underreporting of detected TB cases to the national TB surveillance system (the Sistem Informasi Tuberkulosis Terpadu, SITT), which is maintained by the NTP for the different types of health facilities, and to identify best-practice methods for addressing TB underreporting.

### Methods and main results

A random, nationally representative sample of 23 districts (from a total of 514) was drawn from across the country, using a sampling design with stratification by urban or rural status and three regions: Sumatra, Java/Bali and "Others" (Fig. 3.2). The 23 districts accounted for 10% of the national population of 260 million.

**Fig. 3.2. Districts selected for Indonesia's national inventory study**

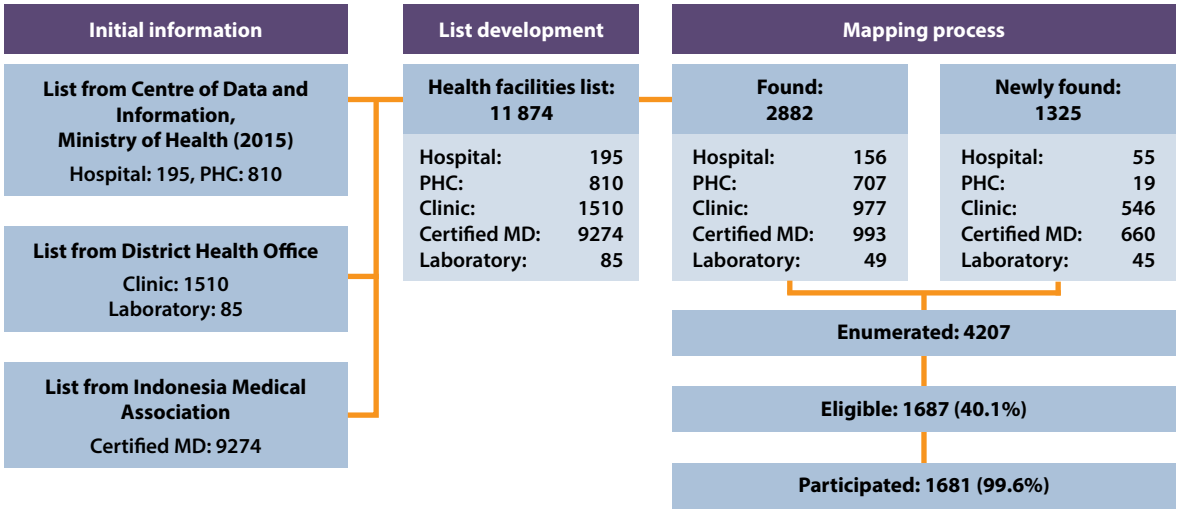



Reproduced from the 2018 Global TB report.

In each of the sampled districts, mapping of all health care providers of TB services was carried out, with a field team confirming existing but outdated lists of health care providers (Fig. 3.3).

A total of 4207 health care providers were enumerated in the 23 districts, of which 1687 were eligible (i.e. the facility reported having diagnosed or treated at least one TB case in the previous 3 months). Of the eligible health care providers, 99% participated in the study – a testament to the success of district-level workshops and meetings with all stakeholders. Pharmacies were not included in the sampling frame of the study.

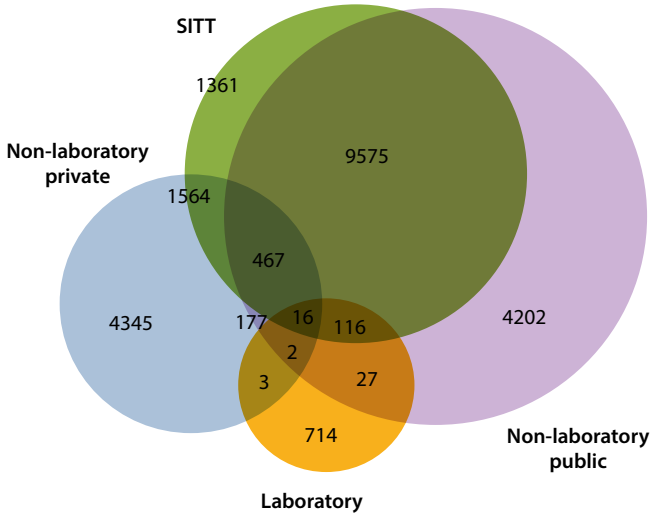
### Fig. 3.3. Health facility mapping




GP: general practitioner; MD: medical doctor; PHC: primary health care.

During the study period (the first quarter of 2017), patient records for a total of 21 320 unique TB cases were detected overall. Of these, 13 211 unique TB cases were notified and registered in SITT. Probabilistic matching made it possible to link records from the TB case lists, and thus to measure their overlap and corresponding underreporting (Fig. 3.4).

**Fig. 3.4. Matching results of TB cases found from the study and registered in the national TB surveillance system (SITT) during the first quarter of 2017**




| Source | n |
|---|---|
| SITT (unique) | 13 211 |
| Study (unique) | 21 320 |
| Non-laboratory puplic[a] | 14 562 |
| Non-laboratory private[b] | 6 557 |
| Laboratory[c] | 1 010 |
| SITT[d] – study (unique) | 22 681 |

n: number; SITT: Sistem Informasi Tuberkulosis Terpadu.

[a] Primary health care, hospitals, clinics
[b] Hospitals, clinics, general practitioners
[c] Public and private
[d] National tuberculosis surveillance system

The overall level of underreporting of detected TB cases (i.e. the proportion of detected cases not in SITT) was estimated to be 41% (95% CI: 36–46%), ranging from 15% (95% CI: 11–20%) underreporting by public primary health care "puskesmas" units (which are part of the existing NTP network), to 65% underreporting by hospitals, to 96% underreporting by the combined category of general practitioners (GPs), clinics and laboratories. Clinically diagnosed and extrapulmonary TB cases as well as cases among children were more likely to be underreported (Table 3.2).

**Table 3.2. Level of TB underreporting (%) by type of health care provider, type of TB case, age, sex and strata, accounting for sampling design**

| | Mean percentage (95% CI) |
|---|---|
| **Total** | 41 (36–46) |
| **By type of health care provider** | |
| Primary health care ("puskesmas") | 15 (11–20) |
| Non-primary health care | 71 (61–79) |
| Hospital | 62 (52–72) |
| Other[a] | 96 (92–98) |
| **By TB case type** | |
| Bacteriologically confirmed | 21 (16–26) |
| Clinically diagnosed | 55 (49–61) |
| **By site of disease** | |
| Pulmonary | 38 (33–44) |
| Extrapulmonary | 58 (49–66) |
| **By age** | |
| <15 years | 54 (44–64) |
| ≥15 years | 39 (34–44) |
| **By sex** | |
| Female | 41 (36–47) |
| Male | 41 (36–46) |
| **By strata** | |
| Sumatra | 40 (24–59) |
| Bali/Java | 42 (18–47) |
| Other | 39 (28–51) |

CI: confidence interval.
[a] Clinics, general practitioners and laboratories.

Incidence was estimated using capture–recapture modelling of the three TB case lists (SITT, study public and study private), according to recommendations and based on estimating the ratio of detected/(detected + not detected) TB cases *(8)*. It was estimated that 18% (95% CI: 15–21%) of incident cases were not detected. The annual incidence rate for 2017 was estimated at 319 (95% CI: 290–349) per 100 000 population per year.[1]

Study results and updated estimates were discussed and agreed upon in a national consensus meeting held in April 2018. The high participation rate among health care providers and the consistency of key results through sensitivity analyses show that the study was implemented to a high standard and produced robust results.

During the course of 2017, the NTP began to take corrective action to reduce underreporting. This led to a substantial increase in TB notifications in 2017 compared with 2016. Although the measure of underreporting in the study during the first quarter of 2017 was 41%, this fell in the subsequent three quarters of 2017, and the overall level of underreporting for 2017 was 36%.

[1] When using population estimates from Indonesia's Statistics Bureau (rather than population estimates from the United Nations Population Division), the estimated TB incidence rate is 322 (95% CI: 294–352) per 100 000 population per year.

## Lessons learned

The key lessons learned from the study were as follows:

- TB underreporting in Indonesia up to the first quarter of 2017 was high;
- of the incident TB cases missed from the TB surveillance system, two thirds were not reported and one third were not detected;
- an up-to-date master health facility list (for both the public and private sectors) needs to be maintained for efficient monitoring of the effectiveness of the policy of mandatory case notification;
- record linkage between the database of the NTP (SITT) and other databases of TB cases should be done routinely at least once a year;
- a unique identifier (e.g. health insurance number) strongly facilitates disease surveillance in general, and record linkage in particular; and
- more than 95% of people with TB diagnosed during the study were treated using a drug regimen that was consistent with national TB guidelines, indicating that the various health care providers are providing good-quality TB care (the low level of drug resistance found among TB patients in the recent national survey of drug resistance is consistent with this finding).

## Policy and programmatic implications

The main implications of the study results (some of which require high-level policy action) are that:

- it needs to be emphasized to health care providers that all TB cases must be reported (previously, emphasis was given to reporting of pulmonary, bacteriologically confirmed cases);
- there is a need to increase human resource capacity for data collection and management; for example, dedicated staff to work on data entry and reporting are needed, in particular, to support engagement with private sector health care providers;
- data recording and reporting needs to be simplified, especially for private sector health care providers – an android application called WifiTB, designed to simplify and facilitate case notification by the private sector, has already been developed by Challenge TB Indonesia *(10)*;
- there is a need to promote the establishment of integrated information systems, especially in hospitals; and
- the NTP needs to increase the involvement and engagement of professional organizations and laboratory networks at district level, to promote adherence with national diagnostic and reporting requirements.

As noted above, the NTP, with partners such as Challenge TB Indonesia and the Global Fund, has been strengthening models of engagement in Indonesia from 2017 to now. The engagement was based on the district public–private mix (PPM) model, in which district staff engage hospitals and puskesmas staff engage local GP networks. The engagement approaches used in the inventory study helped to provide additional ideas and motivation to strengthen these models of engagement with all types of health care providers, particularly those that were not yet part of their network.

## Conclusions and next steps

The 2017 national TB inventory study in Indonesia is the largest study of its kind ever conducted globally. It generated high-quality data, and important evidence with clear policy and programmatic implications.

Following official and wide dissemination of findings in April 2018, results are now being used to help develop national and district level responses for further roll-out.

# 3.3 Operational/implementation research

Tool type: Primary data generation

## Description

In the field of TB, operational research and implementation research (OR/IR) refers to the use of systematic research techniques for programme decision-making, to solve TB control operational and implementation problems *(11)*. OR/IR techniques include health services research that aims to evaluate health services, outcomes and the processes by which services are provided. Within the policy process, OR/IR can be implemented at different stages (e.g. problem identification, detailed problem exploration, solution development, solution translation and delivery, and impact evaluation).

## Implementation

**COST**[1]
Varies

**TIME**[1]
Varies

**FREQUENCY**[1]
Varies

**IMPLEMENTING PARTNERS**
NTPs, university researchers, partner nongovernmental organizations (NGOs)

**FUNDING PARTNERS**
Government (ministries of health and others), national and international research institutions, academic partners, international agencies, developmental and funding agencies – including the Global Fund

## Scenario for using the resources

You might implement this study if the NTP would like to:

- identify gaps and correct inefficiencies in programme performance;
- understand the conditions and strategies likely to facilitate implementation or enhance the scale-up of new interventions at national or subnational levels; and
- measure the effectiveness, acceptability, feasibility, implementation cost, affordability and potential harms of new interventions or recommendations (e.g. new diagnostic tools, treatment regimens, clinical algorithms and approach to care deliveries) under routine programmatic conditions – in this context, implementation research should be integrated in the implementation plan as one of the implementation steps of new tools or strategies (e.g. through a short, focused research project).

## Prerequisites

The main resources required to implement this study are:

- programmatic data available in a format that allows analysis of TB control gaps for guiding research questions;
- prioritization of the TB control issues, and identification of those that require OR/IR;
- a coordination mechanism at country level that involves suitable research collaborators;
- capacity to access and use funds for OR/IR;
- identification of clear questions that are amenable to study and have a direct impact on policy and implementation issues;
- capacity or strong collaboration with a research institution for conducting OR/IR; and
- existence of a national TB research task force or committee (not essential, but advantageous).

[1] These vary according to the nature of the OR/IR being done.

## Metrics to inform planning

What are the key metrics from OR/IR that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| **PROBLEM PRIORITIZATION** | | | |
| **ROOT CAUSE ANALYSIS** | Determine barriers to accessing care among people with TB symptoms through conducting studies such as a health-seeking behaviour study; knowledge, attitudes and practice survey; and qualitative study related to perception of illness | Determine challenges to TB diagnosis or notification, and assess health system performance by conducting studies such as health system performance or system impact study, delay study or qualitative study on health service use | Issues related to delivering people-centred treatment services through conducting studies such as adherence studies, and risk-factor studies on people lost to follow-up or mortality (or both) |
| **INTERVENTION OPTIMIZATION** | OR/IR can assess effectiveness, acceptability, feasibility, affordability and potential harms of new strategies under programmatic conditions | | |

OR/IR: operational research and implementation research.

## Limitations

- The generalizability of the results of OR/IR outside the settings in which they were conducted may be limited.
- Each OR/IR has different limitations, depending on the study design used.

## More information and resources

*Priorities in operational research to improve tuberculosis care and control (12)*

*A global action framework for TB research in support of the third pillar of WHO's End TB Strategy (13)*

*Implementation research for digital technologies and TB (14)*

## Contact

The Special Programme for Research and Training in Tropical Diseases, World Health Organization (tdr@who.int)

## Using operational research to identify programme performance gaps in Cambodia *(15)*

A study by Khann et al. *(16)* found that, in 2011, only a third of notified previously treated TB patients in Cambodia had DST results, despite guidelines that recommend DST testing for people with presumptive TB with previous treatment history. To understand factors associated with this, and to estimate potential DR-TB cases that could be detected from this population if there were no attrition, operational research using a mixed-method design was conducted. Case notification data from 2004 to 2012 were used, complemented by semistructured interviews with health workers. Using some assumptions taken from two prior studies *(16, 17)*, this study demonstrated the potential to detect nearly twice as many DR-TB patients if the following conditions were met: treatment history was correctly classified, all people with presumptive TB with previous treatment history submitted sputum, and results of all collected sputum were provided. One major barrier to detecting DR-TB was correct identification and recording of treatment history; this might have resulted from patients' unwillingness to disclose or from staff challenges in obtaining treatment history (or both). These findings have helped the NTP to measure the magnitude of the problem and explore possible ways to improve the programme.

## Using operational research to develop solutions in Senegal *(18)*

Treatment adherence among TB patients remains a challenge in many countries. In 2000–2002, treatment success for TB patients in Senegal was low, with a high proportion of loss to follow-up. To address this issue, a cluster randomized controlled trial was conducted. Comprehensive multitargeted interventions were given to the intervention groups between June 2003 and January 2005. The interventions included improved counselling and communication with health workers, treatment decentralization, flexibility in the choice of directly observed treatment (DOT) supporter, and enhanced supervision activities to remote health posts. The results showed that treatment success in the intervention groups was higher (88% versus 76%) and the proportion of loss to follow-up was lower (5.5% versus 16.6%) than in the control group. Also, among intervention groups, those with family members as DOT supporters had higher treatment success and lower loss to follow-up than those supported by other treatment supporters. This study suggests possible solutions to address programmatic challenges in the management of TB treatment, which could be scaled up within the country or adopted in other similar resource-poor countries.

## Using operational research to evaluate impact of interventions in Cambodia *(19)*

Nationwide implementation of active case finding (ACF) has been conducted in Cambodia since 2005. The ACF activity targeted household and neighbourhood contacts. To estimate the impact of ACF on case notifications during and after the intervention period, the NTP conducted a quasi-experimental cluster randomized study in 30 operational districts. In the first year, the proportion of additional notified cases for all forms of TB in the intervention districts increased by 18.5%, and the proportion of bacteriologically confirmed cases by 9.6% compared with the trend-adjusted expected cases, while notifications decreased in control districts. In the second year, when there was no control group, the proportion of additional notified cases for all forms of TB in the intervention districts increased by 44.3%, and the proportion of bacteriologically confirmed cases increased by 38% compared with the expected cases. However, the number of subsequent quarterly notifications was lower than expected and, after five to six quarters, it

returned to pre-intervention levels. This might be explained by the time-limited impact of ACF activities. Nevertheless, this study showed that ACF activities can substantially increase case notifications compared with passive case finding. NTPs should carefully consider the periodicity of ACF activities, to make a long-term sustainable impact on TB transmission.

# 3.4 Patient cost surveys

Tool type: Primary data generation

## Description

TB patient cost surveys have two primary objectives. One is to document the magnitude and main drivers of different types of costs incurred by TB patients (and their households), to guide policies to reduce barriers to financial access and minimize the adverse socioeconomic impact of TB. The other is to determine the baseline, and then periodically measure the percentage of TB patients (and their households) treated in the NTP network and incurring catastrophic total costs due to TB.

## Implementation

**COST**
US$ 27 000–166 000

**TIME**[1]
3–6 months

**FREQUENCY**
Every 5 years

**IMPLEMENTING PARTNERS**
WHO, US CDC

**FUNDING PARTNERS**
Global Fund

## Scenario for using the resources

You might implement this survey if:

- evidence suggests that patients may be dropping out of TB care due to the high costs of care seeking, diagnosis and treatment, and if the NTP wishes to better quantify the magnitude of these costs.

You might not need to implement this survey if:

- the country has strong evidence documenting the magnitude of TB patient costs and their composition.

## Prerequisites

The main resource required to implement this survey is a situation assessment that includes:

- TB epidemiology;
- health financing;
- health insurance programmes;
- health care fee structures;
- health care delivery models; and
- social protection schemes.

[1] This refers to the average time required for data collection or field operations. The average time required for study preparation (protocol writing, obtaining ethical approval, training and piloting) is 6–9 months and the post-field operations average time to complete data cleaning and analysis, report writing, results dissemination and policy translation is 6 months.

## Metrics to inform planning

What are the key metrics from a patient cost survey that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| **!** PROBLEM PRIORITIZATION | | Estimated proportion of TB-affected households facing catastrophic total costs due to TB, disaggregated by drug-resistance status | |
| | | Mean cost incurred by TB-affected households: total and breakdowns (direct medical, direct non-medical and indirect costs) | |
| | | Proportion of TB patients facing social consequences (e.g. job loss, divorce, social exclusion or school disruption) | |
| | | Proportion of TB patients who undertook coping strategies (e.g. loans, sale of assets or use of savings) because of TB | |
| **?** ROOT CAUSE ANALYSIS | Number of visits: prediagnosis and during treatment (mean) | | |
| | Reported patient's income: before diagnosis, at diagnosis or during treatment | | |
| | Hours lost by patient/guardian: all, by phase and prediagnosis | | |
| | | | Treatment duration and treatment start delay |
| | | | Analysis of risk factors associated with catastrophic patient costs |
| | | | Proportion of TB patients covered by health insurance or social protection schemes |
| INTERVENTION OPTIMIZATION | | | |

## Limitations

- Catastrophic total costs due to TB are estimated only among TB patients who are diagnosed and treated in the NTP network.
- Patients may not accurately remember the amount of time or money they spent in seeking care for their TB diagnosis and treatment (recall bias).
- Costs after treatment completion are not included.

## More information and resources

*Tuberculosis patient cost surveys: a handbook (20)*

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

## Patient cost surveys - Case study

### Kenya

#### Methods and main results

This case study is based on material from the 2018 global TB report *(9)*. In 2017, the Kenya National Tuberculosis, Leprosy and Lung Disease Programme (NTLD) conducted the first national survey of costs faced by TB patients and their households. The survey involved 1071 patients with DS-TB and 282 patients with DR-TB.

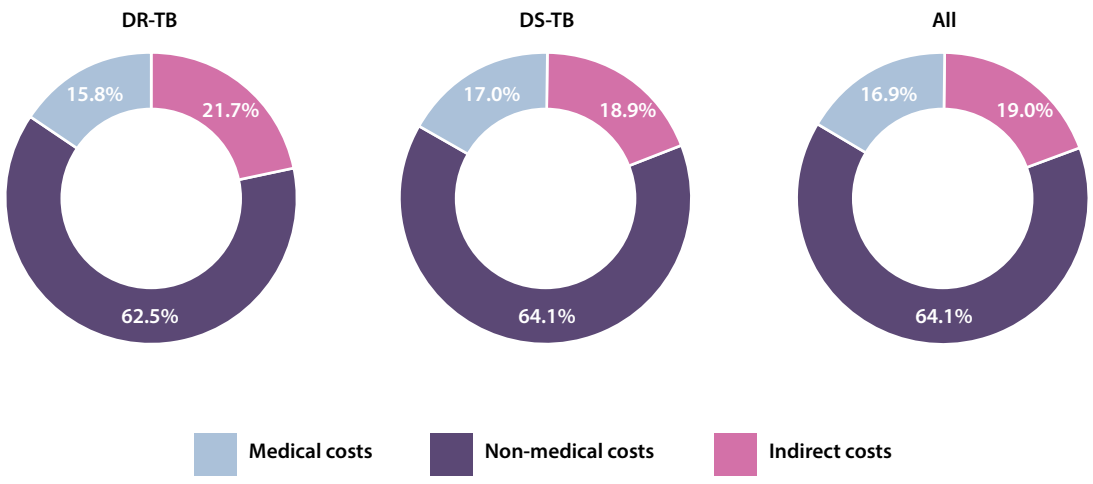
Median costs were US$ 252 for an episode of DS-TB and US$ 1416 for an episode of DR-TB, while the median household annual expenditure was US$ 2516. Survey results suggested that the proportion of TB-affected households facing catastrophic costs was 26.5% (95% CI: 20.7–32.3%), and this proportion was three times greater for patients with DR-TB (86.4%; 95% CI: 78.8–94.1%). Direct non-medical costs – particularly expenses on food and nutritional supplements outside the patient's normal diet – were the largest cost driver, followed by productivity losses (Fig. 3.5).

Significant predictors for experiencing catastrophic costs were being in a low wealth quintile, having no education, having a small household size and presence of DR-TB.

Over half of the patients in the survey were malnourished. Only 13.6% of patients were covered by the National Health Insurance Fund (NHIF) during their TB treatment.

Based on the survey results, a stakeholder consultation was held in July 2018 to guide national efforts and develop a strategy to eliminate catastrophic costs for TB patients in Kenya. The consultation involved non-health actors, including representatives from the National Social Protection Secretariat of the Ministry of Labour and the UN Joint Task Force on Social Protection.

**Fig. 3.5. Breakdown of costs by cost category and by patient group**




DR-TB: drug-resistant tuberculosis; DS-TB: drug-susceptible tuberculosis.

The action plan endorsed by partners at the consultation had five main components, as follows:

- Inclusion of TB into the eligibility criteria for existing social protection programmes in the country, particularly for cash transfer programmes. This also involves systematically identifying TB patients eligible for social protection by enabling M&E of social protection for TB patients through national electronic systems. For example, stakeholders suggested linking the Social Protection Single Registry of vulnerable households and social protection beneficiaries at the Ministry of East African Community, Labour and Social Protection to new TB notifications, to proactively identify vulnerable TB households and trigger assessment of their eligibility for social support.

- Expansion of food support to all TB patients with moderate to severe malnutrition and malnourished children in TB-affected households, and ensuring equity in food support by including vulnerable TB groups such as men.

- Inclusion of TB care in the NHIF benefit package, while increasing coverage of NHIF among TB patients.

- Development and implementation of policies and laws to eliminate discrimination and ensure job security for TB patients, in collaboration with labour sector authorities.

- Engagement of all providers in the provision of timely and quality-assured TB care to reduce delays in accessing diagnosis and treatment.

## More information and resources

- Kenyan TV news reporting on the dissemination of the patient cost survey result, Kenya Broadcasting Corporation (2018) *(21)*

# 3.5 National TB prevalence surveys

Tool type: Primary data generation

## Description

Nationally representative surveys of the prevalence of TB disease are important for:

- obtaining a direct measurement of the absolute burden of disease caused by TB;
- measuring trends in the burden of disease caused by TB;
- providing information beyond both a single point-estimate of the burden of TB and measurement of trends that can be used to inform TB policy, planning and programmatic action; and
- providing results that can be used alongside an in-depth analysis of surveillance data and programmatic data as the basis for a comprehensive update of estimates of disease burden.

## Implementation

**COST**
US$ 2 million – 6 million

**TIME**[1]
1 year

**FREQUENCY**
Every 7–10 years

**IMPLEMENTING PARTNERS**
Independent consultants, WHO, KNCV, US CDC, Research Institute of Tuberculosis – Japan Anti-Tuberculosis Association (RIT/JATA)

**FUNDING PARTNERS**
Ministry of health (MoH), Global Fund, USAID

## Scenario for using the resources

You might implement this survey if:

- a national TB prevalence survey was conducted between 2007 and 2019, and:
  - the estimated prevalence of bacteriologically confirmed TB in the most recent survey was at least 2.5 per 1000 population aged 15 years or more; and
  - the last survey was undertaken more than 7 years ago;
- no national TB prevalence survey was conducted between 2007 and 2019 and all of the following apply:
  - the estimated TB incidence is at least 1.5 per 1000 population per year (all forms, all ages);
  - there is no nationwide vital registration system with standard coding of causes of deaths; and
  - the infant mortality rate is more than 10 per 1000 live births.

For more details, see the background document 4e – *Prevalence surveys of TB disease post-2015 – why, how, where?* – from the WHO Global Task Force on TB Impact Measurement meeting (April 2016) *(21)*.

You might not need to implement this survey if:

- there is a well-functioning surveillance system that can capture all TB cases in the country in an accurate, representative and timely fashion.

## Prerequisites

The main resources required to implement this survey are:

- a strong commitment from the NTP and MoH;
- one or more implementing partners to manage the survey;
- security assurance for survey teams and participants;
- compliance with radiation authorities;
- a rigorous and efficient data management system;
- adequate laboratory capacity, especially for culture;
- reliable, timely procurement; and
- community acceptability and participation.

[1] This refers to the average time required for data collection or field operations and the time needed for completion of all laboratory testing. The average time required for study preparation (protocol writing, obtaining ethical approval, logistical arrangement, training and piloting) is 1–2 years. For post-field operations, the average time to complete data cleaning and analysis, report writing, results dissemination and policy translation is 6–12 months. Newer diagnostic tools could significantly reduce the preparation time.

## Metrics to inform planning

What are the key metrics from a prevalence survey that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| **!** PROBLEM PRIORITIZATION | Ratio of prevalent TB cases to notified TB patients (rates) | Location where care was sought among participants who were symptom-screen positive | Proportion of survey participants who report history of TB treatment (current or past, or both), disaggregated by treatment location |
| | Proportion of symptom-screen positive survey participants who did not seek care | Proportion of survey participants with TB who had sought care but were not diagnosed with TB before the survey | |
| | | Proportion of survey participants with history of TB treatment (current or past, or both), and not registered with the NTP | |
| **?** ROOT CAUSE ANALYSIS | Reasons why care was not sought when symptoms suggestive of TB were present | | |
| | Factors associated with the risk of having pulmonary TB | | |
| INTERVENTION OPTIMIZATION | | Reasons why survey TB cases were not diagnosed by health care providers | |
| | | Reasons why previously diagnosed TB cases (excluding those not currently on treatment) were not registered with the NTP | |

NTP: national tuberculosis programme.

## Limitations

A national TB prevalence survey does not typically include children aged under 15 years and does not attempt to identify those with extrapulmonary TB. However, such cases are accounted for in the extrapolation of prevalence to all forms of TB and for all ages in the final analysis.

## More information and resources

*Tuberculosis prevalence surveys: a handbook (23)* (note: a new edition will be published in 2021)

### CONTACT

WHO Global TB Programme (gtbprogramme@who.int)

# National TB prevalence survey - Case study

## The Philippines national TB prevalence survey – 2016

### Background

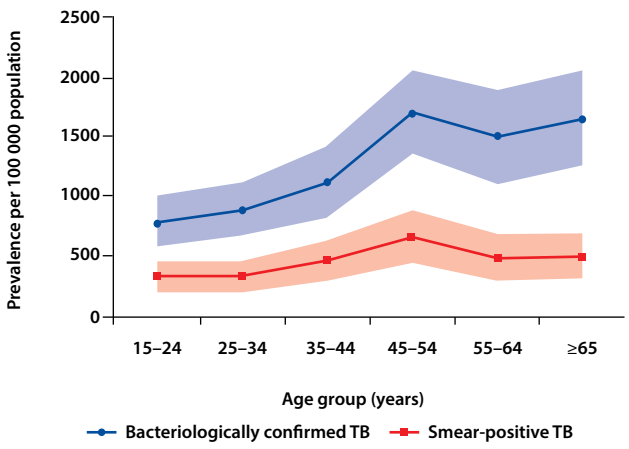
This case study is based on material from the 2017 global TB report *(24)*. The fourth national survey of the prevalence of TB disease in the Philippines was conducted from March to December 2016, following surveys undertaken in 1981–1983, 1997 and 2007. The fourth survey was implemented by the Foundation for the Advancement of Clinical Epidemiology, under the National TB Control Programme, the Department of Health, and the Philippine Council for Health Research and Development. The main objective was to estimate the prevalence of pulmonary TB (bacteriologically confirmed, and culture-positive or Xpert MTB/RIF-positive TB, or both) among the general population aged 15 years or more.

### Main results

From a total of 61 466 individuals (participation rate 76%), 18 597 screened positive by digital chest X-ray or a symptom screening interview, or both. Sputum specimens were collected from these participants and tested with GeneXpert MTB/RIF and solid culture.

A total of 466 bacteriologically confirmed pulmonary TB cases were identified in the survey, of whom 173 had smear-positive TB and 293 had smear-negative TB. Of the 466 bacteriologically confirmed cases, 150 (32%) reported symptoms and 430 (92%) screened positive on chest X-ray. Of the 173 smear-positive TB cases, 88 (51%) reported symptoms and 159 (92%) screened positive on chest X-ray. TB prevalence per 100 000 population aged 15 years or more was estimated as 434 (95% CI: 350–518) for smear-positive TB, and 1159 (95% CI: 1016–1301) for bacteriologically confirmed TB. Prevalence of smear-positive TB was much higher among men (673 [95% CI: 528–819] per 100 000 population) than among women (205 [95% CI: 141–270] per 100 000 population); similarly, prevalence of bacteriologically confirmed TB was much higher among men (1713 [95% CI: 1482–1943] per 100 000 population) than among women (627 [95% CI: 516–739]). Prevalence increased with age (Fig. 3.6). There was no statistically significant variation between the four geographical strata.

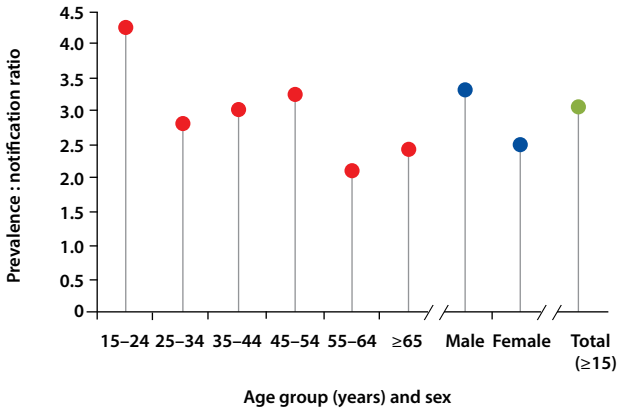
**Fig. 3.6. Prevalence of smear and bacteriologically confirmed pulmonary TB**



Adjustments were made to datasets to compare the 2007 survey with the 2016 survey. The prevalence of culture-positive TB was 463 per 100 000 population (95% CI: 333–592) in 2007 and 512 per 100 000 population (95% CI: 420–603) in 2016. The probability that prevalence did not decline over the period 2007–2016 was estimated at 75%.

Comparing the prevalence (P) of smear-positive TB among participants aged 15 years or more to the case notification rate (N) for smear-positive TB cases in 2016 (142 per 100 000 population) in the same age group gave a P:N ratio of 3.1 (Fig. 3.7). The P:N ratio was higher in men than women, and was particularly high in the age group 15–24 years.

**Fig. 3.7. Ratio of prevalence to notification[a]**




[a] Prevalence is for bacteriologically confirmed smear-positive TB cases in those aged 15 years or more in 2016. Notifications are for all pulmonary smear-positive TB cases in 2016 in those aged 15 years or more.

A total of 170 survey participants (0.4%) reported being on TB treatment at the time of the survey. Most reported taking or obtaining treatment in local health centres or in TB clinics (77%). A total of 2615 (5.6%) survey participants reported a past history of TB treatment.

Of the 466 bacteriologically confirmed TB cases identified in the survey, 150 (32.3%) had symptoms that included at least 2 weeks of a cough or haemoptysis, or both. However, only 43 (29%) of these people had consulted a health care worker, with 33 (77%) having consulted a public provider and 10 (23%) a private provider. There were 56 (37%) people who self-medicated and 51 (34%) who did not take any action at the time they experienced the symptoms.

## Updated estimates of TB disease burden

Results from the 2016 prevalence survey were used to update estimates of TB incidence and mortality, with both estimates revised upwards. The estimate of TB incidence after the survey was 554 (95% CI: 311–866) per 100 000 population, compared with the pre-survey WHO estimate (which had assumed a decline in incidence since 2007) of 322 per 100 000 (95% CI: 277–370). The estimated mortality rate based on the survey was 21 per 100 000 population (95% CI: 21–22) in 2016, compared with a pre-survey estimate of 13 (95% CI: 8.7–19).

## Conclusion

The Philippines has one of the highest burdens of TB in the world. When prevalence was extrapolated to all ages and all forms of TB, it was estimated that about 1 million people in the Philippines had TB disease in 2016.

The lack of decline in TB prevalence since 2007 can be explained by a combination of case-detection gaps, delays (possibly significant) in diagnosis, health system weaknesses, and broader social and economic influences on the TB epidemic.

In response to the high estimate of TB prevalence, the NTP and partners defined eight strategic actions at the local level under the general approach of "reach, cure and protect", as follows:

1. Replace smear microscopy with a rapid point-of-care diagnostic test, such as GeneXpert MTB/RIF, in all DOT facilities and enhance sputum delivery mechanism at all levels.

2. Increase engagement of private providers by expanding the TB service delivery network and human resources, and by enforcing the policy of mandatory TB case notification.

3. Improve the availability of patient-centred health facilities providing quality services through a revised certification programme, an improved Philippine Health Insurance Corporation (PhilHealth) TB package and social protection.

4. Use integrated communication strategies to influence community health care seeking behaviour.

5. Implement chest X-ray screening among high-risk groups, including 4Ps members (these are beneficiaries of a conditional cash transfer programme – the Pantawid Pamilyang Pilipino Program [4Ps] – for maternal child health, older people, contacts, inmates, indigenous populations, people with diabetes and smokers).

6. Undertake intensive supervision and monitoring based on electronic case-based management systems.

7. Network with other government agencies and other key stakeholders to address social determinants.

8. Ensure the governance and sustainable funding of local governance units to support implementation of the End TB Strategy.

It was anticipated that the eight strategic actions could be implemented with the full support of the Department of Health, full mobilization of the health sector (with deployment of sufficient human resources at national and subnational levels), increased domestic funding, a presidential executive order for drug regulation, establishment of a high-level steering group, and measures to ensure financial protection for more than 90% of the poor through increased coverage of PhilHealth and expanded social protection programmes.

It was recognized that ending TB in the Philippines requires not only greater investment to find and cure people with TB, but also comprehensive and sustained poverty alleviation efforts linked to the Sustainable Development Goals and multisectoral partnerships at the national and local levels.

### More information

Details can be found in the complete prevalence survey report *(25)*.

# 3.6 TB service delivery costing studies

Tool type: Primary data generation

## Description

The Costing guidelines for tuberculosis interventions *(26)* and the Value TB costing tool suite (which forms part of the costing guidelines) provide NTPs with standards and tools to estimate the costs of delivering various types of TB service at the facility level. The guidelines provide practical advice on how to collect cost data, perform analysis, and use and disseminate data. The tools can be used to estimate the costs of delivering TB services nationally based on a nationally representative sample of facilities. They can also be used and adapted to estimate the costs of introducing new and emerging TB technologies to inform resource allocation between different TB interventions.

## Implementation

**COST**
US$ 100 000–200 000

**TIME**[1]
6 months

**FREQUENCY**
Every 5 years

**IMPLEMENTING PARTNERS**
London School of Hygiene & Tropical Medicine (LSHTM), University of Capetown (UCT), WHO

**FUNDING PARTNERS**
Bill & Melinda Gates Foundation, Global Fund

## Scenario for using the resources

You might implement this study if:

- a need for primary costing has been identified (based on what the cost estimates are going to be used for, and the level of availability of existing cost data);
- there is a lack of recent and good-quality data about the economic and financial unit costs of delivering TB prevention, diagnosis and treatment services; and
- a new TB intervention has emerged and the cost of delivery is unknown.

You might not need to implement this study if:

- there are recent and good-quality data about the economic and financial unit costs of delivering TB prevention, diagnosis and treatment services; and
- the in-country resource allocation and priority setting for TB is optimal.

## Prerequisites

The main resources required to implement this study are strong in-country capacity for study governance, M&E and communications, including:

- expertise in health facility-based studies;
- expertise in cost data production (top-down and bottom-up, economic and financial costs) – those inexperienced in producing cost data should use the *Costing guidelines for tuberculosis interventions (26)*, paired with the complementary *Reference case for estimating the costs of global health services and interventions (27)*;
- expertise in national sampling design;
- a local trained research team involved in data collection and a local central research team to oversee study implementation (from development of the protocol to dissemination of study results); and
- establishment of a national task force, where possible.

Sufficient time should be given for data collection (3–7 days per facility) and data compilation.

[1] This refers to the average time required for data collection or field operations. The average time required for study preparation (e.g. protocol writing, obtaining ethical approval, logistical arrangement, training and piloting) is 8-14 months. For post-field operations, the average time to complete data cleaning and analysis, report writing, results dissemination and policy translation is 6-12 months.

## Metrics to inform planning

What are the key metrics from a costing study that can inform planning for priority gaps along a patient's pathway to care?


| | |
|---|---|
| **PROBLEM PRIORITIZATION** | |
| **ROOT CAUSE ANALYSIS** | |
| **INTERVENTION OPTIMIZATION** | Cost per direct and ancillary TB service<br>• Total costs of TB services incurred at the facility level<br>• Total quantity of direct and ancillary services delivered at each facility during the costing period<br>• Unit cost of delivering one TB service (e.g. visit, inpatient stay, patient support, diagnostic services, testing for adverse events, screening and prevention)<br>Total and unit costs are detailed by input and cost drivers (including staff time, building space, capital, equipment, supplies) |
| | Cost of TB intervention per patient episode<br>• Main TB interventions are prevention, vaccination, case finding, and first- and second-line drug treatment<br>• Quantities of TB services (e.g. visits and tests) per patient episode<br>• Unit cost data of TB services and interventions (key for planning and budgeting, as well as national strategic planning, health benefit package design, prioritization and economic modelling)<br>Interventions and associated costs (for example) are broken down by delivery platform, target population type and ownership or facility type/level to allow analysis |

## Limitations

- The following assessments are not included:
  - cost savings generated by TB interventions over time;
  - cost–effectiveness of programme interventions; and
  - econometric analytics required to produce cost functions (such analysis is usually conducted on large datasets to explore technical efficiency, extrapolate costs to other settings and understand the determinants of costs).
- TB service costs above the level of facilities are not yet covered in the guidance and tools (but may be added in future).
- Costs borne by TB-affected households in facilities are not assessed, given the focus of costing TB service delivery from the provider perspective.

## More information and resources

*Costing guidelines for tuberculosis interventions (26)*

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

## The Philippines TB service delivery costing study – 2018

### Background

The Government of the Philippines aims to accelerate reductions in the burden of TB disease through the provision of people-centred, universally accessible, acceptable and affordable quality services. Until 2017, the country did not have comprehensive, current or good-quality data on the health service costs associated with providing TB services *(28, 29)*, nor did it have a framework to periodically collect such data. A study conducted in 2018 aimed to fill this gap.

The Philippines and four other countries were part of a multicountry project in which the new TB costing guidelines and tools were first applied *(26)* in 2018. In the Philippines, the costing study was implemented by the NTP in partnership with the University of the Philippines; overall coordination and technical guidance were provided by WHO, LSHTM and UCT.

The purpose of the study was to estimate the cost of delivering TB diagnosis, treatment and prevention services.

### Methods

#### Design

Design, tools, analysis and reporting standards followed those set out in the guidelines *(26)*. The costs of TB services were evaluated from the perspective of health care providers. Data were collected retrospectively and reflected "real world" implementation of interventions. The time horizon was one patient episode of care. Outputs and interventions that were not fully implemented in health facilities at the time of data collection were either renamed to reflect partial implementation or removed from the analysis. No start-up costs or costs of supporting changes were included. Estimation of future savings, above-service-level costs, research costs and other unrelated costs were excluded. A fuller description of this approach is available *(30)*.

Multistage stratified random sampling was undertaken in three purposively selected regions (Central Luzon, Davao and Mimaropa) with 806 facilities. Of these, 28 facilities (61% public and 39% private) were selected for the study.

#### Data collection

Data collection took place between March 2018 and November 2019, and involved six trained data collectors, who worked in pairs to collect data during a week at each facility. Enumerators used Value TB data collection and data entry tools (Excel-based) *(26)*. The data that were collected for top-down and bottom-up estimates included facility characteristics, TB service statistics, building space, equipment, staff time (including observation and interviews or timesheets), drugs and supplies, training, transport and other recurrent costs. Annualized economic costs were assessed in 2017 US dollars. Enumerators measured

resource use – as per Global Health Cost Consortium (GHCC) standards – using direct observation, semistructured interviews and staff timesheets that were completed on a daily basis by facility staff over the sampled week. Costs were collected in Philippine pesos (PHP) and converted to US dollars using the average exchange rate for 2017 (US$ 1 : PHP 50.4).

Ethics approvals were obtained from the Philippine Council for Health Research and Development, LSHTM, the Department of Health Region XI for Davao Region and WHO.

### Analysis

The analysis used standard Value TB analysis programs in Stata 15. Pooled data for 28 facilities generated unit costs per facility and region, and for the country as a whole.

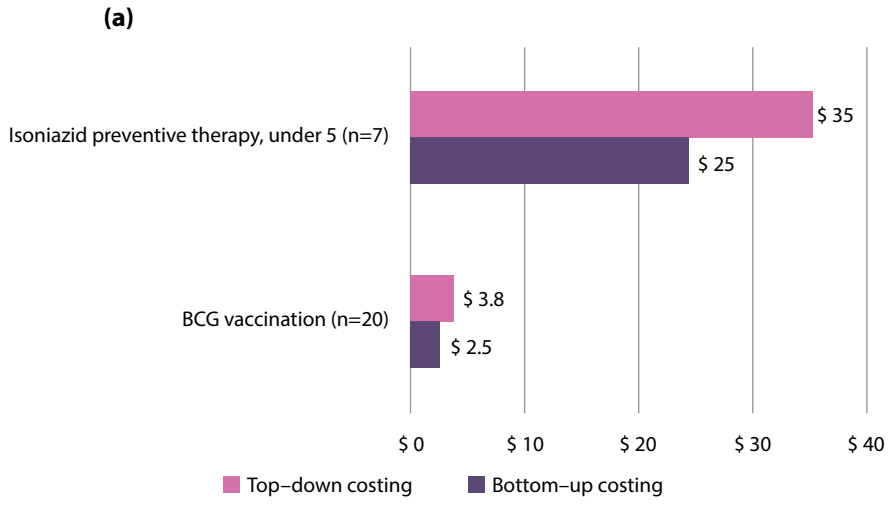
## Results

Mean costs to deliver prevention, diagnosis and care interventions per patient in the Philippines in 2017, for both the top-down and bottom-up costing approaches, are shown in Fig. 3.8.

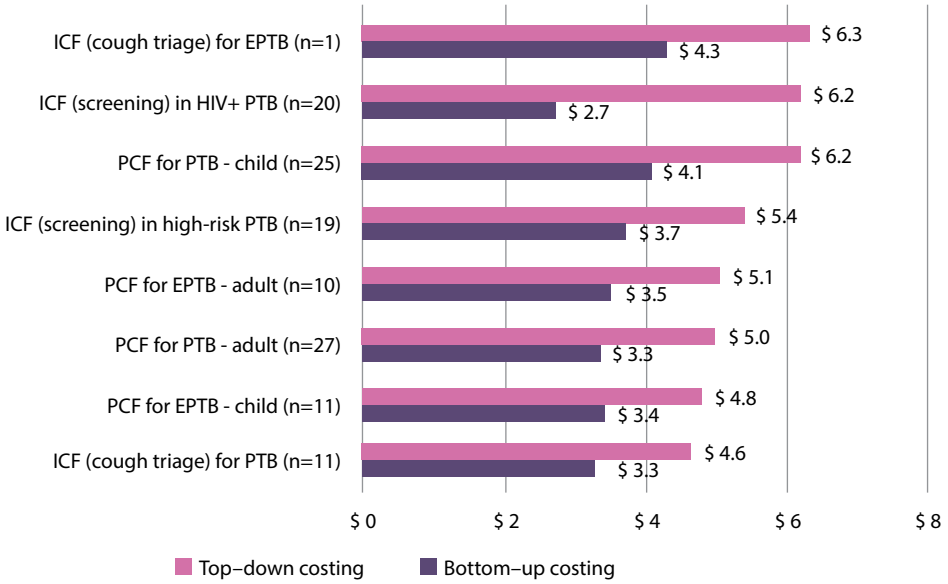
### Major cost drivers

The major cost drivers in TB technologies and services used for prevention, diagnosis and treatment were overhead costs (e.g. shared capital and recurrent costs for security, cleaning, utilities and vehicle fleet) followed by consumables. As highlighted elsewhere *(31)*, mean costs per intervention hide variations across facility type (hospitals and primary care facilities) that are influenced by packages of services included in prevention, case finding or treatment.

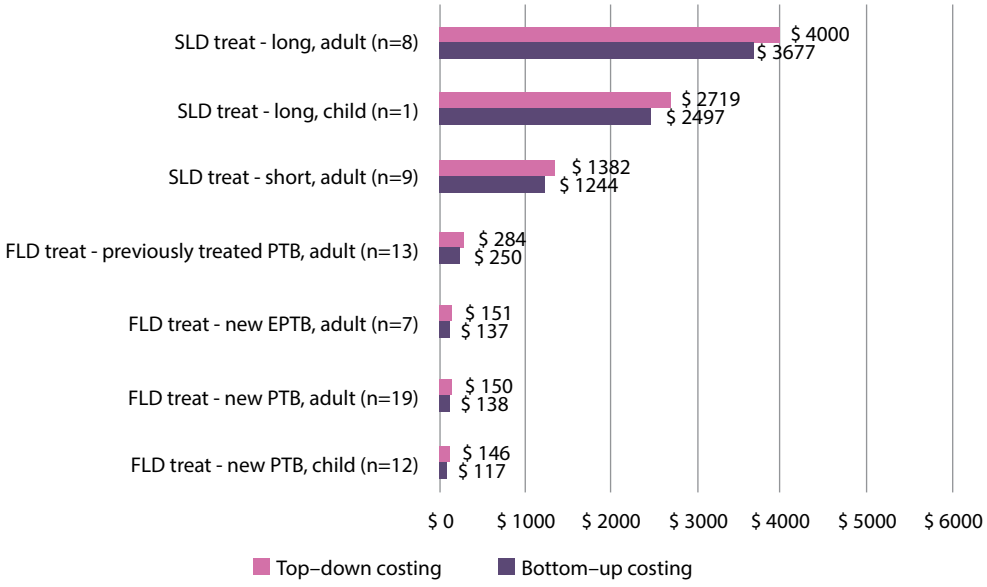
**Fig. 3.8. Prevent, find and treat TB in the Philippines, 2017: mean cost US$ 2017 (US$ 1 : PHP 50.406): (a) prevention of TB, (b) finding TB cases and (c) treating with first- and second-line drugs *(32, 33)***



**(b)**




**(c)**




BCG: bacille Calmette Guérin; EPTB: extrapulmonary tuberculosis case; FLD: patient on first-line drug; HIV: human immunodeficiency virus; ICF: intensified case finding; PCF: passive case finding; PTB: pulmonary tuberculosis case; SLD: patient on second-line drug.

## Conclusion

The study generated estimates of unit costs for the main TB interventions *(32)* and 39 technologies *(33)* in 2017 in the Philippines. The estimates can be used by planners in the Philippines to inform the provision of affordable people-centred services, to fine-tune resource allocation and to design the health insurance package. Thanks to the multi-country Value TB study, standardized unit cost data of TB services and interventions, produced in line with latest global TB costing guidelines *(26)*, are now available for Ethiopia, Georgia, India, Kenya and the Philippines (2018) from data collected across 78 health facilities. Datasets for costs per intervention per patient episode *(32)* and costs of direct and ancillary services (outputs) *(33)* are publicly available.


## Funding

The multicountry study was funded by the Bill & Melinda Gates Foundation through LSHTM from January 2017 to December 2019.

# 3.7 Care cascade analysis

Tool type: Data analysis and visualization

## Description

The TB care cascade offers an approach for assessing the continuum of care and outcomes for the estimated total number of people with TB in a country or region annually. It provides the evidence needed to prioritize interventions to reduce losses along the pathway from health care access to TB diagnosis, treatment initiation and successful treatment completion for everyone with TB. The TB care cascade offers a simple, visual way to illustrate where losses occur in the care continuum, and it can be used on an ongoing basis to track programmatic efforts to close gaps.

## Implementation

**COST**
US$ 50 000

**TIME**
1 month

**FREQUENCY**
Annual

**IMPLEMENTING PARTNERS**
Bill & Melinda Gates Foundation

**FUNDING PARTNERS**
No specific funding sources

## Scenario for using the resources

You might conduct this analysis if:

- the NTP would like to identify which TB interventions to prioritize to improve TB control efforts;
- there is a large gap between WHO incidence estimates and those reported by the TB control programme; and
- there is evidence that people with TB are missed by routine surveillance systems.

You might not need to conduct this analysis if:

- there are minimal gaps between WHO incidence estimates and those reported by the TB control programme;
- TB incidence is declining at acceptable rates; and
- an effective TB control programme is in place nationally.

## Prerequisites

The main resources required to conduct this analysis are:

- estimates of TB incidence (WHO/other);
- supplementary information from the literature or surveys on health care access, private sector care, and pretreatment or initial loss to follow-up;
- routine TB surveillance data on the number notified and treated and treatment outcomes (private and public); and
- laboratory data on the numbers diagnosed by different tests and meta-analysis data on test sensitivity from the literature.

## Metrics to inform planning

What are the key metrics from a care cascade analysis that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | Estimated number of people with TB who have not accessed health services, or have accessed care but not been screened or tested for TB | Estimated number of people with TB who accessed TB diagnosis | Estimated number of people with laboratory-confirmed TB that do not initiate treatment |
| | | Estimated number of people with TB with false negative diagnosis | Number of people with DS-TB and DR-TB who initiated TB treatment |
| | | Number of laboratory-confirmed cases | Treatment outcomes for DS-TB and DR-TB cases |
| ROOT CAUSE ANALYSIS | Gaps in TB care | | |
| INTERVENTION OPTIMIZATION | | | |

DR-TB: drug-resistant tuberculosis; DS-TB: drug-susceptible tuberculosis.

## Limitations

- Estimating the burden of disease is difficult, because the estimation tends to have wide confidence intervals and substantially influences the final cascade outcome.
- The poor availability of granular data may limit the use of this approach to inform and monitor the progress of NTP efforts at subnational levels.
- The care cascade does not reflect the time taken to diagnose, link and effectively treat people with TB; delays in this area contribute to TB transmission and need to be addressed.

## More information and resources

*The tuberculosis cascade of care in India's public sector: a systematic review and meta-analysis (34)*

*The South African tuberculosis care cascade: estimated losses and methodological challenges (35)*

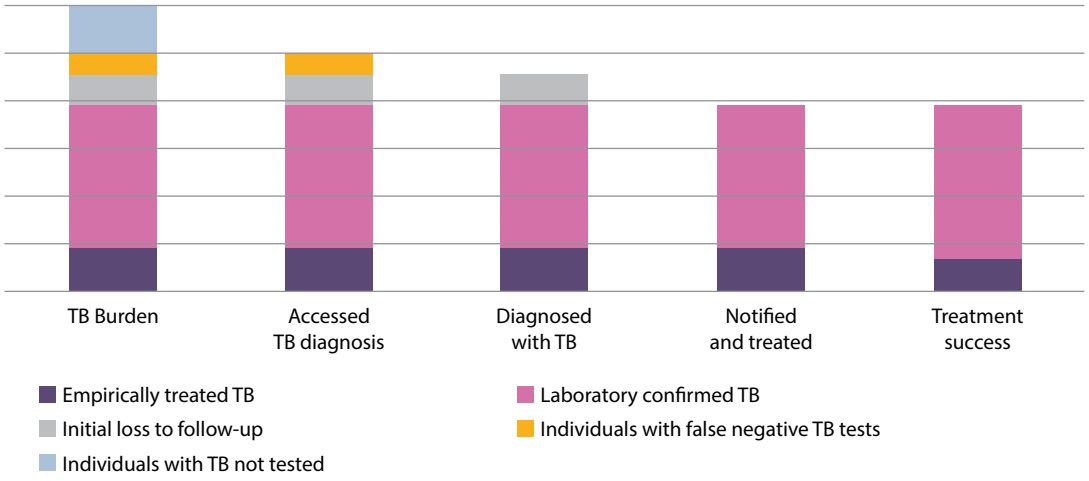
*Constructing care cascades for active tuberculosis: a strategy for program monitoring and identifying gaps in quality of care (36)*

## Care cascade analysis in South Africa – 2016

### Methods

Data from multiple sources were used to estimate the TB burden, number of people with TB accessing diagnosis, number diagnosed, and number initiating and successfully completing treatment for patients with DS-TB or DR-TB (Fig. 3.9).

**Fig. 3.9. Constructing the South African TB care cascade**




#### Steps to building the South African TB care cascade

The steps listed here explain the bars shown in Fig. 3.9.

Step 1 – Treatment success: Treatment outcomes for people with DS-TB or DR-TB were determined from the routine national public health TB surveillance systems (the electronic TB register). Only a few cases are treated in the private sector and these were not included.

Step 2 – Notified and treated: The number of people with DS-TB or DR-TB who were notified and treated was determined from routine national public health TB surveillance systems (the electronic TB and DR-TB registers).

Step 3 – Diagnosed with TB: In addition to "Notified and treated", the number or proportion of people with laboratory-confirmed TB that do not initiate treatment (i.e. initial or pretreatment loss to follow-up) was estimated. Person-level data linking diagnosis and treatment were not available; hence, this value could not be estimated from laboratory and treatment records. Instead, pooled estimates from published studies undertaken in South Africa were used to determine the proportion of people with laboratory-confirmed TB with initial loss to follow-up.

Step 4 – Accessed TB diagnosis: Most of the TB tests in routine use have a sensitivity of less than 100%; therefore, some individuals with TB will be missed at diagnosis. The number of individuals with false negative TB tests was back-calculated from the number of laboratory-confirmed patients (treated and untreated);

that is, the proportion diagnosed by different tests and test sensitivities. A downward adjustment was made, based on data from the literature, to account for patients who are treated empirically despite negative laboratory results.

Step 5 – TB burden: The WHO 2013 estimate for TB incidence was used to estimate TB burden. Case-detection rates from 2012 were also used to estimate the proportion of undetected people with TB from the previous year, assuming that 50% of these still needed to be detected (with the remaining 50% having died or self-cured). The gap between TB burden and accessed TB diagnosis reflects people with TB that have not accessed health services, and those that have accessed services but have not been screened or tested for TB.

The TB care cascade analysis was undertaken in 2016 in South Africa to develop a better understanding of where patients are lost along the continuum of care.

### Data sources

- Routine TB surveillance data from the national electronic TB register on individuals notified and treated in the public health sector (where most TB patients are treated).
- The rate of initial loss to follow-up for DS-TB was estimated from South African studies published in peer-reviewed journals (for RR-TB cases, data from a nationally representative study were used).
- Laboratory data on the numbers diagnosed by smear, GeneXpert and GenoType MTBDR*plus*.
- Literature estimates of test sensitivity, the proportion of smear and GeneXpert-negative cases with a culture test, and estimates of the proportion of false negative cases that were treated empirically in South Africa.
- WHO TB incidence data for 2013 and 2012, and case-detection rates for 2012 (50% of undetected cases were assumed to have died or self-cured by the start of 2013).
- Rifampicin resistance rates from the South African TB drug-resistance survey (2012–2014).

## Key findings

The key findings, shown in Fig. 3.10 and Fig. 3.11, were as follows:

- despite a good network of free primary health care services with access to TB diagnostic tests, only 53% of the estimated individuals with TB were successfully treated;
- 6% of individuals (27 491) either did not access services or, if they did, were not screened or tested for TB;
- 13% of individuals (69 030) with TB were missed at diagnosis, partly due to failure to request the nationally available Xpert MTB/RIF test;
- 12% of individuals (62 906) did not initiate treatment, despite laboratory confirmation of their diagnosis;

- 17% of treated individuals (92 761) were not successfully treated (cure or completion);
- among people living with HIV, the treatment success rate for DS-TB was 52%, compared with 57% among people not infected with HIV;
- overall outcomes were substantially poorer for individuals with RR-TB, with only 22% successfully treated; and
- the root causes of gaps in the TB care cascade were explored through a review of 55 published South African studies, which pointed to implementation failure at multiple points, including:
    - failure to screen and test symptomatic individuals attending clinics;
    - incorrect use of testing algorithms;
    - weak administrative procedures for retrieving test results, and recalling and referring patients;
    - workflow inefficiencies, with long queues, delays and multiple provider interactions before problems were resolved;
    - inadequate care for those coinfected with HIV;
    - poor monitoring of treatment adherence;
    - lack of data integration (among laboratory, pharmacy and clinic); and
    - limited use of data to manage continuity of care.

### Application of findings

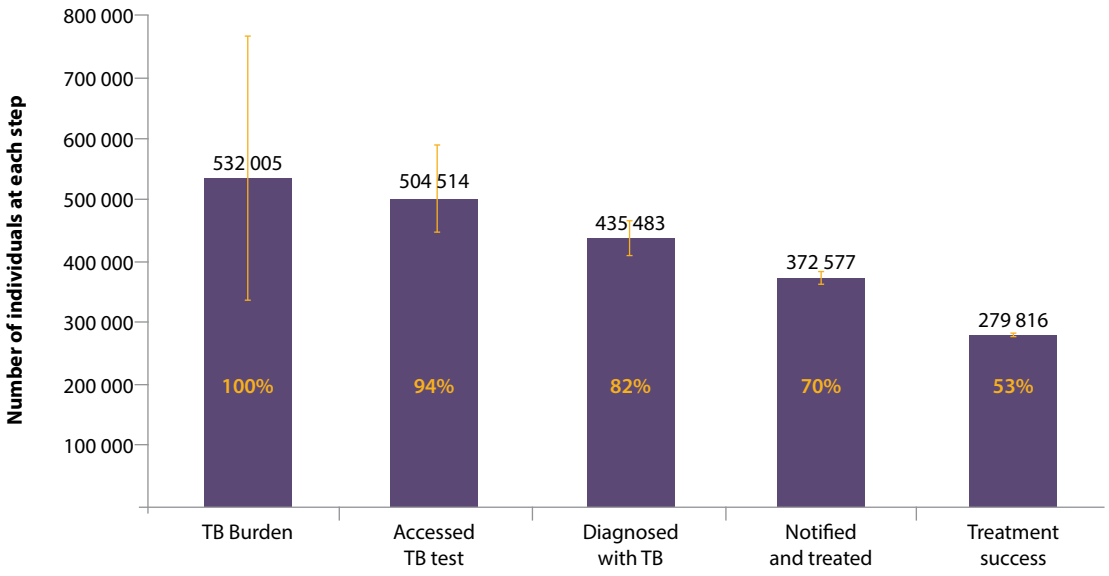
The TB care cascade was one of the tools used to inform the development of the country's National TB Control Program Strategic Plan 2017–2022. Of the seven priority interventions in the plan, six aim to address the findings from the TB care cascade analysis, as follows:

- increase facility-based screening for chronic cough among all adult attendees to 90%;
- increase ACF in selected informal settlements and among household contacts to 90%;
- reduce initial loss to follow-up for DS-TB and DR-TB patients to less than 5%;
- scale up the MDR-TB treatment short-course to reach 90% of eligible patients;
- establish an integrated, real-time TB information system to facilitate improved patient management and health service delivery; and
- implement a quality improvement initiative to reduce gaps in the TB care cascade.

A national case-finding effort is underway to identify 50% (80 000) of the "missing" individuals in Year 1 and to link them to treatment. District targets have been provided to facilitate local action.

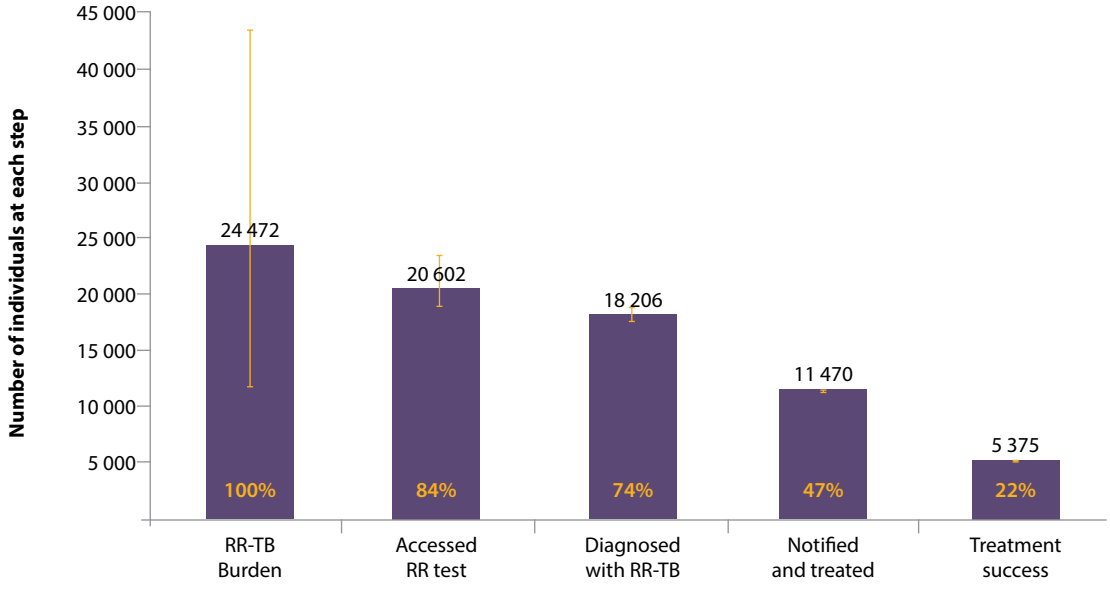
The cascade approach has been enthusiastically embraced at all levels in the health department and is being used to monitor facility-level progress in the quality improvement initiative. Data integration efforts have resulted in routine TB care cascades being available in one province to date, with efforts underway to scale this approach nationally.

**Fig. 3.10. TB care cascade – all cases (2013)**




Source: Naidoo P. et al., 2017 *(35)* (reproduced with permission).

**Fig. 3.11. Rifampicin-resistant TB care cascade (2013)**




RR: rifampicin-resistance; RR-TB: rifampicin-resistant tuberculosis.
Source: Naidoo P. et al., 2017 *(35)* (reproduced with permission).

# 3.8 OneHealth tool for TB budgeting

Tool type: Data analysis

## Description

The OneHealth tool (OHT) was developed using Spectrum software. It can be used to forecast costs and health impacts associated with investments in health care interventions, to inform medium- to long-term strategic planning. The OHT enables costing of interventions related to various diseases and programmes in standard modular format, using a bottom-up, ingredients-based approach. The TB module is aligned with the End TB Strategy and the latest WHO guidelines. The tool also facilitates estimation of cross-cutting health system components.

## Implementation

**COST**[1]
Varies

**TIME**[2]
1–2 months

**FREQUENCY**
Every 3–5 years

**IMPLEMENTING PARTNERS**
Avenir Health, WHO

**FUNDING PARTNERS**
Bill & Melinda Gates Foundation, Global Fund

## Scenario for using the resources

You might use this tool if the NTP would like to use the WHO-promoted standardized methodology for budgeting (i.e. costing for TB integrated within health sector-wide costing).

You might not need to use this tool if:

- the NTP is using an alternative TB costing methodology and tool(s); and
- the TB budgeting process in the country does not require the detailed ingredients-based budgeting approach used in the OHT-TB module.

## Prerequisites

The main resources required to implement this tool are:

- expertise in health costing;
- familiarity with the Spectrum environment and OHT methodology for cost and impact assessment;
- strong collaboration with national health planning teams;
- expertise in mathematical modelling (if the impact on the TB epidemic is to be assessed); and
- ability to collate (or update default or previously collected) data required by the OHT-TB module – this includes epidemiological projections; baseline and targeted levels of intervention coverage; TB programme activity requirements; TB-specific human resources, equipment and infrastructure needs; and the price of commodities, visits and bed days per intervention.

[1] No operational cost is needed, but expert fees may be required in some situations.
[2] Depending on the number of experts involved.

## Metrics to inform planning

What are the key metrics from an application of the OHT-TB module that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | | | |
| ROOT CAUSE ANALYSIS | | | |
| INTERVENTION OPTIMIZATION | Annual and total budget for ACF interventions and other interventions to enable access to services | Annual and total budget for passive and intensified case finding | Annual and total budget for first-line treatment, DR-TB treatment, TB patient support and preventive treatment |
| | | Annual and total budget for PPM interventions | |
| | TB-related health programme and health system requirements (e.g. the number of health workers needed to meet TB intervention coverage targets) | | |
| | A comprehensive budget for an NSP for TB | | |

ACF: active case finding; DR-TB: drug-resistant tuberculosis; NSP: national strategic plan; OHT: OneHealth tool; PPM: public–private mix.

## Limitations

- The OHT-TB module for costing works optimally in combination with the OHT TB modules for impact and estimates (TIME Impact and TIME Estimates);[1] the use of TIME Impact requires expertise in mathematical modelling.
- For TB planners who are not able to use TIME Impact, TIME Estimates[2] can be used instead. However, this module provides projections that do not include estimates of the volume of TB diagnostic tests that are required each year and therefore these need to be estimated by the users.
- The OHT-TB module and mapping function can be used for funding gap analysis, but results may be at a higher level than those needed for funding applications to international funding agencies.

## More information and resources

*OneHealth tool latest version (there are frequent updates to the software) (37)*

*OneHealth manual (38)*

*WHO One Health TB module companion book for TB budgeting and funding analysis (39)* – an Excel book that can be used to collate data needed for the OHT-TB module in Spectrum

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

[1] TIME Impact is a dynamic model that requires calibration and local adaptation.
[2] TIME Estimates is a statistical epidemiology projections module, for input into TB module costing.

# OneHealth tool for TB budgeting - Case study

## Estimating TB plan costs using the OHT-TB module in Ethiopia

### Background

Ethiopia's NSP for TB for the period 2021–2025 included well-defined objectives and core activities that were aligned with the three pillars of the End TB Strategy. The country's National TB and Leprosy Control Programme (NTLCP) and partners decided to use the TIME model (in Spectrum) to evaluate scenarios and prioritize interventions, and the OHT-TB module to estimate costs.

### Methods

The costing process was led by the NTLCP, with technical support from development partners. The NTLCP used the TIME Impact and TIME Estimates models *(40, 41)* to calibrate notifications, incidence and mortality over the period of the plan. Notification projections and other TIME results were used as inputs to other indicators (e.g. the size of target populations) required in the OHT-TB costing module.

#### TIME model calibration

The TIME model was applied in two phases in March–April 2020. In the first phase, modellers worked to update the TIME calibration from the previous NSP. This was done using data collated during the data consolidation phase of the NSP development process. The second phase included modelling of the impact of interventions and additional cost–effectiveness analyses, using TIME Impact and TIME Economics. Experts in the TIME model from LSHTM supported the process in both phases through a series of remote meetings with the NTLCP, WHO country office staff, and KNCV. Five scenarios were assessed:

- Scenario 1: no significant changes to the TB control programme (i.e. business as usual);
- Scenario 2: coverage of GeneXpert as a first-line diagnostic test (in place of smear microscopy) expanded to 80% of presumptive TB patients;
- Scenario 3: chest X-ray screening introduced in 60% of all health facilities and GeneXpert coverage expanded to 80%;
- Scenario 4: Scenario 3 + intensive case finding and PPM expansion; and
- Scenario 5: Scenario 3 + household contact tracing expanded among children aged under 5 years.

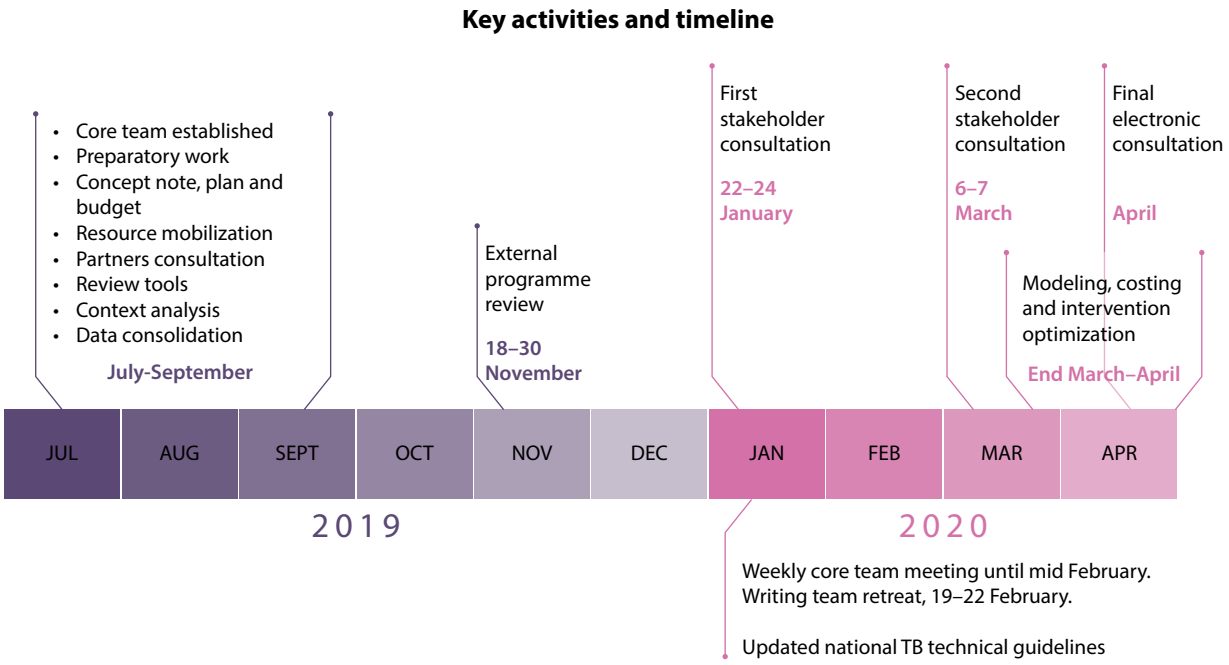
The cost–effectiveness of each scenario was estimated using TIME Impact and TIME Economics. The most cost-effective scenarios were 3 and 5. These results informed prioritization of activities included in the NSP and the related funding request to the Global Fund. Scenarios 3 and 5 were transferred to the OHT, to estimate the funding required for the NSP for TB over the period 2021–2025.

### Completion of the OHT-TB module

The coordination of the costing of interventions in the OHT-TB module was led by a locally based consultant over 30 days. Their terms of reference included guiding the costing process, a planning workshop with stakeholders, development of zero and final drafts of cost analysis reports, and timely submission of a costing of the NSP to the NSP writing team (Fig. 3.12).

The funding required for the NSP (2021–2025) was estimated based on the costing of activities that were described in detail under each of the plan's five strategic objectives using the OHT-TB module. The OHT-TB module was prepopulated with default data related to TB notifications, and the estimated prevalence and incidence of TB derived from TIME (which used data and estimates from the WHO global TB database). During the costing process, the default values for the unit costs of drugs, reagents and supplies built into the tool were replaced by local costs, using newly available evidence from the *Value TB cost study in Ethiopia (42)*. Cost data were collated during the consolidation phase of the NSP development process (March to April 2020), in parallel with the calibration of the impact model.

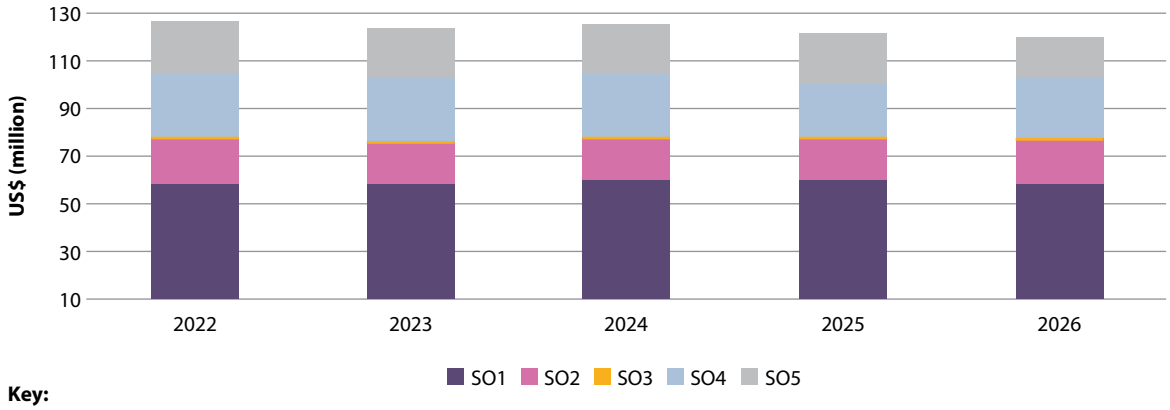
**Fig. 3.12. TB-NSP development key activities, deliverables and timeline**



### Findings

Based on assessment of the cost–effectiveness of alternative scenarios for scale-up of diagnostic tools, expansion of services to PPM schemes and prevention strategies, prioritized interventions included the expansion of GeneXpert as a first-line diagnostic tool to 80% of presumptive TB patients in 2025 (including the private health sector); the introduction of chest X-ray screening to 60% of health care facilities by 2025; and screening of 70% of people at risk of TB who are attending outpatient services, including private facilities (e.g. people living with HIV, people with diabetes mellitus, child health services and household contact tracing). It was estimated that a 5-year investment of US$ 664 million was required for full implementation of the 5-year NSP (Fig. 3.13).

**Fig. 3.13. TB budget by strategic objectives, July 2021 – June 2026**




**Key:**
**SO1** = Address gaps across the patient pathway
**SO2** = Prevent infection and active disease
**SO3** = Provide people-centred equitable quality services
**SO4** = Enhance bold policies and strengthen supportive systems
**SO5** = Strategic information and research

SO: strategic objective.

## Conclusion

It was possible to assess the resource requirements to implement the NSP for TB in Ethiopia, 2021–2025, using the OHT. This was facilitated by the engagement of a consultant, who ensured a participatory process and stakeholder ownership of results. The NTLCP disseminated results through a stakeholder meeting in March 2020 and used the results to mobilize resources. The Government of Ethiopia contributed 11.7% of the total budget for the NTLCP annually; a grant from the Global Fund will provide US$ 56 million over the period 2021–2024. At the time of publication, it was anticipated that remaining budget gaps would be covered by other development partners such as USAID, US CDC, WHO and the German Leprosy and TB Relief Agency.

# 3.9 Diagnostic network optimization

Tool type: Data analysis and visualization

## Description

Diagnostic network optimization seeks to answer the question, "How can we increase patient access to quality diagnosis while improving service delivery efficiency?". It does this by using available programmatic, survey and laboratory data to create a digital network model to visualize and understand the current diagnostics network. A series of country-customized scenarios that more efficiently reach "missing" people with TB are then applied to the model, to identify areas for improvement and understand trade-offs (e.g. between centralized and decentralized service delivery models). Model outputs inform the placement and use of existing equipment and sample referral network design, and can inform investment in new products or services.

## Implementation

**COST**
US$ 80 000–200 000

**TIME**
3–6 months

**FREQUENCY**
Every 6 months

**IMPLEMENTING PARTNERS**
Foundation for Innovative New Diagnostics (FIND), with technical and implementing partners

**FUNDING PARTNERS**
Bill & Melinda Gates Foundation, Global Fund, USAID/US President's Emergency Plan For AIDS Relief (PEPFAR), FIND

## Scenario for using the resources

You might conduct this analysis if the NTP would like to:

- better understand the capacity of the programme's diagnostic network relative to testing demand to meet country TB targets;
- investigate options to increase patient access to services, while optimizing the use of existing diagnostic capacity, including device placement and design of sample referral networks; and
- test implementation scenarios for new diagnostic tools and approaches.

You might not need to conduct this analysis if:

- the prerequisites are not available; or
- resources to collect or compile required data are not available.

## Prerequisites

The main resources required to conduct this analysis are:

- health facility data (locations, services offered, population and catchment);
- routine surveillance data, such as number of people with TB seeking care, screened, tested, diagnosed, notified and initiated on treatment at a particular health facility;
- laboratory data, such as number tested, results, diagnostic test menu, equipment and testing capacity per site; and
- costs (fixed and per test), site operating cost and transport costs.

## Metrics to inform planning

What are the key metrics from a diagnostic network optimization analysis that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | | Proportion of people with TB seeking care at health facilities with and without onsite diagnostics<br>Estimated demand for tests compared with actual test volumes at current state<br>Proportion of notified people with DS-TB and DR-TB with diagnostic tests conducted, by test type (according to national algorithm) | |
| ROOT CAUSE ANALYSIS | | Number of health facilities that have diagnostic services onsite or available via sample referral system at current state<br>Distances between health facilities and diagnostic testing site at current state<br>Type, distribution and capacity of diagnostic tests available at current state | |
| INTERVENTION OPTIMIZATION | | Distances between health facility and diagnostic testing site for optimized network design(s) compared with current state<br>Cost of implementing optimized network design(s), including efficiencies of integrated testing and sample referral<br>Number of health facilities that have diagnostic services onsite or available via sample referral system for optimized network design(s) compared with current state | Availability of diagnostic services for DST and treatment monitoring, especially for DR-TB patients (capacity and placement relative to demand) |

DR-TB: drug-resistant tuberculosis; DST: drug-susceptibility testing; DS-TB: drug-susceptible tuberculosis.

## Limitations

Quality data are essential for good outcomes, but are not always available.

## More information and resources

*Laboratory network optimization to improve service delivery for TB. Satellite symposium at Union World Conference on Lung Health (43)*

An open access, user-friendly tool that will be free of cost to end users in low- and middle-income countries (LMICs) will be available

FIND website *(44)*

## Contact

FIND
(access@finddx.org)

## Diagnostic network optimization in Kenya

### Background

Kenya's 2016 TB prevalence survey found that more than half (53%) of those with TB were undiagnosed or not notified. Although Kenya has scaled up the use of WHO-recommended rapid diagnostic tests, the use of smear microscopy still predominates, with only 47% of notified people with TB receiving a WHO-recommended diagnostic test at initial diagnosis. Diagnostic network optimization was conducted in 2017–2018 as part of a prioritized, evidence-based NSP process of the country's NTLD. Improving use of the existing diagnostic network is crucial to a sustainable and cost-effective system, while placement of diagnostic capacity where people with TB seek care and establishment of efficient sample referral linkages are essential for improving access to services and closing the diagnostic gap.

### Method

The network model design and analysis were conducted using supply chain design and optimization software. They used available data sources, such as NTP reports, the TB prevalence survey, district health information software data (master facility list, see Section 3.16), census and electoral data, DHS data and laboratory costing data.

Overall objectives of the analysis were to:

- map TB burden and current demand for TB diagnostic services;
- map current TB diagnostic network structure;
- identify the extent and distribution of gaps in existing services, according to burden of disease;
- develop a set of diagnostic network designs (defined by NTP and partners) that better and more efficiently reach "missing" people with TB using existing infrastructure; and
- model a set of new network paradigms, including investment in new products and services, to inform national strategic planning and budgeting processes.

Implementation of the diagnostic network optimization in Kenya involved the following steps:

- Initial engagement with NTP and partners – presentation of network optimization purpose, methodology and expected outputs, which coincided with an early planning meeting for NSP development. Discussion and framing of focus of the analysis was based on the current status of the network and planned interventions for NSP (e.g. a focus on GeneXpert capacity, placement and location, and sample referral network design to improve patient access and service delivery efficiency).
- Second workshop – presentation of preliminary analysis and collaborative refinement of data inputs and optimization scenarios.
- Presentation of final report and implementation discussions.

Second phase of the work – the established network models were used to design detailed, integrated sample referral systems for TB, HIV and other samples in 15 counties, including detailed route plans, costs and transport modes.

## Key results

Kenya had sufficient network capacity to meet near-term testing demand and is largely well-placed to meet testing demand. However, overall, the country was not making full use of its GeneXpert capacity. Sample referral for GeneXpert testing was fragmented and limited, particularly in some parts of the country. Health facilities often referred patients to testing sites that were not necessarily closest geographically. The findings indicated that establishing a sample referral network is a priority, to enable scale-up of testing to find missing people with TB.

Future Xpert MTB/RIF testing demand to meet NSP targets for TB case detection is estimated to increase from 275 000 tests in 2017 to about 700 000 in 2021 and 1.4 million tests by 2023. To meet these projected testing demands, there is a need for additional GeneXpert testing sites, from 162 sites in 2017 to a total of 450–500 total sites by 2023 (Fig. 3.14) *(45)*. Sample transport distances were long in hard-to-reach counties in the north of the country, even where optimized linkages were applied. Therefore, these counties were prioritized for placement of new instruments to improve access.

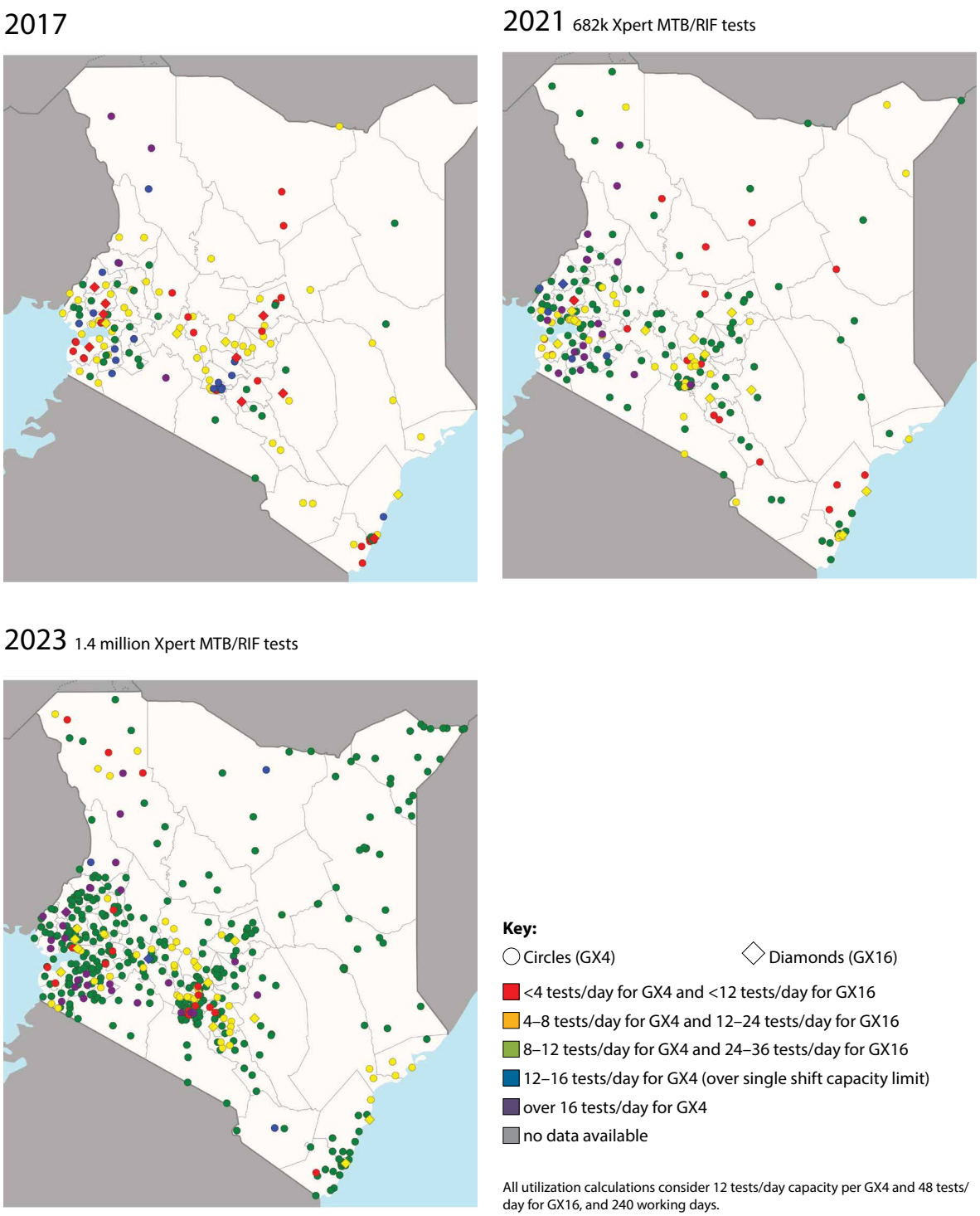
Since the future demand projections are based on NSP targets for screening and case detection, an update of the network model using actual data through the NSP period is recommended, to assess progress towards targets and adjust testing demand if needed.

## Programmatic implications

- Diagnostic network optimization outputs contributed to development of Kenya's NSP for tuberculosis, leprosy and lung disease 2019–2023.

- Integrated sample transport system designs informed a recent revision of Kenya's national integrated sample referral system guidelines, and the development of a practical guide for county operational planning for integrated sample referral systems in Kenya to enable implementation of the national guidelines. County operational plans for 15 counties were developed to implement the recommended network designs.

**Fig. 3.14. Map of baseline allocation and utilization of GeneXpert testing sites (2017) and recommended future placement of GeneXpert sites (in 2021 and 2023) required to meet projected future demand for testing to meet Kenya's NSP targets**




GX4: GeneXpert 4-module device; GX16: GeneXpert 16-module device; NSP: national strategic plan.
Data source: Kenya National Tuberculosis, Leprosy and Lung Disease Programme/Foundation for Innovative New Diagnostics (FIND)/LLamasoft.

# 3.10 Epidemiological modelling

Tool type: Data analysis

## Description

Country-level epidemiological modelling is a quantitative exercise that is designed to help guide discussion between stakeholders throughout the strategic planning process. Mathematical models aim to provide an understanding of how different policy choices could impact future health outcomes, by explicitly representing the mechanistic relationships between the intervention packages and the potential future impact of these actions. The different models and approaches all aim to incorporate and synthesize a wide range of evidence, to estimate outcomes that would be too expensive, impractical or unethical to assess empirically. In an ideal application, a country-level epidemiological model is coupled with a cost model to provide guidance on resource allocation or the exploration of various economic indicators.

## Implementation

**COST**
US$ 30 000–60 000

**TIME**
3–12 months

**FREQUENCY**
Every 3 years

**IMPLEMENTING PARTNERS**
TB Modelling and Analysis Consortium (TB MAC), Australian Tuberculosis Modelling Network (AuTuMN), Optima-TB, Imperial College London, TIME-Avenir, TIME-KNCV

**FUNDING PARTNERS**
Bill & Melinda Gates Foundation, Global Fund, USAID, World Bank

## Scenario for using the resources

You might implement this tool if the NTP would like to:

- investigate the potential future course of the TB epidemic under different scenarios;
- support discussions on setting and reaching targets;
- use quantitative evidence to structure decisions on which interventions to include in a package;
- estimate the resources required for different interventions to inform budgeting and planning activities;
- use the epidemiological impact of different interventions to inform an economic model or analysis; and
- investigate potential intervention alternatives that would not be feasible to investigate empirically due to ethical, cost or time constraints.

You might not need to implement this tool if:

- a simpler approach such as a statistical model could be used (e.g. if the time horizon is short or you are interested in a proximal output of programmatic activities).

## Prerequisites

The main resources required to conduct this tool are:

- WHO Global TB Programme burden estimates;
- routine surveillance data;
- numbers screened or estimated number needed to screen;
- M&E of programmatic activities; and
- data on diagnostic algorithms implemented and coverage.

Desirable prerequisites include data from prevalence surveys (highly desirable), supplementary surveillance (such as of risk groups), drug-resistance surveys, research, epidemiological reviews, inventory studies.

## Metrics to inform planning

What are the key metrics from epidemiological modelling that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| **PROBLEM PRIORITIZATION** | Estimated trends in notifications, incidence, mortality and other key surveillance indicators | | |
| **ROOT CAUSE ANALYSIS** | Estimated change in notifications, incidence, mortality and other key surveillance indicators due to an intervention | | |
| **INTERVENTION OPTIMIZATION** | | | |

## Limitations

- Model outputs depend on the completeness and quality of available data. Assumptions can be used to fill data gaps; however, these need to be taken into account when interpreting model results.
- Because model outputs depend on structure and assumptions, different models applied in the same setting may produce different results.
- Modelling can be technically challenging; thus, it requires training in model use or technical assistance from experienced modellers.

## More information and resources

TB MAC website *(46)*

Guidance for country level TB modelling website *(47)*

## Contact

TB MAC
(tb-mac@lshtm.ac.uk)

# Epidemiological modelling - Case study

## Viet Nam epidemiological modelling

### Background

One of the available country-level epidemiological models, the TIME model, has been used by the Viet Nam TB Programme since 2014. The model is used to support strategic planning and the development of funding requests to the Global Fund.

Throughout 2016, the country's NTP received training to move towards independent use of the model. The NTP continues to use the model independently for strategic planning purposes, and is providing training to expand the local modelling team.

### Model application

The NTP applied the TIME model to support the narrative of its 2017 Global Fund funding request.

Specific aims of the work were to:

- combine available data on the Viet Nam TB epidemic into a single logical framework;
- generate projections of TB burden under different intervention scenarios, to reach 2020 NSP targets; and
- inform discussions on priority interventions for the 2017 Viet Nam funding request.

### Data sources

- 2007 prevalence survey.
- 2005 and 2011 drug resistant surveys.
- WHO Global TB Programme estimates of burden.
- NTP reports.

### Results

The model was calibrated using epidemiological and programmatic data to match the current TB epidemic, including trends since 1990, to provide projections to 2035.

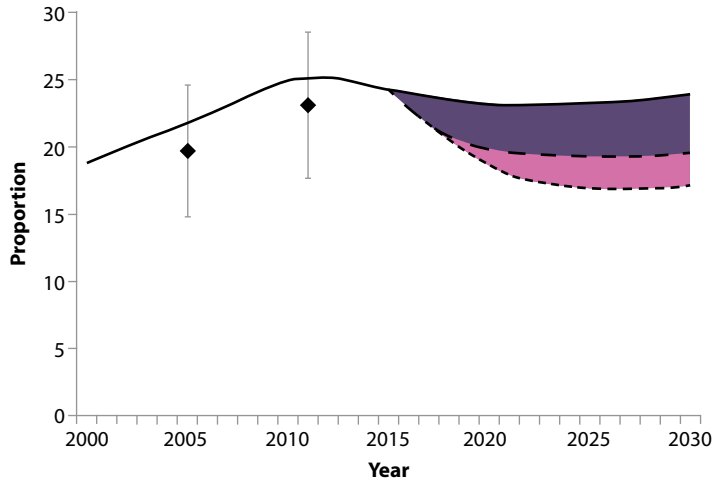
Results from the model were used to make the case for sustained investment in programmatic management of DR-TB activities, by demonstrating the expected impact of reaching the Global Fund funding request targets of improving treatment initiation and outcomes for MDR-TB patients (Table 3.4 and Fig. 3.15).

## Table 3.4. Model inputs

| TIME model | | Activities that will be implemented to achieve these targets |
|---|---|---|
| **Parameter** | **Target** | |
| DST coverage (among new patients) | 80% | • Increase testing coverage of drug susceptibility for first-line drugs among new and previously treated patients |
| DST coverage (among previously treated patients) | 98% | |
| Linkage to care | 95% | • Increase MDR-TB treatment coverage<br>• Implement social protection measures |
| Treatment success | 80% | • Use shorter regimen<br>• Implement social protection measures<br>• Implement early testing for (pre)-XDR-TB |

DST: drug-susceptibility testing; MDR-TB: multidrug-resistant tuberculosis; TIME: tuberculosis impact module and estimates; XDR-TB: extensively drug-resistant tuberculosis.

## Fig. 3.15. Model output – proportion of previously treated TB patients with MDR-TB




◆ Drug-resistance survey data (2005 and 2011)

Proportion of previously treated TB patients with MDR-TB *without* Global Fund investment

Modelled-impact from *initial* Global Fund investment 2014–2016

Modelled-impact from *sustained* Global Fund investment to 2020

MDR-TB: multidrug-resistant tuberculosis.

# 3.11 MATCH

Tool type: Data analysis and visualization

## Description

The mapping and analysis for tailored disease control and health system strengthening (MATCH) approach is an analytical framework for identifying gaps in TB health service delivery. It applies mapping and spatial analysis techniques to existing health data, to then target interventions. Core to this approach is the integration of multiple sources of subnationally disaggregated data to identify people with TB who have been missed along the patient pathway. Triangulating geographical patterns of TB programme and sociodemographic data provides insights into where and why people with TB are missed (e.g. not diagnosed, or diagnosed but not reported to national programmes). These MATCH analyses generate the evidence needed to prioritize subnational areas for targeted case-finding activities.

## Implementation

**COST**
US$ 45 000–75 000

**TIME**
2–4 months

**FREQUENCY**
Annual

**IMPLEMENTING PARTNERS**
KIT Royal Tropical Institute

**FUNDING PARTNERS**
MoH, Stop TB Partnership, Bill & Melinda Gates Foundation

## Scenario for using the resources

You might conduct this analysis if:

- the NTP would like to evaluate whether TB programme activities are equally and equitably available across the country;
- the NTP would like to monitor and evaluate the ability of the programme to detect, diagnose and treat people with TB across regions with varying levels of coverage by the TB programme and the private sector;
- inventory studies indicate that there are geographical areas with undernotification and the NTP would like to understand why this is happening and who is being missed; and
- prevalence study estimates show geographical areas with suboptimal treatment coverage rates and the NTP would like to understand whether this is due to subnational variations in geographical access or service availability.

You might not need to conduct this analysis if:

- the TB programme data are not digitally available at subnational level;
- laboratory results are not digitally available at subnational level; and
- spatial data corresponding to subnational reporting units are not available.

## Prerequisites

The main resources required to conduct this analysis are:

- routinely collected TB programme and laboratory data digitally available at subnational level;
- spatial data of the point locations of TB service providers or spatial data of the outlines of reporting administrative areas; and
- programme commitment and resources to routinely analyse subnational data to plan, monitor and evaluate subnationally differentiated interventions.

## Metrics to inform planning

What are the key metrics from MATCH that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | Spatial incongruences between patterns of TB risk, access to services, diagnostic outputs and TB notification | Subnational estimation of the proportion of the population with physical access to TB services | |
| ROOT CAUSE ANALYSIS | Generation of hypotheses for suboptimal treatment coverage, verified with supervisory M&E | Development of M&E frameworks to uncover reasons for suboptimal treatment coverage | |
| INTERVENTION OPTIMIZATION | Prioritization of subnational areas with high TB risk profiles; Evaluation of scenarios to improve access including outreach activities, GeneXpert placement or sputum referral hubs | | |

M&E: monitoring and evaluation; MATCH: mapping and analysis for tailored disease control and health system strengthening.

## Limitations

- When required data are incomplete, inconsistent or invalid to inform the decision process, investments should prioritize the strengthening of health management information systems. The MATCH approach starts with a data inventory and data quality assessment, to ascertain the validity of the subsequent analysis.
- MATCH is not a "plug-and-play" tool; it requires inputs from TB experts to interpret outcomes.
- MATCH is an analytical framework and methodological approach, not an automated tool.

## More information and resources

The KIT MATCH approach for enhancing TB care coverage *(48)*

Data management plan for MATCH analysis *(49)*

Peer-reviewed publications:

- *A spatial analysis framework to monitor and accelerate progress towards SDG 3 to end TB in Bangladesh (50)*
- *Finding gaps in TB notifications: spatial analysis of geographical patterns of TB notifications, associations with TB program efforts and social determinants of TB risk in Bangladesh, Nepal and Pakistan (51)*

## Contact

KIT Royal Tropical Institute/Health subunit (communication@kit.nl)

## MATCH - Case study

# TB case notification gaps – indications of under detection – MATCH in Bangladesh

### Background

In Bangladesh, the MATCH approach was implemented using district-level TB case notifications, socioeconomic data from the 2013 census and routine laboratory data. During a participatory data analysis workshop, the NTP and implementing partners – Bangladesh Rural Advancement Committee, International Center for Diarrheal Disease Research Bangladesh and Management Sciences for Health – collaboratively mapped and analysed these data using the MATCH framework.

### Findings

In the central-southern region (yellow highlighted districts, Fig. 3.16), TB case notification rates were considerably lower than the country average and notification rates of directly adjacent districts. Analysis and triangulation with other programme components showed that:

- test rates are low, but the proportion of bacteriologically confirmed patients among all notified cases is comparatively high;
- the positivity rate of tests performed is low; and
- the poverty rate in these areas is relatively high when compared with the country average.

#### Programmatic hypotheses

Based on these findings, the following hypotheses were developed:

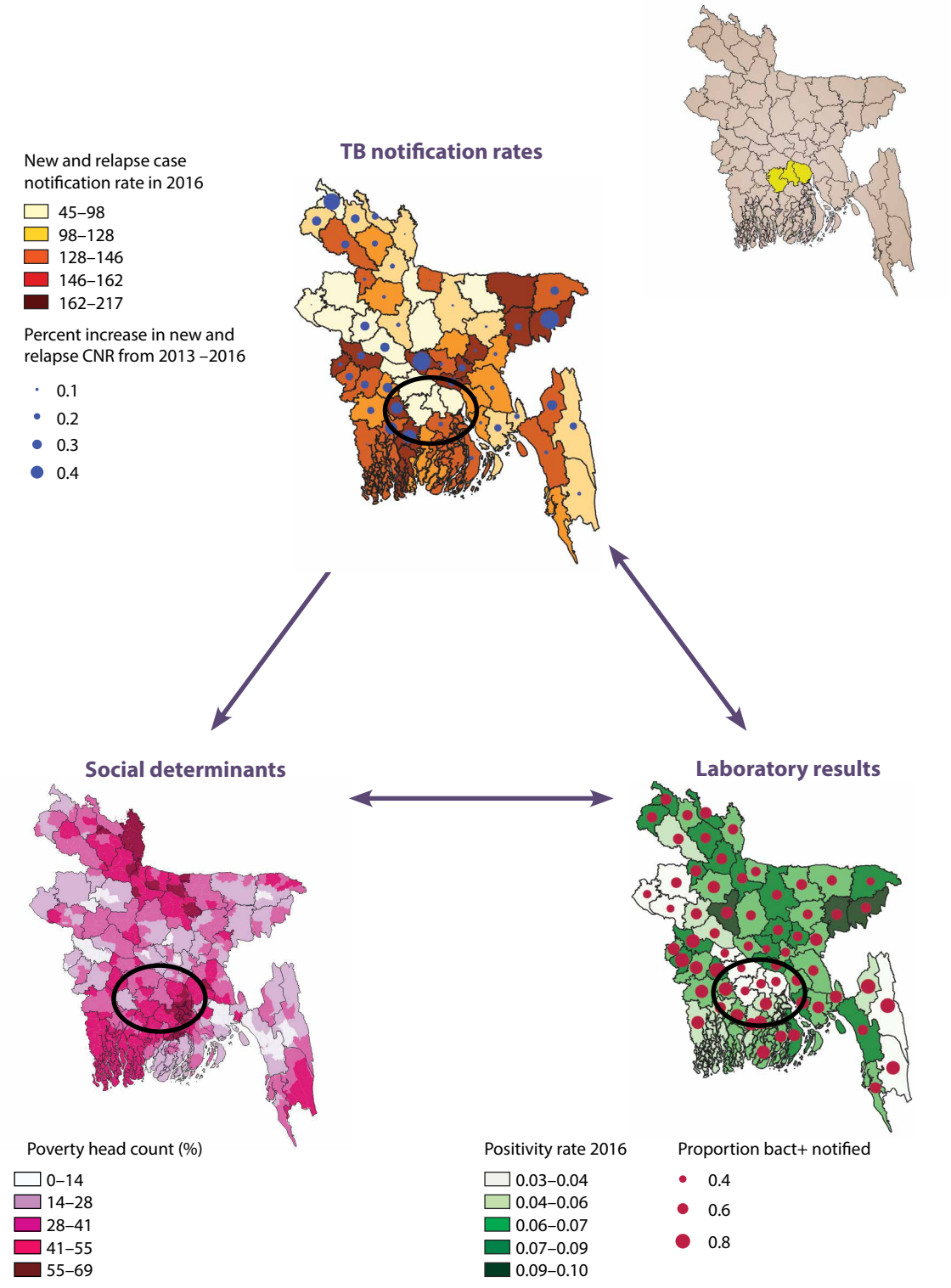
- the information on socioeconomic status and risk factors suggests that the actual burden in this area is not significantly lower than in the neighbouring districts;
- low test rates and low positivity rates suggest that many patients are not reaching quality diagnosis;
- low coverage of microscopic and GeneXpert facilities indicates poor coverage of diagnostic services; and

#### Potential interventions

After verification of these hypotheses, interventions that could be implemented in these areas include:

- increasing presumptive case finding through improved screening in facilities and community;
- improving coverage of Xpert testing for all presumptive cases; and
- conducting more supervisory visits to determine the root cause of lower notification rates over the years.

**Fig. 3.16. Geographical variations and spatial clustering of TB notification rates, social determinants and laboratory results in Bangladesh, 2016**




bact+: bacteriologically confirmed; CNR: case notification rate.
Data source: Bangladesh National TB Programme/KIT Royal Tropical Institute.

# 3.12 Patient pathway analysis

Tool type: Data analysis and visualization

## Description

Patient pathway analysis (PPA) aims to describe the steps people with TB take, from the initial point of seeking care to the point of being cured; it also reviews the availability of TB screening, diagnosis and treatment at various levels of the health system. By examining the alignment of care seeking with service availability, the PPA may reveal where people with TB could experience delay during care seeking or treatment initiation, access inappropriate care, or be lost to follow-up during their journey towards cure.

## Implementation

**COST**
US$ 0

**TIME**
1–5 weeks

**FREQUENCY**
Every 1–3 years

**IMPLEMENTING PARTNERS**
KNCV, Linksbridge

**FUNDING PARTNERS**
Global Fund

## Scenario for using the resources

You might want to conduct PPA if:

- the TB surveillance system is missing a significant share of the estimated TB burden, and the NTP is uncertain where these patients may be within the health system;
- the NTP is concerned about delays in access to TB care; and
- the NTP would like to differentiate TB service delivery across subnational areas to better align with differentiated care-seeking patterns.

You might not need to conduct this analysis if:

- the estimated proportion of missing people with TB in the country is low;
- areas of misalignment between patient care seeking and TB service availability are already well understood; and
- TB services reach people with TB across all regions or other subnational areas of the country, and there is thus no need for differentiated service delivery.

## Prerequisites

The main resources required to conduct this analysis are:

- care-seeking data (typically from population-based surveys);
- service availability data (typically from health facility surveys or a country TB database); and
- master facility list (see Section 3.16) or survey of health facilities, including those with and without TB services.

## Metrics to inform planning

What are the key metrics from PPA that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | Proportion of people with TB seeking care across sectors and levels of the health care system | Proportion of people with TB with access to diagnostic services on their first visit to a health facility | Proportion of people with TB with access to treatment services on their first visit to a health facility |
| ROOT CAUSE ANALYSIS | | TB diagnostic availability in different sectors and levels of the health care system | TB treatment availability in different sectors and levels of the health care system |
| INTERVENTION OPTIMIZATION | | | |

PPA: patient pathway analysis.

## Limitations

- If care-seeking data are not TB-specific, teams will need to assess the assumption that the data source serves as a reasonable proxy for TB care seeking.
- "Access" to services at initial care-seeking signals the presence of a diagnostic or treatment product at the location where a person with TB initiates care. This metric does not account for potential barriers to receiving services (e.g. health worker absenteeism, lack of health worker capacity or cost associated with services).
- Data sources may reflect different points in time.
- PPA reflects access to services at initial place of care seeking, but does not detail patient movement within the health system.

## More information and resources

The PPA website *(52)* contains:

- a detailed description of the methodology, how-to guide and video tutorials; and
- a link to a supplement to the Journal of Infectious Diseases that includes case studies demonstrating PPA use in country programming.

The PPA wizard website *(53)*:

- contains a detailed description of the methodology;
- is set up to allow teams to collaborate; and
- allows for quick revisions as new data are added.

## Contact

KNCV Tuberculosis Foundation (info@kncvtbc.org)

## Kenya PPA – 2016

### Background

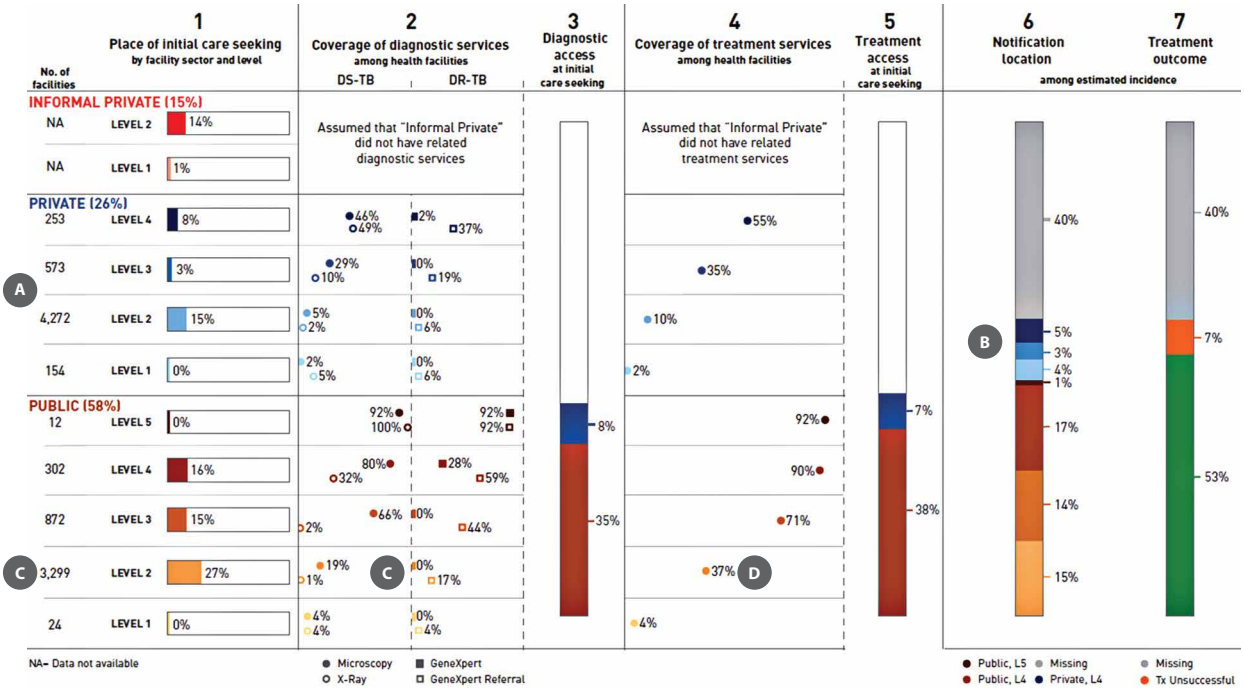
In Kenya, the PPA was conducted at three geographical levels: national level, urban/rural comparison and 47 counties. The PPA helped the NTP to target interventions to improve alignment of TB service delivery with patient care seeking; the aim was to efficiently identify patients that are lost within the health system.

### Data sources

PPAs use commonly available national surveys and data sources. In Kenya these sources included:

- Kenya Master Health Facility List (KMHFL);
- Kenya Household Health Expenditure and Utilization Survey (KHHEUS);
- Kenya Service Availability and Readiness Assessment Mapping (SARAM);
- Kenya NTLD databases on microscopy and GeneXpert capacity and patient treatment records; and
- Kenya DHS.

**Fig. 3.17. PPA output**




DR-TB: drug-resistant tuberculosis; DS-TB: drug-susceptible tuberculosis; L: level; PPA: patient pathway analysis.
Source: Masini et al., 2017 *(54)* (reproduced with permission).

### Interpreting results of PPA

A. Private sector facilities are important places of initial care seeking, with over 40% of patients preferring to start their care-seeking journey in private sector care (either formal or informal) (column 1, Fig. 3.17).

B. Despite significant care seeking in private sector facilities, only 12% of the estimated burden was notified from private sector facilities (column 6, Fig. 3.17), suggesting that there may be patients who seek care in the private sector who are not diagnosed, not put on treatment or not notified to the NTP.

C. In places where care seeking is highest (Level 2 facilities, column 1, Fig. 3.17), smear microscopy coverage remains low (column 2, Fig. 3.17), requiring sample transport or patient referral systems for patients to receive a diagnosis.

D. Treatment availability appears limited even at Level 2 facilities, with only 37% of facilities having treatment services available (column 4, Fig. 3.17). In Kenya, drugs are distributed to the locations where patients will be treated.

# 3.13 Private sector drug sales

Tool type: Data analysis

## Description

A survey of private TB drug sales provides an estimate of the volume of TB patients treated by private providers using non-NTP drugs. These surveys pull TB data from existing databases of all private drug sales in a country. Survey results can be used to advocate for more programming on private provider engagement, and to monitor such schemes (by comparing to the number of private patients reached by these schemes). Complementing these data on TB treatment volumes, other surveys (e.g. the treatment-seeking data in DHS and TB prevalence surveys, as summarized in PPAs) show the amount of initial care seeking to private providers.

## Implementation

**COST**
US$ 5000–40 000

**TIME**
1–6 months

**FREQUENCY**
Every 1–5 years

**IMPLEMENTING PARTNERS**
No specific partners

**FUNDING PARTNERS**
No specific funding sources

## Scenario for using the resources

You might implement this survey if:

- private providers are known or suspected to be significant providers of TB care in the country; and
- the country needs evidence to advocate for more work on private provider engagement, or needs to measure the progress of such efforts.

You might not need to implement this survey if:

- private TB drug sales are banned in your country, and you have evidence that the ban has eliminated private TB drug sales;
- other evidence indicates a minimal role for TB treatment by private providers in your country; and
- commercial suppliers of these sales data (e.g. IQVIA) do not have sufficiently robust data available for your country.

## Prerequisites

The main resources required to implement this survey are drug sales data at national and subnational levels (these data can be from any source, but are typically from IQVIA due to few or no other options being available at scale).

## Metrics to inform planning

What are the key metrics from a private sector drug sales survey that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| PROBLEM PRIORITIZATION | | Number of people with TB diagnosed and treated by the private sector but not notified | |
| ROOT CAUSE ANALYSIS | | Study of prescription patterns can provide limited information on the quality of prescriptions | |
| INTERVENTION OPTIMIZATION | | Of the TB patients who are treated by the private sector, the percentage who are not yet reached by private provider engagement schemes | |

## Limitations

- Data on drug sales is limited in many countries, especially at subnational levels.
- Estimates of duration of TB treatment and accuracy of TB diagnosis in the private sector may not be reliable.
- Several types of TB patients may be missing in the analysis (e.g. those who could be receiving treatment in the informal health care sector or those who have not contacted the health care system).

## More information and resources

*Size and usage patterns of private TB drug markets in the high burden countries (55)*

*The number of privately treated tuberculosis cases in India: an estimation from drug sales data (56)*

*Surveys of private TB drug sales: a short, practical guide (57)*

## Contact

USAID/Washington's TB team
IQVIA
(MIDAS-Solutions@iqvia.com)
STOP TB Partnership
(ta@stoptb.org)

# Private sector drug sales - Case study

## Using private sector drug sales analysis to understand private sector TB care

### Background

TB is typically conceptualized as a public sector issue and response; however, more than 56% of the 2.9 million "missing" people with TB are in the six countries in which private providers contributed 29% of notifications in 2019 (equivalent to 20% of estimated incidence) *(58)*. In these six countries in 2016, private for-profit providers contributed just 18% of total TB notifications, equivalent to only 9% of estimated TB incidence *(58)*.

These private providers may refer patients with TB symptoms, or may diagnose and treat TB themselves. To differentiate between these two scenarios, a study published in 2011 *(55)* used commercial TB drug sales data from IMS Health (now IQVIA Institute for Human Data Science) to outline the TB drug sales volumes in 10 high burden countries. This study also established a method for converting these sales volumes into an estimated patient volume (with uncertainty around the true patient volume, since the length of actual regimens prescribed are not known).

The study established, for example, that the numerous private providers in Bangladesh relied more heavily on referral to the public sector. In contrast, in India, Indonesia, Pakistan and the Philippines, large numbers of private providers retained patients and treated them with non-NTP drugs. Thus, large numbers of TB patients in these four countries were being diagnosed but not notified, and were not reached by any monitoring, adherence or quality improvement efforts. The clear implication (i.e. that TB, a public sector disease, is widely treated by the private sector) resulted in the study being picked up by many international news outlets; in turn, this fed into national-level conversations about why work with private providers was being neglected. Two years later, a similar study in the Philippines *(59)* repeated this finding at a single country level.

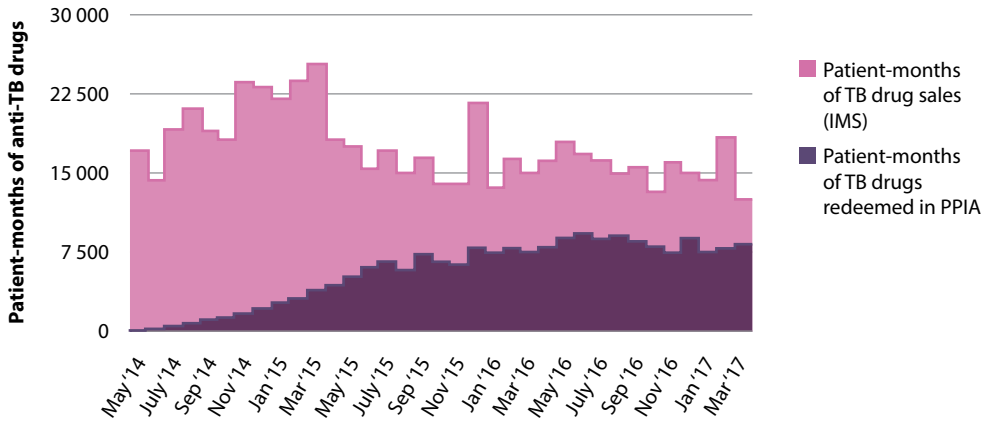
### India's experience

As the country with the highest TB burden in the world and a thriving private health sector, India has been an obvious priority for private provider engagement work in TB. India's National TB Elimination Programme and its partners embarked on an effort to use technology to reach the numerous private providers in a more systematic way. To determine a baseline for this engagement work, teams used IMS Health data (as in the earlier study), but calculated private TB drug and patient volumes down to the state level. This allowed the prioritization of states with a higher ratio of private to public sector TB drugs, and establishment of state-level targets for engagement. Publication of the sales data in a 2016 article *(56)* again led to widespread press coverage, this time focused on country-specific advocacy. Importantly, ongoing monitoring of these figures allowed for tracking of the effective intervention coverage of the private provider engagement effort (Fig. 3.18), establishing this method as not just a one-off study but as an ongoing method of monitoring.

### Scope for future expansion

There is potential for TB drug sales data to constitute an integral element of an NTP's ongoing surveillance information. Discussions are currently ongoing to establish the data reliability at different health system levels in high burden countries, and to standardize data agreements, costing, and the existing methodologies for TB data extraction and patient volume estimations. A short practical guide provides details of surveys of private TB drug sales *(57)*.

## Fig. 3.18. Universal access to TB care patient coverage against pharmacy surveillance of anti-TB treatment sales




| PPIA Patna, patient coverage (March 2017) | |
|---|---|
| Patient-months of anti-TB drug sales | 12 568 |
| Patient-months of PPIA e-vouchers validated | 8 323 |
| % Patient coverage in PPIA | 66% |

IMS: institute for healthcare informatics; PPIA: public–private interface agency.

# 3.14 ScreenTB

Tool type: Data analysis

## Description

ScreenTB is a web-based tool to assist TB programme managers and implementation partners designing TB screening programmes. It enables comparisons of different TB screening methods that could be applied in a given country, or that could be applied to different risk groups at the national or subnational levels. The tool also includes graphics to illustrate the risk of false positive diagnoses for screening; these graphics are specific to the risk of TB in the group being screened and the accuracy of the screening algorithm being used. ScreenTB also enables programme managers to assess the expected cost and effectiveness of potential approaches, and their risks and benefits.

## Implementation

**COST**[1]
Varies

**TIME**[2]
Varies

**FREQUENCY**
As needed

**IMPLEMENTING PARTNERS**
WHO, KNCV

**FUNDING PARTNERS**
N/A

## Scenario for using the resources

You might implement this tool if the NTP:

- is reviewing TB screening policies;
- would like to prioritize different target populations by comparing potential yield and cost–effectiveness; and
- would like to optimize screening algorithms by comparing cost, yield and cost per case detected.

You might not need to implement this tool if:

- the NTP already has data on the estimated yield and costs of screening across different risk groups, and the performance of screening algorithms in those risk groups;
- most people with TB in the country are detected and successfully treated with routine health services and current screening methods, and the cost is acceptable.

## Prerequisites

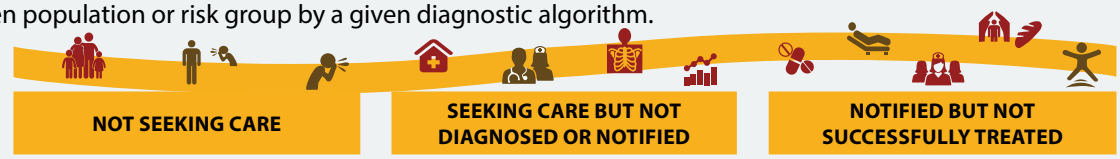
The main resources required to implement this tool are information on:

- population size and estimated TB prevalence of the general population;
- TB prevalence in selected risk groups (relative risk), and personnel with a good understanding of diagnostic test accuracy and related epidemiology, to properly interpret the result;
- size of selected risk groups;
- reachability and acceptability of screening; and
- costs of screening and diagnostic tests.

[1] No operational cost is needed but fees for experts may be required.
[2] Depending on complexity and extensiveness of analysis needed.

## Metrics to inform planning

What are the key metrics from ScreenTB that can inform planning for priority gaps along a patient's pathway to care? The following is for a given population or risk group by a given diagnostic algorithm.




**PROBLEM PRIORITIZATION**

**ROOT CAUSE ANALYSIS**

**INTERVENTION OPTIMIZATION**

| |
|---|
| Number of true positive TB cases detected |
| Number of cases missed |
| Number of false positive diagnoses expected (overdiagnosis) |
| Number needed to screen |
| Total cost of screening |
| Cost per case detected |

## Limitations

- ScreenTB defines a TB case as bacteriologically confirmed pulmonary TB, in line with the data sources for the diagnostic performance (sensitivity and specificity), but does not take into account extrapulmonary TB or clinical diagnosis.
- In the absence of country-specific relative risks of developing TB among different risk groups, relative risks from systematic reviews or other studies are used. This may lead to underestimation or overestimation of the potential yield of screening in any of the risk groups modelled through the tool.
- ScreenTB does not account for overlap between risk groups.
- ScreenTB has not been comprehensively evaluated.

## More information and resources

*WHO consolidated guidelines on tuberculosis. Module 2: screening – systematic screening for tuberculosis disease (60)*

*ScreenTB – target prioritization and strategy selection for tuberculosis screening (active case finding) (61)*

*ScreenTB: a tool for prioritising risk groups and selecting algorithms for screening for active tuberculosis (62)*

*Determining the local calibration of computer-aided detection (CAD) thresholds and other parameters: a toolkit to support the effective use of CAD software for pulmonary TB detection (63)*

## Contact

WHO Global TB Programme
(gtbprogramme@who.int)

## ScreenTB - Case study

# National workshop approach to determine strategies to address TB among key populations

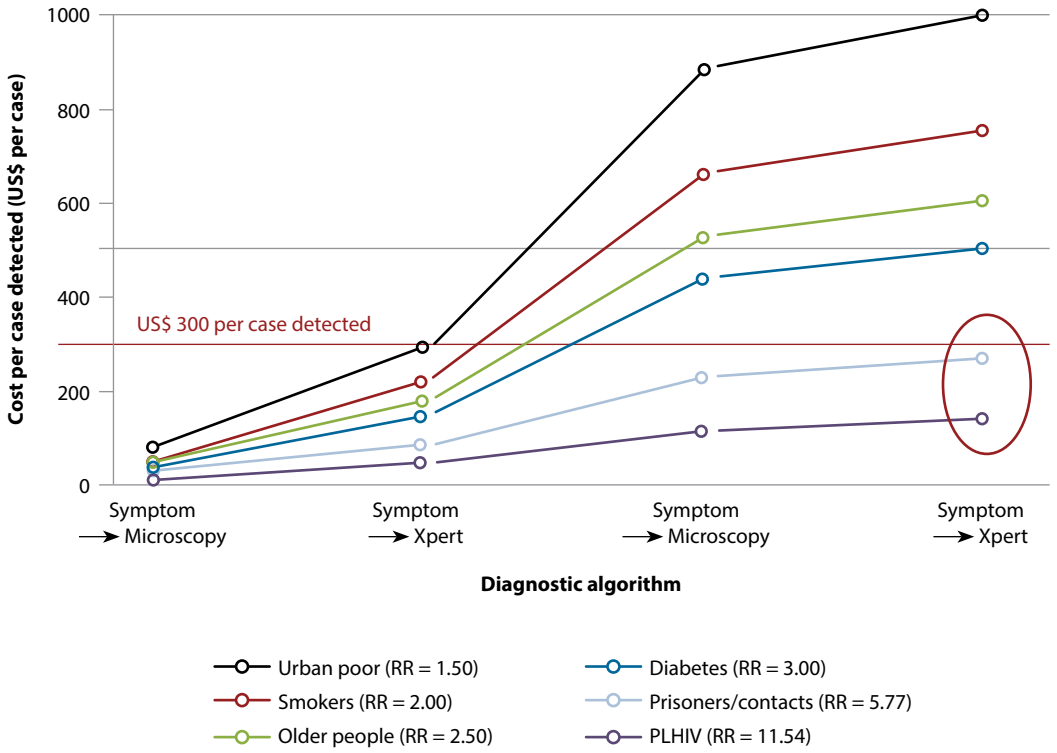
### Background

ScreenTB has been used to assist country-level priority setting and strategic discussion within the overall national policy formulation for TB key populations. Although TB screening can provide opportunities to improve access to care, especially for early diagnosis and treatment, it should not be used as an isolated strategy to organize TB services among key populations. Moreover, profiles of priority key populations vary by country and locality. Comprehensive discussions on TB among key populations are preferable to simply discussing TB screening. Organizing national workshops with NTPs and national and international stakeholders can facilitate comprehensive discussions to formulate strategies and policies for TB key populations.

In Cambodia, a national workshop on key populations was organized. The aims were to review in-country evidence on the TB burden among key populations, and discuss potential areas of collaboration among government and nongovernmental partners for improved access to TB services for key populations. A wide range of health and non-health partners discussed the TB epidemic among seven key populations: TB contacts, people living with HIV, urban poor, prisoners, people with diabetes, smokers and older people. Participants discussed needs and characteristics of the key populations, including TB risk, population size, level of health access and any issues specific to treatment support. The workshop identified three activities as priority initiatives: community-based screening targeting TB contacts, organized by the NTP; TB screening services provided to migrants who are repatriated from a neighbouring country in collaboration with the NTP and immigration authority; and community-based TB screening in urban deprived communities, conducted by an implementing partner. The workshop also recognized the need for a standardized, comprehensive approach to enhance TB activities in prisons, and all partners (NTP, prison authorities and NGOs) agreed on further steps towards addressing that gap.

Fig. 3.19 represents the estimated cost per case detected by different screening algorithms for various target populations. Based on this analysis, recommendations were made to employ extensive screening strategy using X-ray and GeneXpert for community-based contact screening and screening for prisoners; carefully consider screening algorithms for the urban poor; and deprioritize other risk populations (e.g. smokers, people with diabetes and older people).

## Fig. 3.19. Estimated cost per case detected by diagnostic algorithm and by risk group[a]




PLHIV: people living with human immunodeficiency virus; RR: relative risk.

[a] All assumptions were defined during the national workshop. The benchmark of US$ 300 per case detected was applied to prioritize cost-effective targets and algorithms during the workshop.

# 3.15 Standards and benchmarks assessment

Tool type: Data analysis

## Description

A standards and benchmarks assessment evaluates the ability of the TB surveillance system to directly measure TB incidence and mortality. The assessment is carried out using a standardized "checklist" comprising 13 standards and associated benchmarks, to assess data quality, systems coverage, TB mortality, and surveillance of TB/HIV, DR-TB and TB in children. There is also a descriptive section comprising 18 questions on TB surveillance and M&E (which involves carrying out a desk review of documents and conducting interviews with staff). The results of the assessment allow the NTP to identify activities required to strengthen M&E and develop an associated investment plan.

## Implementation

**COST**
US$ 15 000–30 000

**TIME**
1–2 weeks

**FREQUENCY**
3–5 years

**IMPLEMENTING PARTNERS**
WHO, WHO roster of experts, KNCV, US CDC

**FUNDING PARTNERS**
USAID, Global Fund, local government

## Scenario for using the resources

You might conduct this assessment if the NTP:

- has recently made large changes to the TB surveillance system (e.g. introducing an electronic surveillance system), and would like to assess the impact on data quality and coverage;
- recognizes that there is a need to make changes to the TB surveillance system or M&E processes (or both), but requires technical or financial support for implementing key activities;
- would like to assess whether it is possible to implement an inventory study using existing data sources; and
- would like to provide donors, stakeholders and research reviewers with evidence that TB surveillance data are accurate and that analysis can be trusted.

You might not need to conduct this assessment if the NTP:

- has carried out a standards and benchmarks assessment in the past 5 years and has not made any major changes to TB surveillance since that assessment.

## Prerequisites

The main resources required to conduct this assessment are:

- prior training and expertise in carrying out a standards and benchmarks assessment; and
- availability of the M&E/surveillance/strategic information team within the NTP to be fully engaged in the process.

## Metrics to inform planning

What are the key metrics from a standards and benchmarks assessment that can inform planning for priority gaps along a patient's pathway to care?

| | NOT SEEKING CARE | SEEKING CARE BUT NOT DIAGNOSED OR NOTIFIED | NOTIFIED BUT NOT SUCCESSFULLY TREATED |
|---|---|---|---|
| **PROBLEM PRIORITIZATION** | Proxy indicators for access to care | Estimated magnitude of potential underreporting<br>Coverage of the TB surveillance system for all cases<br>Capacity of the vital registration system to capture TB deaths<br>Capacity and quality of the surveillance system to accurately record and report notifications and treatment outcomes | |
| **ROOT CAUSE ANALYSIS** | Barriers to seeking health care | Barriers to efficient TB surveillance<br>Factors associated with underreporting and poor system coverage<br>Challenges for establishing a robust vital registration system | Identification of challenges to successful treatment outcomes |
| **INTERVENTION OPTIMIZATION** | Programmatic recommendations to address barriers and improve treatment coverage through targeted response (e.g. geography and populations) | Recommendations for strengthening surveillance of TB cases by addressing M&E bottlenecks and by strengthening case notification (e.g. through improvements to recording and reporting) | |

M&E: monitoring and evaluation.

## Limitations

- Each benchmark that is used in the assessment comes with a particular limitation; these limitations are discussed in the user guide.

## More information and resources

*Standards and benchmarks for tuberculosis surveillance and vital registration systems: checklist and user guide (64)* (a French translation of this document is available on request)

## Contact

WHO Global TB Programme (gtbprogramme@who.int)

## Strengthening TB surveillance through implementation of the WHO standards and benchmarks checklist and associated M&E investment plan in Indonesia

### Background

The Indonesian TB surveillance system has been assessed through the WHO standards and benchmarks checklist three times: in 2013, 2017 and 2019. Each assessment resulted in a set of recommendations to address identified gaps and weaknesses. Investment and implementation of these recommendations have led to overall improvements in the country's surveillance system, as demonstrated by the results of the repeat assessments (Table 3.5). Major recommendations that have been implemented since the first review include transitioning from a paper-based system to an electronic system, implementing a unique identification (ID), carrying out an inventory study to measure the levels of underreporting and conducting an anti-TB drug-resistance survey to provide a direct measure of DR-TB in new cases. Key recommendations related to the 2019 assessment are shown with a checkmark (tick) in Table 3.6.

The 2019 assessment was carried out as part of an epidemiological review to inform the development of a new NSP. This assessment demonstrated continued progress in improving the country's surveillance system. Of the 13 standards, four were met, three were partially met, five were not met and one was not applicable (Table 3.5, 2019 column).

Since the 2017 assessments, three standards have improved:

- B1.3, through improved timeliness and completeness of reports as well as significant efforts in addressing underreporting;
- B1.8, through implementation of mandatory notification; and
- B2.1, through implementation of a drug-resistance survey in 2017–2018.

Childhood TB surveillance (B2.3) has appeared to weaken; however, the 2017 assessment was based on aggregate data, whereas the 2019 assessment was based on case-based data from the country's upgraded system (SITT). The standard was reassessed retrospectively using case-based data from SITT, showing that it would not have been met in 2017 if the assessment had been made using the same data source as in 2019. This finding showed that the downgrading of B2.3 does not necessarily reflect a worsening of programme performance, but rather an issue in using inconsistent data sources. Additionally, between 2017 and 2019, Indonesia has made progress in its electronic recording and reporting (eRR) system, known as SITB. The new eRR merges Indonesia's SITT (system for DS-TB) and eTB Manager (eRR for DR-TB) into one comprehensive system, and was being piloted when the 2019 assessment was conducted.

### Interpretation of standards and benchmarks assessments

Summarizing progress based on whether standards were met in a repeat assessment is simple but does not provide the full picture – this approach can conceal important progress that is being made. Clearly, if a recommendation is not implemented, or is only partially implemented, then there is no improvement. However, the implementation of recommendations does not necessarily lead to an immediate improvement or to a standard being met, because some standards (e.g. vital registration and universal access to health care) are not within the remit of an NTP. These standards also require a longer term implementation plan over several years, as was the case for the expansion of health insurance in Indonesia, and the development or strengthening of civil registration and vital statistics.

Some standards under the direct control of the TB programme at the national level have shown clear improvement when recommendations are implemented. Good examples are recommendations related to recording and reporting, DR-TB, childhood TB and mandatory notification. These standards are linked to normative guidance that outlines clear activities that can be easily identified, funded and implemented within a relatively short time period (e.g. drug-resistance surveillance, an inventory study, updating of recording and reporting tools, and a ministerial decree for TB notification).

Standards that are within the control of the NTP but involve all levels of the programme are more difficult to tackle and take longer. Examples include standards related to improving data quality and the coverage of TB/HIV testing. To strengthen these standards, multiple activities are required, including the development of guidance and processes, training, routine monitoring and supervision, and hiring staff with the appropriate skills to deliver the work.

**Table 3.5. Monitoring progress with strengthening surveillance in Indonesia through implementation of recommendations from repeat standards and benchmarks assessments**

| Themes | Standards | 2013 | 2017 | 2019 |
|---|---|---|---|---|
| Recording and reporting | B1.1 Case definitions are consistent with WHO guidelines | | | |
| | B1.2 TB surveillance system is designed to capture a minimum set of variables for reported TB cases | | | |
| | B1.3 All scheduled periodic data submissions have been received and processed at the national level | | | |
| Data quality | B1.4 Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent (for paper-based systems only) | | | |
| | B1.5 Data in the national database are accurate, complete, internally consistent and free of duplicates (for electronic case-based or patient-based systems only) | | | |
| | B1.6 TB surveillance data are externally consistent | | | |
| | B1.7 Number of reported TB cases is internally consistent | | | |
| Mandatory notification | B1.8 All diagnosed cases of TB are reported | | | |
| Access to health care | B1.9 Population has good access to health care[a] | | | |
| Vital registration | B1.10 Vital registration system has high national coverage and quality[a] | | | |
| Drug resistance | B2.1 Surveillance data provide a direct measure of DR-TB in new cases | | | |
| TB/HIV | B2.2 Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases | | | |
| Childhood TB | B2.3 Surveillance data for children reported with TB (defined as ages 0–14 years) are reliable and accurate AND all diagnosed childhood TB cases are reported | | | |

**Key:**
= Met
= Partially met
= Not met
= Not applicable

DR-TB: drug-resistant tuberculosis; HIV: human immunodeficiency virus; NTP: national tuberculosis programme; WHO: World Health Organization.

[a] Out of the direct sphere of control of the NTP.

## Table 3.6. Key recommendation areas from the 2019 assessment in Indonesia[a]

| | |
|---|---|
| **Recommendations related to standards and benchmarks assessment** | |
| √ | Increase human resources capacity for surveillance and M&E |
| √ | Develop or review SOPs or tools for data quality and validity |
| | Training of staff on recording and reporting to improve data quality |
| √ | Strengthen routine supervision for data quality checks or hold validation workshops |
| | TB module of service availability and readiness assessment for data validity and completeness |
| √ | Transition towards and strengthen a case-based electronic platform |
| | Measure the level of underreporting with inventory study |
| | Make TB notification a legal requirement |
| √ | Improve reporting from the public and private sectors |
| √ | Ensure that all people diagnosed with TB are notified (e.g. initial default, DR-TB, death before starting treatment) |
| √ | Improve diagnostic capacity (e.g. TB in universal health coverage package, improve health facility network) |
| √ | Improve availability and quality of TB mortality data (e.g. civil registration and vital statistics, and use of specific ICD codes) |
| √ | Improve diagnosis and reporting of childhood TB |
| | Implement a drug-resistance survey to estimate the burden of DR-TB in new cases |
| √ | Improve TB/HIV services, and recording and reporting |
| **Recommendations related to transitioning towards case-based electronic surveillance** | |
| √ | Review existing paper recording and reporting tools |
| | Transition from paper to an aggregate electronic platform |
| | Transition to an electronic case-based system (DR-TB only) |
| √ | Transition to an electronic case-based system (all cases) |
| √ | Review the existing electronic platform |
| **Supplementary recommendations from epidemiological review** | |
| √ | Strengthen data analysis and use for decision-making |
| √ | Strengthen OR/IR |
| | Undertake a prevalence survey |
| | Undertake PPA |
| | Undertake a patient cost survey |
| | Review existing data (e.g. fill data gaps, data validation) |
| | Safeguard data at tbhistoric.org |
| | Implement a unique ID |
| | Implement ACF and ICF activities |

ACF: active case finding; DR-TB: drug-resistant tuberculosis; HIV: human immunodeficiency virus; ICD: International Classification of Diseases; ICF: intensified case finding; ID: identification; M&E: monitoring and evaluation; OR/IR: operational research and implementation research; PPA: patient pathway analysis; SOP: standard operating procedure.

[a] This is a standardized table to track high-level recommendations from epidemiological review and standards and benchmarks assessment. A tick denotes that the high-level recommendations has been made for the country based on the review and assessment.

# 3.16 Mini-profiles

| Tool's name | Description and resources | Scenario for using the tools |
|---|---|---|
| **Primary data collection** | | |
| Laboratory information management system (LIMS) | LIMS is software that enables the laboratory to automate workflows, integrate instruments, and manage samples and associated information. It facilitates easy record-keeping and reporting, promoting the provision of accurate and timely information for patient care, public health planning and policy decisions.<br><br>More information and resources:<br>*Informatics self-assessment tool for public health laboratories (65)*<br><br>WHO webpage on LIMS *(66)* | You might implement this tool if:<br>• the (public health) laboratories do not have an (electronic) information management system to facilitate linkages between laboratories and linkages with the disease surveillance system.<br><br>You may not need to implement this tool if:<br>• the overall health system is operating with a low budget (LIMS is often expensive); or<br>• the country already has a high-functioning LIMS. |
| Service availability and readiness assessment (SARA) | SARA is a health facility assessment designed to assess and monitor the service availability and readiness of the health sector to provide basic health care interventions relating to family planning, child health services, basic and comprehensive obstetric care, HIV/AIDS, TB, malaria and noncommunicable diseases.<br><br>More information and resources:<br>WHO webpage on SARA *(67)*<br><br>*SARA reference manual, version 2.2 (68)* | You might implement this tool if the country would like to:<br>• detect change and measure progress in health;<br>• generate the evidence base to feed into country annual health reviews; and<br>• provide information to support national planners in planning and managing health systems.<br><br>You may not need to implement this tool if:<br>• another type of national-level assessment has been conducted (or routine data are available) to address similar objectives. |
| Master facility list (MFL) | MFL is a complete, up-to-date, authoritative listing of the health facilities in a particular country that must be validated, continuously updated and accessible. The MFL includes the data needed to accurately identify each facility (e.g. facility name, unique facility identifier, location and contact information) and administrative data to categorize the facility (e.g. facility type, ownership and operational status).<br><br>More information and resources:<br>*Master facility list (MFL) resource package: guidance for countries wanting to strengthen their MFL (69)* | You might implement this tool if:<br>• the country would like to have a comprehensive list of health facilities for greater efficiency, facilitate exchange of health information, and support monitoring of infrastructure and services across the health system.<br><br>You may not need to implement this tool if:<br>• the country already has an up-to-date national comprehensive health facility registry that contains all types of health facilities (public and private, licensed and unlicensed). |
| Demographic and health surveys (DHS) | DHS are nationally representative household surveys that provide data for a wide range of monitoring and impact evaluation indicators in the areas of population, health and nutrition. They include data on household characteristics, nutritional status, reproductive behaviour and intentions, contraception, health-seeking behaviour, infant and child mortality, and other health issues (e.g. TB, HIV/AIDS, malaria and use of tobacco). DHS have a particular focus on infants, children and women.<br><br>More information and resources:<br>DHS Program website *(70)* | You might implement this tool if the country:<br>• would like to know the child and infant mortality in the absence of reliable vital registrations systems; and<br>• requires nationally representative data that would not be covered by vital registration or in-depth censuses (e.g. fertility intentions and contraceptive practices), to monitor and design programmes and strategies (e.g. to improve maternal and child health and family planning).<br><br>You may not need to implement this tool if:<br>• another type of national-level study has been conducted (or routine data are available) to address similar objectives. |
| **Tool's name** | **Description and resources** | **Scenario for using the tools** |
| Quality of care (mystery shopper studies) | Trained individuals visit individual medical providers and use a standard script to report TB symptoms or test results. They then report back on the action suggested by the medical provider, and this is checked against the recommended action for such a patient.<br><br>More information and resources:<br>QuTUB website *(71)* | You might implement this tool if:<br>• the country would like to know the quality of care and missed opportunities for diagnosis and correct treatment in public or private sectors (or both);<br>• prevalence surveys have highlighted missed opportunities to diagnose TB, with large numbers of patients seeking care but not being diagnosed, and the country would like to understand and correct these issues; and<br>• provider training has been completed, and the training team wants to know whether the increased knowledge has translated into improved practices.<br><br>You may not need to implement this tool if:<br>• the quality of TB care is already known. |

**Table Continue**

| | | |
|---|---|---|
| Patient journey studies | A group of existing TB patients are asked about each stop they made with different providers, before their eventual diagnosis. Ideally, patients are also asked about the time and cost associated with each consultation.<br><br>More information and resources:<br>• *How did the TB patients reach DOTS services in Delhi? A study of patient treatment seeking behavior (72)*<br>• *Transaction costs of access to health care: Implications of the care-seeking pathways of tuberculosis patients for health system governance in Nigeria (73)*<br>• *Pathway to care for drug resistant tuberculosis cases identified during a retrospective study conducted in high TB burden wards in Mumbai (74)*<br>• *Pulmonary tuberculosis in Patna, India: durations, delays, and health care seeking behaviour among patients identified through household surveys (75)*<br>• *Durations and delays in care seeking, diagnosis and treatment initiation in uncomplicated pulmonary tuberculosis patients in Mumbai, India (76)* | You might implement this tool if:<br>• the country wants to reduce patient diagnostic delays and costs by understanding and correcting the complex pathways that patients take to a final TB diagnosis, with an emphasis on the private provider contributions; and<br>• projects or countries would like to establish a baseline for client and provider behaviour, and generate ideas about which steps can be built upon, eliminated or streamlined via private provider engagement interventions.<br><br>You may not need to implement this tool if:<br>• previous studies have established that patient delay is not a concern; or<br>• patient cost studies have already collected these data (although some prediagnostic data from patient cost surveys have been problematic, because they are gathered in the context of a longer and time-consuming interview). |
| **Data analysis** | | |
| Cost–effectiveness analysis (CEA) | CEA estimates the costs and health gains of alternative interventions. It is used to inform health sector resource allocation decisions across interventions.<br><br>More information and resources:<br>*Making choices in health: WHO guide to cost–effectiveness analysis (77)*<br><br>WHO-CHOICE webpage *(78)* | You might implement this tool if the country would like to:<br>• prioritize health interventions under constraint (resources, ethical or political) through better use of evidence and transparent processes;<br>• assess which spending produces the most health outcomes or improves efficiency; and<br>• understand how much an intervention may cost (per unit of health gained) compared with an alternative intervention.<br><br>You may not need to implement this tool if:<br>• N/A |
| Health insurance claims analysis | The comparison of TB notifications with TB insurance claims makes it possible to use routine data to estimate the treated but not notified population, and identify the facility types with the highest level of un-notified TB treatment. Insurance claims data may also allow quantification of referral patterns. | You might implement this tool if:<br>• the country has one or more large health insurance schemes that collect data on TB.<br><br>You may not need to implement this tool if:<br>• the country has no large health insurance schemes, or the existing schemes do not collect any claims data on TB; or<br>• TB insurance claims are always accompanied by (or otherwise linked to) notification. |

AIDS: acquired immunodeficiency syndrome; HIV: human immunodeficiency virus; N/A: not applicable; WHO: World Health Organization.

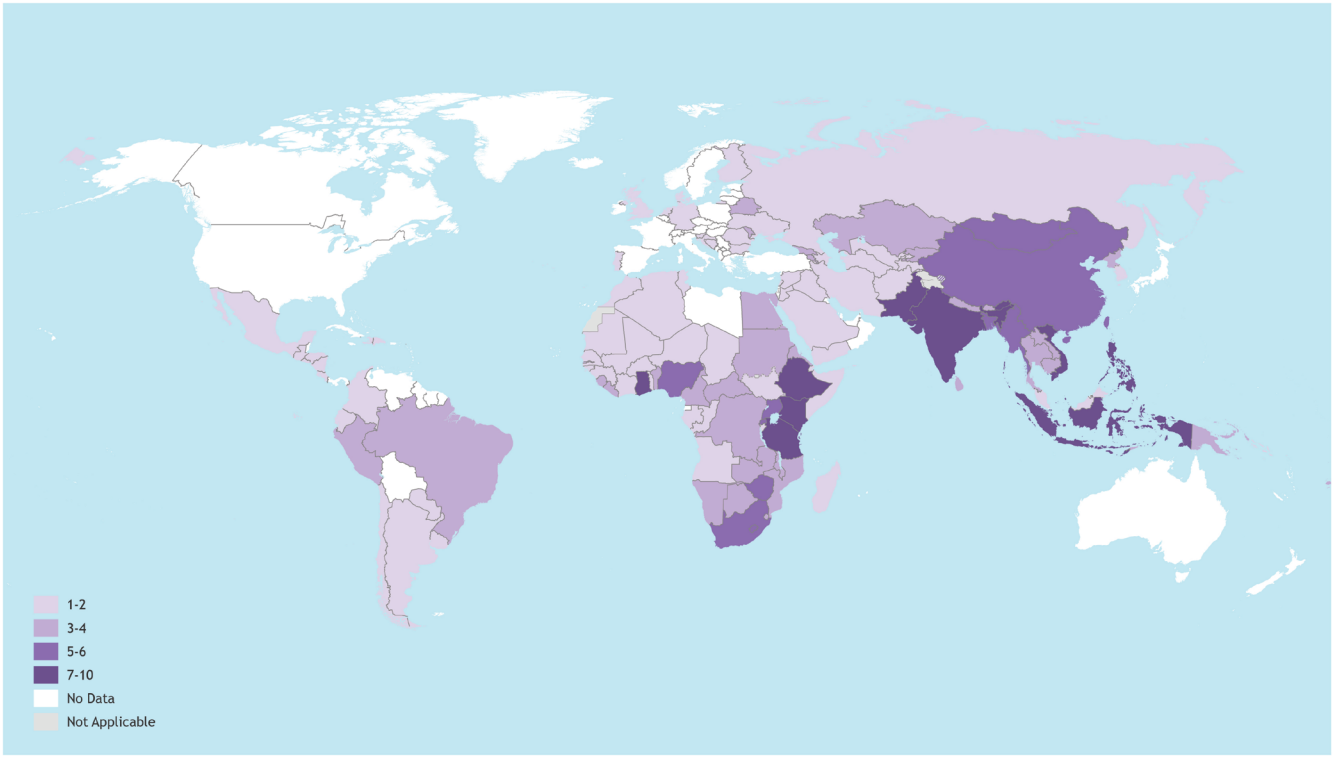
CHAPTER 4

# Country implementation

# 4. Country implementation

This section summarizes the implementation of various tools for TB planning and programming at country level. Fig. 4.1 shows the number of tools in use in various regions, while Table 4.1 provides information on the use of tools in 30 high TB burden countries.

**Fig. 4.1. Number of data and evidence-related tools implemented at country level (as of August 2020)**




The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

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## Table 4.1. Tool implementation tracking in 30 high TB burden countries (from 2000 to August 2020)

| Countries | DRS | IS | PCS | TBPS | CCA | DNO | EM | MATCH | PPA | P-Rx | SB | CS | OHT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Angola | | | | | | | | | | | 2016<br>2019 | | |
| Bangladesh | 2011<br>2019 | | | 2008<br>2015 | | | 2016<br>2019 | 2017 | | 2011 | 2014<br>2019 | | |
| Brazil | | | | | | | 2018 | | | | 2018 | | |
| Central African Republic | 2009 | | | | | 2020 | | | | | 2019 | | |
| China | 2007<br>2013 | 2018 | 2016 | 2000<br>2010 | | | 2015 | | | 2011 | | | |
| Congo | | | | | | | | | | | 2019 | | |
| Democratic People's Republic of Korea | 2014 | | | 2016 | | | | | | | 2017 | | |
| Democratic Republic of the Congo | 2017 | | 2019 | | | | | 2019 | | | 2017<br>2019 | | |
| Ethiopia | 2005,<br>2018 | | | 2011 | | | 2019 | | 2017 | | 2013,<br>2016 | 2019 | 2015, 2020 |
| Gabon | | | | | | | | | | | | | 2018 |
| India | 2016 | 2016 | | 2020 | 2016 | 2019 | 2019 | | | 2011<br>2016 | 2019 | 2019 | |
| Indonesia | 2018 | 2017 | | 2004<br>2014 | | | 2017<br>2019 | | 2017 | 2011 | 2013<br>2017<br>2019 | | |
| Kenya | 2014 | 2013 | 2017 | 2015 | | 2019 | 2019 | 2019 | 2017 | | 2013<br>2017 | 2019 | |
| Lesotho | 2014 | | 2019 | 2019 | | 2017 | 2015 | | | | 2014<br>2017 | | |
| Liberia | | | | | | | 2018 | | | | 2015<br>2019 | | 2017 |
| Mongolia | 2007,<br>2006 | | 2017 | 2015 | | | 2019 | | | | 2015,<br>2018 | | |
| Mozambique | 2007 | | | 2017 | | | 2019 | | | | 2013 | | |
| Myanmar | 2003<br>2008<br>2013 | | 2015 | 2009<br>2017 | | | 2019 | | | | 2014<br>2017 | | |
| Namibia | 2008<br>2015 | | | 2017 | | | | | | | 2016<br>2019 | | |
| Nigeria | 2010 | 2015 | 2017 | 2012 | | | 2017<br>2019 | | | | 2013<br>2017<br>2020 | | |
| Pakistan | 2013 | 2012<br>2017 | | 2011 | | | 2017<br>2019 | 2017<br>2018<br>2019 | 2017 | 2011<br>2020 | 2013<br>2016<br>2019 | | |
| Papua New Guinea | 2014 | | 2019 | | | | 2018<br>2019<br>2020 | | | | 2017 | | |

CCA: care cascade analysis; CS: TB service delivery costing study; DNO: diagnostic network optimization; DRS: drug-resistance survey; EM: epidemiological modelling; IS: inventory study; MATCH: mapping and analysis for tailored disease control and health system strengthening; OHT: OneHealth tool; PCS: patient cost survey; PPA: patient pathway analysis; P-Rx: private sector drugs sales analysis; SB: standards and benchmarks; TBPS: TB prevalence survey.

**Table 4.1. Continue**

| Countries | DRS | IS | PCS | TBPS | CCA | DNO | EM | MATCH | PPA | P-Rx | SB | CS | OHT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Philippines | 2004<br>2012<br>2019 | | 2017 | 2007<br>2016 | | 2019 | 2016<br>2018 | | 2017 | 2011<br>2013 | 2013<br>2016<br>2019 | 2019 | |
| Sierra Leone | | | | | | | 2016 | | | | 2015<br>2020 | | 2018 |
| South Africa | 2002<br>2014 | | | 2017 | 2019 | | 2015<br>2016<br>2017<br>2020 | | | 2011 | 2015<br>2019 | | |
| Thailand | 2001<br>2006<br>2012<br>2018 | | | 2006<br>2012 | | | | | | 2011 | 2013 | | |
| Uganda | 2011 | | 2018 | 2015 | | | 2020 | | 2019 | | 2013,<br>2019 | | |
| United Republic of Tanzania | 2007<br>2018 | | 2019 | 2012 | | | 2014<br>2020 | 2019<br>2020 | 2019 | | 2013<br>2018 | | |
| Viet Nam | 2006<br>2012 | 2017 | 2016 | 2007<br>2017 | | | 2014<br>2017<br>2019 | | | 2011 | 2013<br>2019 | | |
| Zambia | 2000<br>2008 | | | 2014 | | | 2016<br>2019 | | | | 2014<br>2016<br>2020 | | |

CCA: care cascade analysis; CS: TB service delivery costing study; DNO: diagnostic network optimization; DRS: drug-resistance survey; EM: epidemiological modelling; IS: inventory study; MATCH: mapping and analysis for tailored disease control and health system strengthening; OHT: OneHealth tool; PCS: patient cost survey; PPA: patient pathway analysis; P-Rx: private sector drugs sales analysis; SB: standards and benchmarks; TBPS: TB prevalence survey.

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# Annex

# Overview of the people-centred framework for TB programme planning and prioritization

The people-centred framework *(4)* has been developed to facilitate a systematic approach to country-led, data-driven and people-centred planning and prioritization for tuberculosis (TB). It provides a structure for organizing data for discussion and decision-making in a national TB programme (NTP). The framework has three main elements: it uses the care continuum, uses three types of evidence and includes three planning steps, as outlined below.

## The framework uses the care continuum

The continuum of care provides the structure for extracting, reviewing and mapping relevant data; prioritizing problems that need to be addressed and analysis of their root causes; and identifying priority interventions to address root causes. The care continuum is divided into three parts: people not accessing the health care system; people with TB who seek health care but are either not diagnosed or not notified; and people with TB who are notified, but not successfully treated. Fig. A1.1 illustrates how data – usually derived from national TB or health system surveys and assessments of TB surveillance systems – are consolidated along the continuum of care.

## The framework uses three types of evidence

To promote holistic people-centred analysis and discussions, three major types of evidence are used (Fig. A1.1):

- *Epidemiological evidence* – this includes data about the burden of TB disease, including its distribution (such as by age and sex) and trends, for both drug-susceptible TB (DS-TB) and drug-resistant TB (DR-TB). Sources include TB epidemiological reviews, national surveillance systems, global TB reports, national surveys of TB prevalence and drug resistance, national TB inventory studies, mortality studies and national vital registration systems.

- *People-centred evidence* – this includes the risk profiles (e.g. age, sex, socioeconomic status and HIV status), knowledge, perceptions, expectations and behaviour of people with TB or at risk of developing TB. Sources include adherence studies, patient pathway analysis (PPA), national surveys of TB prevalence, demographic and health surveys (DHS), national surveys of costs faced by TB patients and their households, surveys on nutrition and other risk factors, health expenditure and utilization surveys (HEUSs), and World Bank data on economic and poverty.

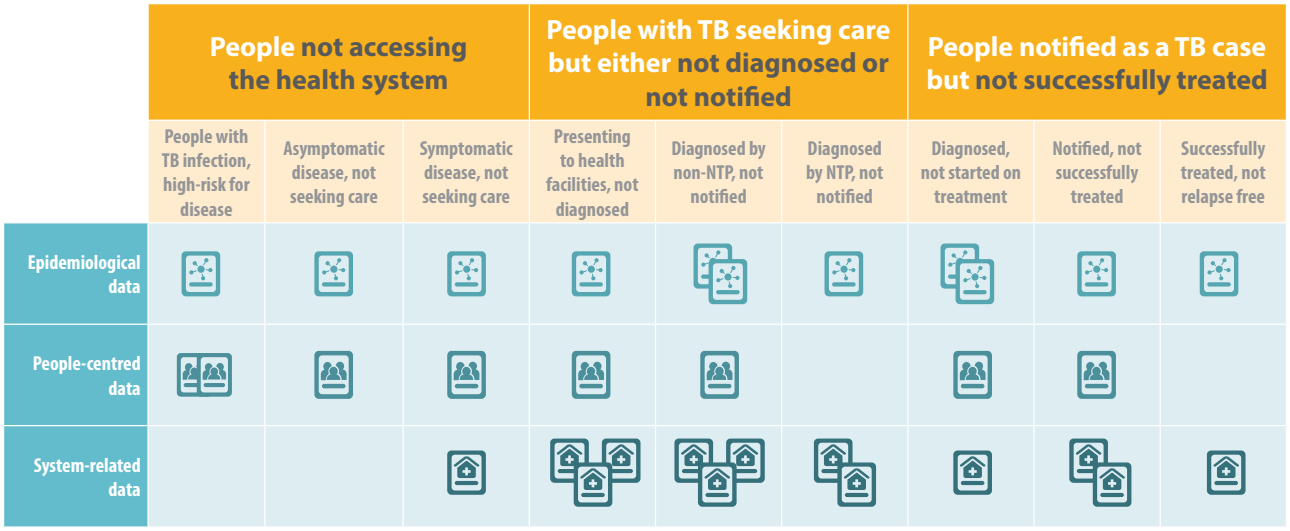
- *System-related evidence* – this includes the capacity, performance, limitations and distribution of health and social services, both TB-specific and general. Sources include health system reviews, service availability and readiness assessment (SARA) mapping, HEUSs, PPA and national TB inventory studies.

## The framework includes three planning steps

1. **Problem prioritization**
   The first step is to assess the magnitude and scope of problems by systematically reviewing existing data along the continuum of care, to identify the priority issues for the TB response.

2. **Root cause analysis**
   Once the main programmatic priorities have been identified, including missed opportunities

**Fig. A1.1. Conceptual framework for consolidation and mapping of data along the continuum of care**




NTP: national tuberculosis programme.

to reach people with TB or at risk of developing TB, the root causes that are driving suboptimal outcomes are discussed and identified.

3. **Intervention optimization**
   Intervention strategies are developed to address root causes and priority problems.

## When should the people-centred framework be used?

The framework is most effectively applied during the development of a country's national strategic plan (NSP). However, countries that are in the implementation phase of the NSP can use the framework for other purposes such as:

- prioritization for additional funding or programme revisions;
- NTP review, or annual or quarterly review meetings;
- harmonization of support for the NTP;
- setting research priorities; and
- routine data collection.

Detailed explanation of how the framework can be applied, together with some case studies on some of those applications can be seen in Chapter 3 and Annex 1 of the people-centred framework user guide *(4)*.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