# Guidance on conducting reviews of tuberculosis programmes

## Web annex B. Thematic tools

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Thematic tool 1

Systematic screening for tuberculosis

This tool covers assessment of systematic screening for tuberculosis (TB).

1.1 Objectives
At the end of the review, experts should be able to comment on:
► national policies on TB screening and active case finding (ACF);
► availability of screening and ACF services and tools;
► implementation of contact investigation;
► availability of strategic data, recording and reporting practices; and
► gaps in the implementation of systematic screening and their impact on equity.

1.2 Background
Systematic screening for TB is critical for increasing the number of patients diagnosed with TB who would otherwise be missed or be detected late in the course of the disease. Such screening improves the health of the individuals who are diagnosed and of the community at large. The recommendations on screening in the World Health Organization (WHO) consolidated guidelines (WHO 2021) identify the main populations to target with active TB case finding, and the best tools and algorithms to use, based on the most recent evidence.

1.3 Staff to be interviewed
Various personnel have roles in screening; it may be useful to meet these staff as part of the programme review. The main personnel are:
► managerial staff – these include staff from the national TB programme (NTP); national HIV/AIDS programme; and other state sectors such as primary care, hospitals, occupational health services (e.g. mining industry), prison health services, residential care facilities and migrant screening facilities;
► health care workers conducting screening in health facilities (e.g. for people living with HIV [PLHIV] and people presenting with risk factors for TB) or in occupational and prison settings;
► community health workers conducting ACF and contact investigation activities; and
► health care workers conducting screening in health facilities (e.g. for PLHIV and people presenting with risk factors for TB) or in occupational and prison settings.

1.4 Key areas and sample questions
This section outlines key areas of TB screening to be assessed during the review; items marked with an asterisk are usually assessed centrally.

Vulnerable populations and policies
► Review the national guidelines or other policy documents on TB screening and ACF (i.e. which high-risk groups are targeted, what screening programmes are available outside the NTP and which tools are included).
Review epidemiological data to identify the most relevant vulnerable populations and risk groups in the country.

**Human resources and service provision**

- Review the role of health care workers and community workers in screening people and identifying presumptive TB.
- Assess the level of training of health care workers on TB screening and testing (including on data recording and reporting).
- Assess the role of different services providers (e.g. civil society organizations, occupational health services, prison health services, residential care facilities and migrant screening facilities) in ACF.

**Screening**

- Review the use of sensitive screening tools, focusing on chest radiography, including with the use of portable digital radiography equipment and computer-aided detection (CAD) software. What is the proficiency and capacity of staff reading of chest radiographs?
- Assess whether the screening and diagnostic algorithms being used are adequate across all screening settings, and whether all risk groups are being screened (e.g. assess whether the algorithms are of sufficient sensitivity to improve detection of prevalent TB beyond existing passive case detection).
- Assess whether algorithms and standard operating procedures (SOPs) are in place and are followed; also, assess the appropriateness and quality of the algorithms and SOPs (for drug-susceptible and drug-resistant TB).
- Review the quality and implementation level of TB contact investigation activities, and the appropriateness of their coverage and implementation.
- Review TB screening services (and their results) for contacts of people with TB, PLHIV and other high-risk groups relevant to the country context. Is ACF linked to TB preventive treatment for eligible populations?

**Recording and reporting, and strategic data**

- Assess the availability and quality of records and registers for screening programmes, including for tracking of people with presumed TB referred for diagnostic evaluation and people with confirmed TB starting on treatment. Critical questions include the following: are records kept on paper or digitized, and can the TB notification system distinguish between TB patients detected passively or actively?
- Consider the inputs, process, outputs and outcomes indicators relevant to this area (adopt indicators from the table below and add items as needed). Assess the availability of strategic data in this area, including estimates of population size and TB risk or TB prevalence in high-risk groups, and the level of coverage with screening and diagnostic services.

**Impact and gaps**

- Assess the gaps, effectiveness, yield, efficiency, sustainability and impact on equity of screening interventions conducted to date in this area.
- Assess how the achievements or gaps in this area are affecting the country’s progress towards the impact and outcome targets of the national strategic plan (NSP) and meeting the targets of the End TB Strategy.

**1.5 Indicators**

Table 1.1 shows the data that should be collected to calculate the process indicators listed in Table 1.2. Data can be found from screening registers (e.g. for household contacts and people with HIV). If screening registry data are not readily available, a sample of data from screening activities can be used.
Table 1.1  Data to be collected to calculate screening process indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>The number of people eligible for screening across different targeted risk groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>The number of people screened</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>The number of people with presumptive TB identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>The number of people undergoing diagnostic investigation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>The number of people diagnosed with TB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>The number of people with TB initiated on TB treatment</td>
<td></td>
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Table 1.2  Process Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Remarks</th>
</tr>
</thead>
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<tr>
<td>Reach or acceptability</td>
<td>B</td>
<td>A</td>
<td>Reach indicates the coverage or extent of the intervention. Acceptability indicates how the screening programme is received by the population being screened.</td>
</tr>
<tr>
<td>Screen positivity rate</td>
<td>C</td>
<td>B</td>
<td>The proportion of the population that screen positive indicates the appropriateness of the screening test for the population being screened. A positivity rate that is too low suggests that the test may not be sensitive enough to detect TB prevalent in the population, whereas a rate that is too high will overwhelm the laboratory system performing diagnostic evaluation and will require extensive resources.</td>
</tr>
<tr>
<td>Testing retention</td>
<td>D</td>
<td>C</td>
<td>Testing retention indicates the proportion of people who screen positive and go on to receive a diagnostic evaluation, to either establish a diagnosis of TB or rule it out. It indicates the success of the screening programme in avoiding loss to follow up along the care cascade.</td>
</tr>
<tr>
<td>Linkage to care</td>
<td>F</td>
<td>E</td>
<td>Linkage to care indicates the proportion of people diagnosed with TB and screening efforts that are retained in care through treatment initiation.</td>
</tr>
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The programme indicators listed in Table 1.3 can be calculated from national case detection data.

Table 1.3  Programme indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Remarks</th>
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<tr>
<td>National contribution of screening and ACF to case notifications</td>
<td>Number of cases detected through screening, including ACF, contact investigation and other systematic TB screening efforts</td>
<td>Total number of cases notified annually</td>
<td>The contribution of all screening efforts to national case detection is a good measure of the impact of the activities on national case detection rates.</td>
</tr>
<tr>
<td>Contact investigation coverage</td>
<td>Number of TB cases diagnosed annually</td>
<td>Number of TB cases diagnosed in a year, meeting eligibility criteria for contact investigation</td>
<td>The proportion of eligible index cases of TB for which contact investigations were undertaken indicates how systematically contact investigation is being implemented.</td>
</tr>
<tr>
<td>National case detection coverage</td>
<td>Total number of cases notified annually</td>
<td>Number of estimated cases annually</td>
<td>The national case detection rate indicates the case detection gap in the country that needs to be addressed through further efforts in screening and ACF.</td>
</tr>
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1.6 Useful resources

Useful resources include:

► WHO guidance on screening for TB:

► ScreenTB tool, an online tool to help NTPs and their partners plan TB screening activities by modeling the potential outcomes of screening programs, including yield of TB cases diagnosed (true- and false-positives), costs, and cost-effectiveness, specific to the populations screened and the diagnostic algorithms used, and a related publication;

► PreventTB, a digital tool from WHO used to register data and generate indicators on screening and TB preventive treatment.

► Recommendations for investigating contacts of persons with infectious TB in low- and middle-income countries:

► A guide to adapting and implementing the above recommendations;

► Information on contact investigation for frontline workers:
Thematic tool 2

Diagnostics

This tool covers assessment of diagnostics for tuberculosis (TB).

2.1 Introduction

Diagnostics are essential in the overall TB care pathway, which aims to ensure that individuals receive an accurate, rapid and quality-assured diagnosis to inform appropriate treatment. The End TB Strategy sets targets to significantly reduce mortality, incidence rates and catastrophic costs related to TB by 2035. The first component of Pillar 1 of the strategy requires the early diagnosis of TB, including universal drug susceptibility testing (DST) and systematic screening of contacts and high-risk groups. In 2011, the first World Health Organization (WHO)-recommended rapid diagnostic (WRD) was approved for detecting TB and rifampicin-resistant TB (RR-TB), marking a significant step forward from smear microscopy to a next-generation molecular test. Over time, that WRD has been found to be highly accurate; also, it reduces time to diagnosis, improves patient-important outcomes (e.g. mortality) and is cost effective. Currently, several other WRDs are also recommended, providing options for different contexts.

One target is to ensure that all patients notified with TB are tested with a WRD as the initial test by 2025; however, by 2020, a decade on from the first recommendation, the rate was only 33%. A key issue is access: only 22% of TB diagnostic sites have WRDs whereas almost 100% have smear microscopy. Where WRDs are available, they have also improved the detection of rifampicin resistance, increasing the global proportion of bacteriologically confirmed TB patients tested for RR-TB (e.g. in 2020 the proportion was 69% among new patients and 87% among previously treated patients). The new definition for extensively drug-resistant TB (XDR-TB) and the roll-out of new shortened regimens for RR-TB means that having capacity to undertake DST for new and repurposed drugs is an urgent new priority. Strengthening the quality of laboratory services is another critical diagnostic priority.

Two essential parts of a programme review on TB diagnostics are the diagnostic services and the diagnostic cascade, both of which are discussed below. These two parts are closely interrelated and should be assessed together.

2.2 Objectives

Diagnostic services

1. Review the diagnostic policies, algorithms and tools in place. Are these aligned with WHO recommendations?
2. Assess human capacity, recording and reporting, and connectivity.
3. Evaluate the available diagnostic testing capacity, timeliness and biosafety at all levels.
4. Assess whether the diagnostic infrastructure, tools and procedures meet the service and quality requirements.
5. Review the structure of the diagnostic network, and the link between the laboratories and clinical services.
6. Report on the strength and weaknesses of diagnostic services and make recommendations on priority actions to improve them.
Thematic tool 2

Diagnostic cascade
1. Review the complete diagnostic cascade, from individuals with presumptive TB entering a health centre to a final TB diagnosis (include drug resistance status, and TB being ultimately appropriately notified and managed).
2. Identify gaps between each step of the diagnostic cascade that need to be addressed.
3. Assess strengths and weaknesses at each step of the cascade.
4. Make recommendations to prioritize actions to improve the continuum of the diagnostic cascade.

2.3 Background
To ensure that patient needs are met and the targets of the End TB Strategy can be achieved, diagnostic services require a robust laboratory network that has full capacity, is quality assured, and generates timely and impactful results. Testing should be conducted primarily in a laboratory that has the necessary infrastructure and equipment, and has appropriately skilled staff to perform the testing; also quality management systems should be applied and the required biosafety precautions available. However, each laboratory should be linked into a tiered network, to ensure good coverage, consistency of services and quality oversight. The laboratory network should primarily be designed to serve clinical needs; also important is the interface between the clinical services, which requires coordinated activities and good communication.

To reach the best overall diagnostic outcomes, a holistic patient-centred approach is needed. The diagnostic cascade is a helpful model for visualizing the process and undertaking a thorough evaluation of the diagnostic component of a TB programme. The diagnostic cascade includes the following main stages: 1) presumptive TB, 2) access to testing, 3) testing, 4) diagnosis and 5) notification.

Stage 1: Presumptive TB
The first stage relates to the demand for diagnostics, and its effect on the systems that are in place to investigate individuals with presumed TB who have been identified through screening (initiated by the patient or provider) based on symptoms or use of screening tools (e.g. chest radiography, C-reactive protein or molecular WRD [mWRD]). Addressing issues related to stigma in seeking health care is also an important consideration at this stage.

Stage 2: Access to testing
Access to testing includes the availability of a health facility with testing either onsite or through remote sputum collection and sample referral. The health facility needs to be within a reachable distance for the patient; also, the patient needs to be able to access transport and have the financial means to cover it. Access is often underappreciated; it may be an important barrier, leading to delayed diagnosis or excessive patient out-of-pocket costs for referral. Reviewers should focus on what is needed to strengthen the existing network (e.g. by matching needs with capacity, expanding sample referrals, or creating less centralized testing services), depending on the local circumstances.

Stage 3: Testing
The testing that is offered is another consideration. It should include the best available WRDs, and efforts should be made to achieve a bacteriologically confirmed diagnosis before starting a patient on treatment.

Stage 4: Diagnosis
Diagnostic efforts eventually lead to a bacteriological diagnosis; however, that diagnosis needs to be timely and quality assured, and the aim should be to identify all people with TB. Achieving universal DST is also important, and referral mechanisms should be in place. The quality of laboratory services should be strengthened to improve the reliability of laboratory results.
**Stage 5: Notification**

The last stage of the diagnostic cascade involves ensuring that a person with a confirmed diagnosis is notified. However, this is not the last stage in the total continuum of care; rather, that involves ensuring that appropriate treatment is initiated and a cure is eventually achieved.

**2.4 Assessment**

The assessment is usually conducted in two phases: a remote desk review and an in-country visit.

**Phase 1 – Desk review**

The desk review will aim to gather as much background information as possible. This allows the team to make the best use of the time spent in the country; also, it means that the country staff can understand the type of information required and the areas to be covered. Before the country visit, it is useful to gather a minimal set of information for the previous years, as outlined below.

**Diagnostic services**

Useful information on diagnostic services includes:

► national TB strategic plan (NSP);
► national TB laboratory development plan (either separate standing or part of the NSP);
► national diagnostic algorithm(s);
► national prevalence review for drug-resistant (DR-TB) (or other available estimations on TB and DR-TB prevalence, disaggregated by region and province if data are available); and
► reports from previous review missions.

**Diagnostic cascade**

Useful information on the diagnostic cascade includes:

► number of presumptive TB cases stratified by initial diagnostic assay (if unknown, sum the number of WRDs + diagnostic smears + other diagnostic investigations, bearing in mind that this will be an underestimate);
► total number of diagnostic sites and instrument capacity;
► information on:
  — number of sites providing access to a functional WRD, smear or culture (number and percentage of clinical sites that have access to these TB diagnostic tools either onsite or through regular sample referral), and volumes of tests by laboratory;
  — whether the testing is free-of-charge to patients;
  — stratification of access to testing, where possible (e.g. primary, secondary or tertiary health facilities);
► details of quality assurance systems and accreditation of sites;
► total number of WRD, smear, culture and line-probe assay (LPA) tests conducted both nationwide and in each diagnostic site;
► number of WRD, smear, culture and LPA tests that are positive for TB, both nationwide and per diagnostic site;
► number of RR-TB cases detected, both nationwide and per diagnostic site;
► number of isoniazid mono-resistant cases detected, both nationwide and per diagnostic site;
Thematic tool 2

- number of RR-TB cases tested for resistance to fluoroquinolones (molecular and phenotypic), both nationwide and per diagnostic site;
- number of cases resistant to fluoroquinolones detected (molecular and phenotypic) nationwide and for each diagnostic site;
- number of RR-TB cases tested for resistance to bedaquiline, clofazimine, linezolid and pretomanid nationwide and per diagnostic site;
- number of RR-TB cases detected with resistance to bedaquiline, clofazimine, linezolid and pretomanid nationwide and per diagnostic site; and
- number of bacteriologically confirmed TB cases notified nationwide and per administrative unit.

The availability and quality of the data for the diagnostic cascade may vary, and they may not be completely accurate; however, the data will provide a quick snapshot to decide on areas to prioritize during the in-country visit.

Phase 2 – In-country visit

Country overview

Using the findings of the desk review and the gaps identified, the country overview delves deeper into the specific gaps and issues identified. Stakeholders should include the national TB programme manager, national reference laboratory, laboratory director and coordinators from general health services, representatives from the regions, partners aiming for laboratory strengthening in the country, clinical staff (where possible), donors and international development agencies, and other relevant individuals and organizations.

Specifics to be covered include the following:

- **Screening** – What approaches are being used for patient and provider-directed screening? How well are these approaches working in terms of closing the case detection gap? Are sensitive and accurate tools used in case finding (e.g. chest radiography for screening)? Have any issues been identified with health-seeking behaviour, or access to health facilities or services? Does the cost of services present an obstacle to patient access? Are there regional differences? Does the patient pathway often start in the private sector; if so, what is being done to ensure engagement with that sector?

- **Diagnostic policy** – Does the diagnostic policy require all presumptive TB patients to be tested with a WRD? Does the algorithm include testing for at least rifampicin, and if the TB is rifampicin resistant, is testing for fluoroquinolones and other Group A drugs available (i.e. bedaquiline, clofazimine, linezolid and pretomanid)? If such testing is not available, why is this the case? Does the policy or algorithm include upfront testing for isoniazid resistance? If so, is this for specific populations or areas? Is the national algorithm available and taught at all health facilities? Is there specific consideration or algorithms for the diagnostic work-up of childhood and adolescent TB and extrapulmonary TB?

- **Access to WRDs** – How many health facilities have access to WRDs for TB diagnosis? Is the use limited to diagnosis of rifampicin resistance? Relative to the notified burden, what is the coverage (onsite or through sample referral) for WRDs? How large is the gap between diagnostic capacity using WRDs and the number of presumptive TB patients needing a test? Has any assessment been undertaken to evaluate the performance of the diagnostic network and efforts to optimize it? If so, what was assessed and what were the findings?

- **Resistance** – How many health facilities have access to culture-based TB diagnosis and detection of resistance to fluoroquinolones, bedaquiline, clofazimine, linezolid and pretomanid? Relative to the notified burden, what is the access coverage (onsite or through sample referral) for culture-based TB diagnosis and DST? Has any assessment been undertaken to evaluate the performance of the diagnostic network and efforts to optimize it? If so, what was assessed and what were the findings?
Thematic tool 2

- Private sector – Is there a significant private laboratory network providing access to WRD and culture-based TB diagnosis?

- Bacteriological confirmation – What proportion of pulmonary TB is bacteriologically confirmed? If there is a large gap (>20%) what is the reason for this situation? What measures are in place to ensure such clinically diagnosed pulmonary TB patients are tested before receiving empirical treatment? Is this monitored?

- Protocols – Is there a protocol in place for diagnosis of extrapulmonary TB and another for TB diagnosis in children?

- Monitoring – Does the administrative unit regularly monitor trends in WRD, or overall TB positivity and resistance to rifampicin (and other drugs), and are results used to inform programmatic actions or investigations? Does the positivity rate vary by different administrative unit; if so, can this variation be explained?

- Turnaround time – Is the laboratory turnaround time (TAT) monitored for the TB tests used at national, province and district levels? If so, is the TAT below 48 hours for at least 80% of tests? Are there any areas where TAT is more than 48 hours; if so, is this situations being investigated and addressed?

- Correlation – How do the numbers of patients tested and positive for TB, and resistant to rifampicin and Group A drugs, correlate with notified TB and DR-TB cases? Are there gaps; if so, what explains these gaps?

Field visits

Following the country overview meeting and provision of clarifications, the field visits should be used to obtain a clearer picture of the diagnostic services and diagnostic cascade that is operationalized in the field. This is an opportunity to validate in the field some of the findings and explanations provided. Ideally, visits to different sites and levels should be undertaken. Where possible, it can be informative to visit a site that is performing well and another that is performing less well.

Specific items to be reviewed in the field visits (preferably at 2-4 different sites) are outlined below, as are levels of sites that should be visited and specifics for each level.

General health care facility (outpatient and inpatient)

- Investigate patient flow in the facility and efforts to ensure that all presumptive patients enter the diagnostic cascade.

- Investigate patient sampling and specimen transportation procedures (including infection control, staff training and patient education), and the request forms used for test requisitioning. Are logs used to track samples between the health facility and the laboratory? What is the frequency of samples sent to the laboratory (e.g. daily collection)? What mode of transportation is used? How are samples stored if they are not collected on the same day? What packaging of samples is used during transport? Are couriers trained and do they understand biohazard risks and mitigation?

- Review a sample of records from patients with presumed TB (about 10) to determine the time from sample collection to results received at the clinic. Is the sputum collection report clear and does it provide key information (e.g. on the patient and the reason for investigation)?

- Is the positive test returned linked to care and does it appear in the notification register? Make a list of positive laboratory results and see whether they correlate to the reporting in the TB register. Is the classification entered as bacteriologically confirmed? What is the time lag between results reporting and entry into the TB register?

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1. Laboratory TAT refers to the time taken from collection of a specimen at the health facility to the issuing of a laboratory test result. The overall TAT (from specimen collection to receipt of the result by the clinician) may be longer and is dependent on various factors such as speed of referral of specimens to the laboratory and delivery of results to the clinician.

2. Fluoroquinolones, bedaquiline, clofazimine and linezolid.
Thematic tool 2

Peripheral TB laboratory diagnostic site

- Review the spectrum of TB tests performed and the volume trends in the past 3 years, and identify any specific issues encountered in delivering the services.
- Review staffing levels and ratio of staff to number of tests, staff training and competence for test procedures, and staff turnover.
- Review linkage between the clinical services and laboratory (this can be done by reviewing the laboratory registers or sample logs to determine the regularity of sample reception from different sites and the number of clinical sites receiving results from a laboratory facility of interest). Are contact details across the service available?
- If patients are referred to the laboratory site for testing, review:
  - patient or sputum sample flow in the facility and efforts to ensure that all referred patients or sputum samples are entering the diagnostic flow and being registered; and
  - patient sampling procedures (including infection control, staff training and patient education), and the request forms used for test requisitioning.
- If patient samples are referred to the laboratory for testing, review:
  - frequency of samples sent to or collected in the laboratory (e.g. daily collection); and
  - how samples are stored if they are not collected on the same day.
- Is the sputum collection report clear and does it provide key information on the patient, reason for investigation and so on?
- Review a random selection of laboratory test records (about 20) to determine time from sample collection to test performed, and positivity rate. If the tests are not performed the same day, why is this the case? If positivity is higher or lower than neighbouring regions or facilities, why is this the case?
- Is the quality of sputum monitored? Observe the frequency for poor quality samples (saliva). What is the frequency of no result, error, invalid result and indeterminate result for WRD?
- Review a random selection of records (about 20) to determine the laboratory TAT. Is the TAT below 48 hours for at least 80% of results? If the TAT is above 48 hours, what are the reasons for this?
- Does the laboratory participate in external quality assessment (EQA) activities? If so, what kind of activities? Is the rate of error of WRD tests below 4%? Is smear re-checking performed; if so, is there consistency? Verify monitoring visits and EQA reports on site.
- Check that maintenance logs of equipment are up to date, and staff are trained and confirmed to be competent.

National reference laboratory – specifics

- Are biosafety and infection control systems in place. What infrastructure is available for processing samples (e.g. biosafety cabinet Class II)? Is personal protective equipment (PPE) available for staff; if so, is it used appropriately (e.g. are N95 masks available and are these fit tested)? What workflow routines are used to reduce cross contamination? What packaging of samples is used during transport? Are couriers trained and do they understand biohazard risks and mitigation? How is waste disposed of?
- Are liquid cultures and phenotypic DST processed? What is the biosafety level and what other precautions are in place?
- Are LPAs or sequencing performed? Are standard operating procedures (SOPs) and quality assurance systems in place?
- Is phenotypic DST to new and repurposed drugs performed; if so, is testing quality assured?
- What systems are in place to monitor the quality of laboratory testing in the network?
Thematic tool 2

Are national testing data compiled centrally and is analysis conducted to monitor trends in the overall services provided and the results obtained?

Is there an agreement with a supranational reference laboratory (SRL)?

What EQA programmes are in place? What tests are covered by EQA programmes? What are the particularities of the programme for each test or method. What is the track record over time for each test or method? What were the results of the previous SRL EQA rounds?

Does the laboratory participate in public health activities, such as surveys or surveillance?

Are the equipment maintenance and quality records up to date (e.g. incubator temperatures, autoclave logs, Biosafety level 3 (BSL3) validation and verification)?

In terms of quality systems assessment, is the site ISO 15189 accredited or has the site undertaken a Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) process; if so, is the certificate available? Are the quality manual, SOPs for the equipment and procedures, and records and logs on equipment maintenance available? Has the site participated in an EQA programme for each test method performed; if so, what is the track record over time?

Intermediate level laboratory – specifics

Are biosafety and infection control systems in place? What infrastructure is available for processing samples (e.g. biosafety cabinet Class II)? Is PPE available for staff and used appropriately (e.g. are N95 masks available and are these fit tested)? What workflow routines are used to reduce cross contamination? What packaging of samples is used during transport of samples? Are couriers trained and do they understand biohazard risks and mitigation? How is waste disposed of?

Are liquid cultures processed? If so, what is the biosafety level and are other precautions in place?

Are LPAs or sequencing performed? If so, are there SOPs and quality assurance systems in place?

Is phenotypic DST to new and repurposed drugs performed; if so, is testing quality assured?

Are there strong linkages between this level and the national and peripheral levels?

What type of reporting and clinical interaction is provided for diagnostic tests?

What are the levels of staff qualification and experience?

Are equipment maintenance and quality records available (e.g. incubator temperatures, autoclave logs, and BSL3 validation and verification).

In terms of quality systems assessment, is the site ISO 15189 accredited or has the site undertaken a SLIPTA process? If so, is the certificate available? Are the quality manual, SOPs for the equipment and procedures, and records and logs on equipment maintenance available? Has the site participated in an EQA programme for each test method performed; if so, what is the track record over time?
### Table 2.1 Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator</th>
<th>Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of health care facilities that have access to WRDs (onsite or through sample referral)</td>
<td>Number of health care facilities that have access to WRDs (either onsite or through a sample referral system)</td>
<td>Total number of health care facilities</td>
</tr>
<tr>
<td>Percentage of WRD testing needs that are covered by existing testing capacity</td>
<td>Number of tests that can be performed with the current functional WRDs in country</td>
<td>Number of tests needed based on all presumptive TB patients expected (or estimated)</td>
</tr>
<tr>
<td>Percentage of new and relapse TB patients tested using a WRD at the time of diagnosis (stratified by pulmonary TB and extrapulmonary TB)</td>
<td>Number of notified new and relapse TB cases tested using a WRD at the time of diagnosis</td>
<td>Number of notified new and relapse TB cases</td>
</tr>
<tr>
<td>Percentage of new and relapse TB cases with bacteriological confirmation</td>
<td>Number of notified new and relapse TB cases with bacteriological confirmation</td>
<td>Number of notified new and relapse TB cases</td>
</tr>
<tr>
<td>Percentage of notified, bacteriologically confirmed TB cases with DST results at least for rifampicin</td>
<td>Number of notified, bacteriologically confirmed TB cases with DST results for rifampicin</td>
<td>Number of notified, bacteriologically confirmed TB cases</td>
</tr>
<tr>
<td>Percentage of notified MDR/RR-TB cases with DST results for fluoroquinolones</td>
<td>Number of notified MDR/RR-TB cases with DST results for fluoroquinolones</td>
<td>Number of notified RR-TB cases</td>
</tr>
<tr>
<td>Percentage of notified pre-XDR-TB cases with DST results for Group A drugs other than fluoroquinolones</td>
<td>Number of notified pre-XDR-TB cases with DST results for Group A drugs other than fluoroquinolones</td>
<td>Number of notified pre-XDR-TB cases</td>
</tr>
<tr>
<td>TAT for testing from sample collection to results reported from laboratory (stratified for each method): ▶ WRD = 48 hours ▶ Low complexity aNAAT (fluoroquinolones) (XDR-TB) = 48 hours ▶ LPA/high complexity rNAAT (pyrazinamide) = 7 days ▶ Culture = max. 44 days (liquid) / max. 58 days (solid)</td>
<td>Number of tests below standard TAT (stratified for each method)</td>
<td>Total number of tests performed</td>
</tr>
<tr>
<td>Percentage of WRD laboratories meeting the minimum quality indicator</td>
<td>Total number of laboratories with WRD error rates ≤4%</td>
<td>Number of laboratories performing WRD testing</td>
</tr>
<tr>
<td>Percentage of diagnostic testing sites that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed</td>
<td>Number of diagnostic testing sites (stratified by type of diagnostic testing) that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed</td>
<td>Number of testing sites (stratified by type of diagnostic testing)</td>
</tr>
<tr>
<td>Percentage of diagnostic testing sites (stratified by type of diagnostic testing) that demonstrated proficiency (&gt;90%) through EQA testing</td>
<td>Number of diagnostic testing sites (stratified by type of diagnostic testing) that demonstrated proficiency (&gt;90%) through EQA testing</td>
<td>Number of testing sites (stratified by type of diagnostic testing) enrolled in an EQA programme</td>
</tr>
<tr>
<td>Indicator</td>
<td>Numerator</td>
<td>Denominator</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Percentage of diagnostic testing sites (stratified by type of diagnostic testing) that are accredited or are in the process of establishing a formal quality management system towards achieving accreditation</td>
<td>Number of diagnostic testing sites (stratified by type of diagnostic testing) that are accredited or are in the process of establishing a formal quality management system towards achieving accreditation</td>
<td>Number of testing sites (stratified by type of diagnostic testing)</td>
</tr>
<tr>
<td>Contamination rate for solid culture (analysed by batch)</td>
<td>Number of contaminated cultures</td>
<td>Number of cultures processed</td>
</tr>
<tr>
<td>Contamination rate for liquid automated culture (analysed by batch)</td>
<td>Number of contaminated cultures</td>
<td>Number of cultures processed</td>
</tr>
<tr>
<td>Percentage of testing sites using a WRD at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system</td>
<td>Percentage of testing sites using a WRD at which a data connectivity system is used</td>
<td>Total number of testing sites using a WRD</td>
</tr>
<tr>
<td>Correlation of WRD and smear tests</td>
<td>Number of patients with congruent results positive (smear positive and WRD positive) and negative (smear negative and WRD negative)</td>
<td>Total number of patients with both smear and WRD results available</td>
</tr>
<tr>
<td>Correlation of WRD and culture tests</td>
<td>Number of patients with congruent results positive (culture positive and WRD positive) and negative (culture negative and WRD negative)</td>
<td>Total number of patients with both culture and WRD results available</td>
</tr>
<tr>
<td>Correlation of WRD and phenotypic DST</td>
<td>Number of patients with congruent results resistant (drug resistant in WRD and drug resistant in pDST) and susceptible (drug susceptible in WRD and drug susceptible in pDST)</td>
<td>Total number of patients with both WRD and pDST results available</td>
</tr>
</tbody>
</table>

Thematic tool 3

Treatment and care for people with tuberculosis

This tool covers treatment and care for people with tuberculosis (TB).

3.1 Objectives

At the end of the review, experts should be able to comment on:

► TB treatment coverage, regimens and outcomes;
► TB treatment and care delivery for drug-susceptible TB (DS-TB) and drug-resistant TB (DR-TB) at different levels of health care;
► interventions to enhance treatment adherence (e.g. treatment support, social support and digital adherence technologies), active TB drug safety monitoring and management (aDSM) and models of care; and
► gaps to be addressed to improve quality of treatment and care for patients with TB.

3.2 Background

Provision of treatment and care for TB patients is a key function of a national TB programme (NTP). Effective treatment and care for both patients with DS-TB and those with DR-TB could help to save lives; also, it could reduce TB transmission and TB burden. A comprehensive assessment of the TB treatment and care as part of the NTP is crucial to identify and address gaps in the provision of services for people affected by the disease.

3.3 Key areas for assessment

Policies

► Alignment of national policies on treatment and care of DS-TB and DR-TB with the current World Health Organization (WHO) recommendations.
► Implementation of (or adherence to) the national TB guidelines on the programmatic and clinical management of TB at different levels of the health care system.

Treatment regimens

► Treatment regimens used.
► Uptake of newly recommended treatment regimens.

Treatment coverage

► Treatment coverage (for DS-TB and DR-TB).
► Treatment enrolment.
► Access to TB treatment for people in need of such treatment.
Thematic tool 3

**Treatment outcomes**
- Treatment outcomes (separate cohorts of DS-TB and DR-TB).
- Monitoring treatment response.
- Outcome assessment.
- Recording and reporting.

**Treatment safety monitoring and management**
- Monitoring and management of adverse events for patients being treated for TB.
- Implementation of aDSM for patients being treated for multidrug-resistant TB or rifampicin-resistant TB (MDR/RR-TB).

**TB care and support**
- Policy and implementation of TB care and support interventions to enhance treatment adherence. Such interventions include treatment support, social support (e.g. information and educational, psychological and material support) and digital adherence technologies.
- Model of care and programmatic management aspects for DS-TB and DR-TB patients.
- Access to palliative care and end-of-life care for TB patients.

**Summary of findings**
- Achievements, gaps and needs for expanding or improving TB treatment and care services.

### 3.4 Useful resources

Useful resources for the assessment are listed below.

**WHO guidance on TB treatment:**

Outcomes of WHO meetings on definitions in TB treatment:
Thematic tool 4

Programmatic management of tuberculosis preventive treatment

This tool covers the programmatic management of tuberculosis (TB) preventive treatment (PMTPT).

4.1 Objectives

The review should check how the TB preventive treatment (TPT) is implemented in public and private health services, by checking that:

► national guidelines are updated in line with the latest global recommendations, and the national strategic plan (NSP) provides adequate resources for the implementation of the guidelines;
► appropriate staff, stakeholders and expert groups are engaged in implementation of the guidelines;
► clear guidance is in place for identifying the target populations for TPT; ruling out TB disease; diagnosing TB infection or assessing patient eligibility for TPT; and providing TPT where necessary;
► medication support is in place to help people start and complete their TPT effectively;
► data are systematically recorded to generate and monitor key indicators across the cascade of care for TPT; and
► other implementation support measures are in place, such as training, advocacy and management of commodities.

4.2 Background

PMTPT fits within a larger framework of preventive actions envisaged by the End TB Strategy, such as active TB case-finding, infection control, prevention and care of comorbidities (e.g. HIV), access to universal health care, social protection and poverty alleviation. In the absence of an effective, scalable vaccine, TPT is the only intervention that can prevent TB at both the individual and community levels. A combination of approaches that maximize treatment of both TB disease and TB infection at large scale would be expected, by 2035, to bring down the TB burden to the levels envisaged by the End TB Strategy.

4.3 Staff to interview

Various personnel have a role in TPT implementation and may be encountered as part of the programme review:

► *managerial staff* – staff managing the national and subnational TB programme, the national HIV/AIDS programme;
► *health workers and community health workers* – those involved in TB and HIV care, household contact evaluations, diagnostic services in health care facilities (in both the public and private sectors, and at both primary and secondary levels of health care); and
► *staff working in other state sectors* – staff in sectors such as primary care, hospitals, occupational health services (e.g. mining industry), prison health services and migrant screening facilities.
4.4 Key areas and sample questions

This section provides sample questions for each key area; questions marked by an asterisk are those that are mostly relevant at the national level.

Governance and policies
► Is TPT included in the NSPs for TB and HIV?
► Is there a national coordinating mechanism or national technical expert group that supports PMTPT?
► Is there a plan to disseminate guidance and expand implementation across the country and key target populations (e.g. a plan for engagement of a physicians association or of private providers)?
► Do the funding and resources available match those needed to support national implementation of TPT guidelines?
► Are the national TB and HIV guidelines aligned with the latest World Health Organization (WHO) recommendations?
► Are the (priority) target groups for TPT (e.g. adult household contacts of TB patients, prisoners, health care workers and clinical risk groups) clearly identified in the guidelines?
► Is there a plan to scale up the shorter rifamycin-containing TPT regimen?
► Is there a plan to enhance access to chest radiography and tests for TB infection; for example, for evaluation of people living with HIV on antiretroviral therapy (ART) or adult household contacts of TB patients?
► Is there provision of incentives or support for travel, to ensure systematic TB screening and evaluation of individuals targeted for provision of TPT?

Human resources and community engagement
► Have training materials for staff and health education materials for the general public been developed?
► Are physicians, nurses, health staff and community health workers trained on identification of target populations, TB screening and evaluation for TPT eligibility and provision of TPT?
► Has mapping of community-based health facilities or community health workers to be engaged for TPT been undertaken?
► Are community-based organizations engaged in awareness generation and implementation of TPT and follow-up?

Diagnosis and treatment
► Are the diagnostic algorithms clearly defined (e.g. for the role of test for TB infection and chest radiography)? If so, do those algorithms interact with other algorithms, such as those for TB case finding or TB screening?
► Are preventive treatment options and criteria for choice of regimens clearly defined?
► Are shorter TPT regimens and regimens with rifapentine implemented?
► Is rifapentine included in the national list of essential medicines?
► Does rifapentine have a marketing authorization in the country, or are waivers in place to facilitate importation of rifapentine?
► Is procurement of TPT medicines and diagnostics integrated with procurement and supply chain management for other TB commodities?
Monitoring and evaluation

► Is there a plan for monitoring and evaluation (M&E) of TPT? Are national indicators for PMTPT included in the national health management information system (HMIS)?
► Are recording and reporting tools aligned with national TPT indicators?
► Are digital tools used to collect and analyse data on TB screening and TPT across different target populations?
► Are the TPT indicators generated and reviewed at subnational and national levels?
► Is there a mechanism to report and manage adverse drug reactions?

4.5 Indicators

The programme should be able to report at national level on the three main indicators of TPT as per Table 4.1.

Table 4.1 Indicators for programmatic management of TPT

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition</th>
<th>Numerator</th>
<th>Denominator</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact investigation</td>
<td>Number of contacts of bacteriologically confirmed TB patients evaluated for TB disease and TB infection out of those eligible, expressed as a percentage</td>
<td>Total number of contacts of bacteriologically confirmed TB patients who completed evaluation for TB disease and TB infection during the reporting period</td>
<td>Total number of contacts of bacteriologically confirmed TB patients during the reporting period</td>
<td>Contact investigation identifies people recently exposed to TB with a high risk of developing TB disease. This activity is poorly implemented in many countries and needs urgent improvement. It is also one of the top 10 indicators of the WHO End TB strategy.</td>
</tr>
<tr>
<td>TPT coverage</td>
<td>Number of individuals initiated on TPT out of those eligible, expressed as a percentage</td>
<td>Total number of individuals eligible for TPT who initiated treatment during the reporting period</td>
<td>Total number of individuals eligible for TPT during the reporting period</td>
<td>This indicator (also referred to as TPT initiation indicator) should include all people deemed to be at risk and eligible for TPT by the national policy. A time trend analysis of the numerator provides information on the trajectory of TPT scale-up. Disaggregation could be done for people with HIV (newly or currently enrolled on ARV); contacts &lt;5 years and ≥5 years; by TPT regimen (e.g. 3HP, 3HR, 6H).</td>
</tr>
<tr>
<td>TPT completion</td>
<td>Number of individuals completing TPT out of those initiating treatment, expressed as a percentage</td>
<td>Total number of individuals who completed a course of TPT started during the reporting period</td>
<td>Total number of individuals who initiated a course of TPT during the reporting period</td>
<td>This indicator helps assess the quality of implementation of TPT given that treatment effectiveness depends upon its completion. When reported alongside the other two indicators above, the reporting period should be earlier (e.g. 6 months or 12 months preceding) to allow time for completion of the TPT. Individuals could be grouped into “cohorts” for regimens lasting &gt;6 months and others lasting less to analyse TPT completion within a practical time window.</td>
</tr>
</tbody>
</table>

ARV: antiretroviral drug; H: isoniazid; HIV: human immunodeficiency virus; P: rifapentine; R: rifampicin; TB: tuberculosis; TPT: TB preventive treatment; WHO: World Health Organization.

* See the TPT operational handbook for the proposed thresholds of completion by regimen type.
4.6 Useful resources

Useful resources for the assessment are listed below.

WHO guidance on TB prevention and screening:


A digital tool from WHO used to register data and generate indicators on screening and TB preventive treatment:


Resources that provide programmatic staff and consultants with the essential tools for PMTPT:


Resources that provide frontline staff with useful detail on how to accomplish the key actions for TB household contact investigation:

Thematic tool 5

Management of child and adolescent tuberculosis

This tool covers assessment of the management of child and adolescent tuberculosis (TB).

5.1 Objectives

At the end of the assessment, reviewers should provide a comprehensive assessment and recommendations on the following:

► the management of child and adolescent TB as part of national policies on TB and child and adolescent health;
► the appropriateness of the procedures used to manage and prevent TB in children and adolescents;
► the level and quality of the implementation of interventions to screen, diagnose, manage and prevent TB in children and adolescents; and
► recording and reporting on child and adolescent TB, and the use of these data for improving programmes at various levels of the health system.

5.2 Background

The prevention, diagnosis and treatment of TB in children and adolescents, along with the required budget for such activities, should be included in the national strategy to prevent and control TB. Children (aged <10 years) with TB differ from adults in their response to the disease, and this difference has important implications for the screening, prevention, diagnosis and treatment of TB in children. Children exposed to TB are a priority group for TB preventive treatment (TPT) because they are at an increased risk of progressing from primary TB infection to TB disease. Also, they are at higher risk than adults for developing disseminated disease and TB meningitis, which are associated with high morbidity and mortality. The presentation of TB in children is an indicator of recent and ongoing transmission of Mycobacterium tuberculosis within the community. TB is also common in adolescents (aged 10–19 years), especially in those aged 15–19 years. TB has a major impact on the health and well-being of adolescents. In contrast to young children, adolescents are an important risk group for transmission, owing to the infectious nature of their disease (similar to adults with TB) and their high social mobility.

Diagnosing pulmonary TB in children is more difficult than in adults. Diagnosis relies on a careful and thorough assessment of all evidence derived from an accurate history, clinical examination including growth, and relevant investigations (i.e. rapid molecular testing of paediatric specimens for bacteriological confirmation, chest radiography and tests for infection). Bacteriological confirmation is not always feasible in young children; however, it should be sought whenever possible, and using less invasive specimen types where feasible. The approach to diagnosis of extrapulmonary TB in adolescents is similar to that for adults. The approach to the diagnosis of extrapulmonary TB in both children and adolescents depends on the site of presumptive disease. The diagnosis in children of common forms of extrapulmonary TB (e.g. lymph node TB, pleural TB and miliary TB) is often more straightforward than the diagnosis of pulmonary TB.

Children with TB usually do not present to TB services and are usually not managed within those services. Instead, children usually present to services that provide care to sick children, or to maternal and child health, HIV or nutrition services. Nonetheless, national TB programmes (NTPs) have an important role to play. NTPs should promote the integration of child and adolescent TB screening, prevention, diagnosis and treatment into the appropriate services, and at the level of the health system where children and
adolescents with TB or at risk of TB present. This can be achieved, for example, by updating national strategies and policies to include children and adolescents as key populations for TB interventions, mobilizing dedicated funding and building the capacity of the health workforce (including private sector health providers).

5.3 Location

The main sites to be assessed are the central unit of the NTP (which should, ideally, have a dedicated child TB focal point); maternal, child and adolescent health programmes; nutrition programme; HIV programme (as relevant); coordination units at the intermediate health level; and health facilities.

5.4 People to be interviewed

People to be interviewed include managers of the NTP and of programmes in maternal, child and adolescent health, nutrition and HIV; other members of the child and adolescent TB technical working group or paediatric association (as relevant); staff at coordination units at the intermediate health level; and staff at health facilities.

In addition, it would be useful to speak with community health workers, counsellors, representatives of civil society organizations, representatives of national paediatric associations, and child or adolescent TB survivors and their families and caregivers.

5.5 Key areas and sample questions

Policies and guidance

► Has the management of TB in children and adolescents been considered in the national TB strategic plan (NSP)? Has the budget for activities to address TB in children and adolescents been clearly identified in the budget of the NSP? Have any funding gaps been identified for these activities? What continuing sources of funding have been identified for activities to address TB in children and adolescents (e.g. Global Fund to Fight AIDS, Tuberculosis and Malaria)?

► How is child and adolescent TB covered in national guidelines on TB management? When were the latest guidelines published?

► Are the standard operating procedures (SOPs) and guidelines provided aligned with the latest recommendations from the World Health Organization (WHO) on child and adolescent TB? If this is not the case, are there plans for updating the SOPs and guidelines?

► Are guidelines available at the health facilities visited? If so, is there evidence that guidelines and SOPs are being used?

► Are there any best practices or achievements related to child and adolescent TB that the country is particularly proud of? If so, what are the plans for scaling up these practices?

Capacity-building, mentoring and supervision

► What training materials are available on child and adolescent TB? How is training on child and adolescent TB organized?

► Is there evidence of recent training available, including feedback from participants?

► How is mentoring and supervision for child and adolescent TB organized and who provides it?
Thematic tool 5

**Programme management**

- Is a focal point for child and adolescent TB available in the central unit or NTP?
- Is there a national working group on child and adolescent TB (either stand-alone or as part of a different working group)? If so, does this group have clear terms of reference? Who are the members? How often do they meet?
- What technical or funding support from partners is available for supporting the implementation of activities around child and adolescent TB (including operational research)?
- Are there any specific needs for technical assistance around child and adolescent TB? If so, what are these?

**TB screening and contact investigation**

- What tools are in use for TB screening in children and adolescents?
- How is contact investigation implemented, and for which age groups is it implemented?
- How are children and adolescents who are contacts of people with infectious TB linked to diagnostic evaluation or preventive services?

**TB prevention**

- What is the policy on bacillus Calmette-Guérin (BCG) vaccination and what is the latest BCG coverage?
- Are there any issues regarding BCG supply, and are there cold chain or other issues that might affect BCG delivery?
- Who are the target groups for TPT?
- What TPT regimens are used for the different target groups and age groups (including for drug-resistant TB (DR-TB))?
- Are TB infection tests or chest radiography available? If so, are these required to determine eligibility for TPT for the contacts of HIV-uninfected older children and adolescents (aged 5–9 or 10–19 years)? If not, does this form a barrier to providing TPT?
- Are there any costs associated with TB infection testing or chest radiography used for screening?
- Which TPT formulations are available?

**TB diagnostic approaches**

- Which investigations are available at the different levels to confirm the diagnosis of TB in children (e.g. Xpert MTB/RIF or Ultra, smear microscopy, tuberculin skin testing or chest radiography)?
- Which specimens are used for Xpert testing?
- Are any fees charged for tests performed for TB diagnosis, including chest radiography?
- Which treatment decision algorithms, scoring systems or other tools are in use to support a diagnosis of TB in children (including for a clinical diagnosis)?
- What are the common forms of extrapulmonary TB that are notified in children? Are cases of TB meningitis being detected and treated?
- How is intrathoracic lymph node TB classified (as pulmonary or extrapulmonary TB)? What implications would a change in the classification of intrathoracic lymph node TB to pulmonary TB have for the programme?
Treatment of TB

► Which treatment regimens are used to treat child and adolescent DS-TB? Are they aligned with the latest WHO recommendations?

► Which child-friendly first-line formulations are available and at which level? Is there specific monitoring of use of formulations for children to inform procurement and distribution? Note: check central drug stocks and availability of child-friendly TB formulations in TB clinics and basic health centres and district facilities.

► How is severity of disease assessed to determine treatment duration of children with drug-susceptible TB (DS-TB)?

► How is DS-TB meningitis treated (regimen and level of care)?

► What regimens are available for the treatment of DR-TB in children? Are these aligned with the latest WHO recommendations (including on the use of bedaquiline and delamanid for all ages and all oral regimens)? Which child-friendly second-line formulations are available and at which level?

► What are the policies on hospitalization of children and adolescents with DS-TB or DR-TB?

► Are there any formal assessment and follow-up services for post-TB sequelae in children with TB?

► Is palliative care available for children and adolescents with TB?

Decentralized and integrated, family-centred models of child and adolescent TB care

► Are TB screening, prevention, diagnosis and treatment services for children and adolescents decentralized? If so, which services are available at what level? Are appropriate linkages and sample transport facilities available from lower facility to district or higher facility? Are there plans for further decentralization?

► How are children with pneumonia and malnutrition screened or investigated for TB and managed if they have TB?

► How are pregnant women screened for TB and managed if they have TB? How are neonates exposed to a mother with TB managed (including prevention and timing of BCG)?

► How are TB services for children and adolescents integrated or harmonized with other programmes (e.g. HIV, nutrition, child health, and reproductive, maternal, newborn, child and adolescent health)?

► How and where are children with both TB and HIV managed (e.g. TB screening tools and frequency, TPT, diagnostic approach, treatment and timing of antiretroviral therapy [ART], management of drug–drug interactions and use of differentiated service delivery models)?

► Private sector engagement:
  — Are children and adolescents with TB managed in the private medical sector? If so, which aspects are covered and how many children and adolescents are managed there?
  — Are private providers using national guidance to manage TB?
  — Are private providers required to report data on child and adolescent TB to the NTP?

► How does the NTP ensure that TB services for adolescents are adolescent- and family-friendly?

Recording and reporting

► Are children and adolescents with TB recorded in the TB treatment registers at the basic management units and the relevant health facilities?

► In what age groups does the programme report children and adolescents (e.g. 5-year age groups – ideally 0–4, 5–9 and 10–14 years; 0–4 and 5–14 years; or 0–14 years only)?
Thematic tool 5

► Are treatment outcomes available for children and adolescents?
► Is the country using or considering electronic recording and reporting?
► Are children with DR-TB recorded and reported?
► Are data on TB in children and adolescents that are collected in other programmes (e.g. HIV or nutrition, or children with severe disease such as TB meningitis treated in hospital) reported to the NTP?
► Are data on child and adolescent TB available at national, subnational and district level? Is the paediatric TB burden in different areas as expected compared with the adult TB burden?
► Are facility level data used for identifying gaps and areas that need attention?

Table 5.1 Indicators for assessing child and adolescent TB

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Calculation</th>
<th>Source of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of persons with TB aged:</td>
<td>Number of children and adolescents with TB in each age group:</td>
<td>TB treatment register and relevant reports</td>
</tr>
<tr>
<td>0–4 years</td>
<td>by gender</td>
<td></td>
</tr>
<tr>
<td>5–9 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10–14 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–14 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15–19 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of children and adolescents with TB (by age group) who have:</td>
<td>Number of children with:</td>
<td>TB treatment register and relevant reports</td>
</tr>
<tr>
<td>bacteriologically confirmed pulmonary TB</td>
<td>bacteriologically confirmed pulmonary TB</td>
<td></td>
</tr>
<tr>
<td>clinically diagnosed pulmonary TB</td>
<td>clinically diagnosed pulmonary TB</td>
<td></td>
</tr>
<tr>
<td>extrapulmonary TB</td>
<td>extrapulmonary TB (by type)</td>
<td></td>
</tr>
<tr>
<td>Proportion of children and young adolescents among all persons with TB who were notified (including trends)</td>
<td>Numerator: number of children and young adolescents (aged 0–14 years) with TB (by year) Denominator: total number of persons of all ages with TB notified (by year)</td>
<td>TB treatment register and relevant reports</td>
</tr>
<tr>
<td>Treatment success rate for child and adolescent TB</td>
<td>Numerator: number of children and young adolescents with TB who were cured or who completed TB treatment within a specified period of time (by age group or combined for 0–14 years) Denominator: number of children and young adolescents with TB who were notified during the same period (by age group or combined for 0–14 years)</td>
<td>TB treatment register and relevant reports</td>
</tr>
<tr>
<td>Number and proportion of children and young adolescents among all persons with MDR/RR-TB who were started on second-line treatment</td>
<td>Numerator: number of children and young adolescents (aged 0–14 years) started on second-line treatment for MDR/RR-TB (by year) Denominator: total number of persons of all ages with MDR/RR-TB who were started on second-line treatment (by year)</td>
<td>MDR/RR-TB register and relevant reports</td>
</tr>
<tr>
<td>BCG immunization coverage among 1-year-olds (%)</td>
<td>The percentage of 1-year-olds who have received one dose of BCG vaccine in a given year</td>
<td>MCH registers, EPI reports and UNICEF reports</td>
</tr>
<tr>
<td>Coverage of households eligible for contact screening and management</td>
<td>Numerator: number of households with contact screening initiated Denominator: number of index cases with bacteriologically confirmed pulmonary TB and any household contacts</td>
<td>Contact screening register</td>
</tr>
<tr>
<td>Indicator</td>
<td>Calculation</td>
<td>Source of information</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Number of eligible children and adolescents who were contacts of persons with bacteriologically confirmed pulmonary TB who initiated TPT | Number of children and adolescents who received TPT:  
▸ by age group (e.g. <5, 5–9, 10–14, 15–19 years)  
▸ by HIV status  
▸ by TPT regimen (e.g. 3HR, 6H, 3HP and 1HP) | Contact investigation information system, HIV/AIDS information system, TPT register and relevant reports |
| Proportion of eligible children (0–9 years) and adolescents (10–19 years) who initiated TPT who received a short rifamycin-based TPT regimen (by regimen) | Numerator: Number of children and adolescents (0–19 years) who received a short rifamycin-based TPT regimen  
Denominator: Number of children (0–9 years) and adolescents (10–19 years) who received TPT:  
▸ by age group (e.g. <5, 5–9, 10–14, 15–19 years)  
▸ by regimen (e.g. 3HR, 3HP, 1HP or 4R) | Contact investigation information system, HIV/AIDS information system, TPT register and relevant reports |
| Proportion of children and adolescents (0–19 years) who completed TPT | Numerator: Number of children and adolescents (0–19 years) who completed TPT  
Denominator: Number of children and adolescents (0–19 years) who received TPT:  
▸ by age group (e.g. <5, 5–9, 10–14, 15–19 years) | Contact investigation information system, TPT register and relevant reports |
| **TB/HIV indicators (for high TB/HIV burden countries only):** | **HIV testing rate:**  
Numerator: Number of children and young adolescents (0–14 years) with TB who have an HIV test result recorded  
Denominator: Number of children and young adolescents (0–14 years) with TB | TB register, HIV/AIDS information system and relevant reports |
| HIV testing rate among children and young adolescents with TB  
TB/HIV coinfection rate (among children and young adolescents with a known HIV status)  
Children and young adolescents with TB/HIV coinfection who are on ART | **TB/HIV coinfection rate:**  
Numerator: Number of children and young adolescents (0–14 years) with TB who have a positive HIV test result recorded  
Denominator: Number of children and young adolescents (0–14 years) with TB who have an HIV test result recorded  
**% TB/HIV coinfected on ART:**  
Numerator: Number of children and young adolescents (0–14 years) with TB who are living with HIV who are on ART  
Denominator: Number of children and young adolescents (0–14 years) with TB who have a positive HIV test result recorded | TB register, HIV/AIDS information system and relevant reports |
| Proportion of children with TB aged below 10 years who received child-friendly formulations (dispersible tablets) | Numerator: number of children aged below 10 years with TB who received child-friendly formulations (by year)  
Denominator: total number of children aged below 10 years with TB notified (by year) | Relevant reports |
| Proportion of children with MDR/RR-TB aged below 10 years who received child-friendly formulations (dispersible tablets) | Numerator: number of children aged below 10 years with MDR/RR-TB who received child-friendly formulations (by year)  
Denominator: total number of children aged below 10 years with MDR/RR-TB started on second-line treatment (by year) | Relevant reports |

Useful resources

Useful resources include:

WHO guidance on management of TB:


WHO’s roadmap for ending TB in children and adolescents:

Thematic tool 6

Tuberculosis and HIV, and other comorbidities

This tool covers assessment of tuberculosis (TB) with HIV and other comorbidities.

6.1 Objectives

At the end of the review, experts should be able to comment on:

► the response to HIV-associated TB and other related TB comorbidities, and health-related risk factors (e.g. disorders due to alcohol and drug use, diabetes, mental disorders, tobacco smoking and undernutrition, and viral hepatitis and silicosis where relevant) in the context of the goals, objectives and targets that have been specified in the national strategic plan (NSP) to end TB, as well as the NSPs for each of the comorbidities, if these are separate documents;

► the gaps relating to TB and comorbidities within the existing NSP, which might provide opportunities for further enhancing the TB response in the next iteration of the NSP;

► the impact of the main identified health-related drivers of TB and risk factors for poor TB treatment outcomes (unless this has already been done as part of a review of TB epidemiology and determinants);

► the adoption and implementation of World Health Organization (WHO) recommendations that aim to reduce the burden of TB among people with health-related risk factors and comorbidities, and to reduce the burden of comorbidities among people with TB;

► the political will and level of collaboration between the different health programmes and other stakeholders at the levels of policy, health facility and community;

► the level of integration (and opportunities for integration) of services for diagnosis, treatment, care and prevention for people with TB and different comorbidities;

► human resource capacity, and supervision and mentoring for assuring quality delivery of services for TB and related comorbidities, as well as access to related equipment and commodities for the diagnosis, care and prevention of TB and related comorbidities; and

► how the activities are monitored and evaluated.

6.2 Background

Integrated patient-centred care and prevention for TB, including for HIV-associated TB and other comorbidities, are key components of Pillar 1 of the End TB Strategy. The importance of integrated people-centred services was reiterated in the political declarations of the respective United Nations (UN) high-level meetings on the fight against TB, on noncommunicable diseases (NCDs), on HIV and AIDS, and on universal health coverage.

To date, with the exception of the WHO policy on collaborative TB/HIV activities, there has been limited uptake of guidance on TB and related comorbidities. Actions to address TB and comorbidities can broadly be categorized as interventions to reduce the burden of TB among people with the health-related risk factor or factors, and interventions to reduce the burden of comorbidities among people with TB (Table 6.1).

To review the level of implementation of these actions, it is necessary to meet the relevant stakeholders at national level. It is also necessary to visit the facilities and interview staff and clients, to assess how the respective health services that care for people with HIV, diabetes and other relevant health-related risk factors work to reduce the burden of TB among their clients and, conversely, how the TB services screen
for and address the relevant comorbidities among people in TB care. It is also critical to assess how the programmes work together and how the separate services collaborate to ensure a seamless continuum of care, follow-up and referral for the end users, reducing the time they need to attend health care services and reducing the costs for transport, out-of-pocket costs and time away from work. It is also important to assess how the interventions are recorded and reported.

Table 6.1  Health-related risk factors and TB comorbidities, with related interventions recommended in current WHO guidelines

<table>
<thead>
<tr>
<th>Health-related risk factors for TB</th>
<th>Interventions to reduce the burden of TB among people with comorbidities and health-related risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key drivers for TB</strong></td>
<td><strong>Find and treat TB</strong></td>
</tr>
<tr>
<td>Diabetes</td>
<td>✓</td>
</tr>
<tr>
<td>Disorders due to alcohol use</td>
<td>✓</td>
</tr>
<tr>
<td>HIV</td>
<td>✓</td>
</tr>
<tr>
<td>Smoking</td>
<td>☐</td>
</tr>
<tr>
<td>Undernutrition</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Other health-related risk factors and comorbidities</strong></td>
<td></td>
</tr>
<tr>
<td>Disorders due to drug use</td>
<td>✓</td>
</tr>
<tr>
<td>Silica exposure, silicosis</td>
<td>✓</td>
</tr>
<tr>
<td>Viral hepatitis</td>
<td>✓</td>
</tr>
<tr>
<td>Other clinical risk factors: treatment with anti-TNFα, a dialysis, organ or haematological transplantation</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities associated with poorer TB treatment outcomes</th>
<th>Interventions to reduce the burden of comorbidities among people with TB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key drivers for TB</strong></td>
<td><strong>Find and treat comorbidities</strong></td>
</tr>
<tr>
<td>Diabetes</td>
<td>✓</td>
</tr>
<tr>
<td>Disorders due to alcohol use</td>
<td>✓</td>
</tr>
<tr>
<td>HIV</td>
<td>✓</td>
</tr>
<tr>
<td>Smoking</td>
<td>✓</td>
</tr>
<tr>
<td>Undernutrition</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Other comorbidities</strong></td>
<td></td>
</tr>
<tr>
<td>COVID-19</td>
<td>✓</td>
</tr>
<tr>
<td>Mental disorders</td>
<td>✓</td>
</tr>
<tr>
<td>Viral hepatitis</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ = recommendation exists; ☐ = currently no recommendation.
* Currently, there is no recommendation on TB screening for people receiving treatment with anti-TNFα; however, treatment of TB infection is recommended.
6.3 People and organizations to meet

The main people and organizations to meet are:

► national TB programme (NTP) manager and focal points for the related comorbidities;
► national AIDS control programme manager and focal points, and the programmes or ministry of health departments overseeing NCDs, tobacco use, substance use disorders, nutrition and primary health care;
► people with TB and the different comorbidities or health-related risk factors;
► health care workers in the public and private sector, community workers and peer supporters;
► representatives of professional associations;
► international agencies funding or supporting the related comorbidities, such as the United States (US) Centers for Disease Control and Prevention (CDC), the US President’s Emergency Plan for AIDS Relief (PEPFAR) implementing agencies, the Joint UN Programme on HIV/AIDS (UNAIDS), the UN Office on Drugs and Crime (UNODC), the UN Refugee Agency (UNHCR), the United Nations Children’s Fund (UNICEF), the United States Agency for International Development (USAID) and the World Food Programme;
► civil society organizations, nongovernmental organizations and community-based organizations working on TB or related comorbidities; and
► workers in other settings such as prisons, refugee camps, drop-in centres for people who use drugs, the mining sector, and feeding and nutritional rehabilitation centres.

6.4 Key areas and sample questions

Burden

► What is the burden and spread of comorbidities and risk factors among the general population and among people with TB, and what is the impact on TB treatment outcomes? Is the burden higher among any particular populations (e.g. geographical area or specific populations)?
► How are the programmes or health facilities performing on the recommended interventions (e.g. TB screening, comorbidity assessment, initiation of comorbidity treatment or management, TB treatment outcomes, TB preventive treatment [TPT] and TB infection prevention and control [IPC], and comorbidity prevention)?
► What are the identified or perceived reasons for a difference in treatment outcomes compared with other people with TB?

Governance

► How is the response to TB and each of the comorbidities coordinated, and who is represented in the national, regional and district coordination bodies?
► How is the response to each comorbidity funded, both at domestic level and externally?
► Which comorbidities are addressed in the NSP for TB? Is TB addressed in the NSPs for the various comorbidities?
► Which policies are in place to address TB/HIV and other comorbidities? Are they in line with the latest WHO policies?

Coverage

► What is the geographical coverage of the services for TB and for each of the comorbidities, including in primary care, private providers and other sectors (e.g. prisons) and for vulnerable populations (e.g. migrants, miners and people who use drugs)?
Thematic tool 6

- What is the coverage of the combined TB and comorbidity services? What are the barriers and the opportunities for further expansion?
- What is the extent of integration at each level of the health system, and what are the opportunities for integrated service delivery down to community level?

Patient perspective
- How accessible are the services for people with TB and the various comorbidities? Do those people have appointments at the same time with the same provider? If not, what mechanisms are in place for linkage between services?
- What is the financial burden to the end user in accessing care for both conditions or all comorbidities?
- Are clients well informed about the dynamic between TB and the comorbidity or comorbidities they have, their treatment and prevention regimens?
- Do clients have access to existing social protection schemes, psychosocial support or other treatment support?

Health care worker perspective
- What is the capacity of the workforce to provide people-centred care for TB and comorbidities, and what is their acceptance of such patients?
- How are staff mentored and supervised?
- When were staff last trained?
- Which staff can do what and is there room for task sharing?
- What challenges do staff face?

Infrastructure, equipment and supplies
- How are the facilities designed, equipped and supplied with tools, commodities and standard operating procedures (SOPs) for assessing, diagnosing, treating and preventing TB and the different comorbidities according to WHO recommendations?
- Are the screening and diagnostic tools in place (e.g. scales, height measure, diabetes test strips, HIV tests, and screening questionnaires for mental illness, substance use and tobacco use in TB services); for comorbidity services, are there TB screening and diagnostic algorithms, molecular WHO-recommended diagnostic tests (WRDs) or regular linkage by sample transportation to the TB laboratory network, and lateral flow urine lipoarabinomannan (LF-LAM) test (for HIV facilities)?
- Are the drugs for treatment and prevention available for TB treatment, TPT (for people living with HIV, and people who use drugs), metformin and insulin (for people with diabetes) and opioid agonist maintenance treatment (for people who use drugs); also, are nutritional supplements and food packages available?
- What barriers prevent patients from accessing these commodities?
- How does the structure of the facilities support safe, people-centred care, including IPC and patient confidentiality for counselling?

Monitoring and evaluation
- How are data on TB and the various comorbidities captured? How have the recording and reporting tools been adapted to include such data?
- Are the health management information systems (HMIS) linked?
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- Which indicators are captured at patient level and which are reported to national level?
- How complete are the data?
- How and how often are the data reconciled between the different programmes?
- Are the systems digitized? Are there unique patient identifiers?
- What level of understanding do health care workers have about the joint burden at facility level, and do they receive feedback on the bigger picture?

6.5 Indicators

Indicators are listed in Table 6.2. Countries have largely adopted indicators for HIV-associated TB. For more information and additional indicators, please see the relevant publications in the ‘Useful resources’ section below.

WHO does not currently collate data on TB and the other comorbidities and risk factors, but suggested indicators for the screening and prevalence of diabetes and undernutrition are given in Table 6.2. The same approach may be used for other comorbidities.

Table 6.2. Indicators for comorbidities

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number and proportion of registered new and relapse TB patients with documented HIV status</td>
<td>Number and proportion of new and relapse TB patients notified during the reporting period tested for HIV at the time of TB diagnosis or with documented HIV status at the time of TB diagnosis, expressed as a percentage of the number of registered new and relapse TB patients. This indicator is reported by the NTP to the WHO Global TB Programme. Source: A guide to monitoring and evaluation for collaborative TB/HIV activities</td>
</tr>
<tr>
<td>Number and proportion of registered new and relapse TB patients with documented HIV-positive status</td>
<td>Number of registered new and relapse TB patients who are found to be HIV-positive, expressed as a percentage of the number registered with documented HIV status during the reporting period. This indicator is reported by the NTP to the WHO Global TB Programme. Source: A guide to monitoring and evaluation for collaborative TB/HIV activities</td>
</tr>
<tr>
<td>Proportion of HIV-positive new and relapse TB patients on ART during TB treatment</td>
<td>Number of HIV-positive new and relapse TB patients who receive ART during TB treatment, expressed as a percentage of those registered during the reporting period. This indicator is reported by the NTP to the WHO Global TB Programme. The numerator should match the numerator for ART coverage reported by the national AIDS programme. Source: A guide to monitoring and evaluation for collaborative TB/HIV activities</td>
</tr>
<tr>
<td>Percentage of estimated HIV-positive incident TB cases who received treatment for both TB and HIV</td>
<td>Number of HIV-positive new and relapse TB patients started on TB treatment during the reporting period who were already on ART or started on ART during TB treatment within the reporting year, expressed as a percentage of the number of people estimated to have HIV-associated incident TB. This indicator is reported by the national AIDS programme to UNAIDS. The numerator should match the numerator for ART coverage reported by the TB programme. Source: UNAIDS Online reporting tool</td>
</tr>
<tr>
<td>Percentage of people newly enrolled on HIV treatment who are diagnosed with TB disease</td>
<td>Total number of people living with HIV with active TB, expressed as a percentage of those who are newly enrolled on HIV treatment during the reporting period. This indicator is reported by the national AIDS programme to UNAIDS. Source: UNAIDS Online reporting tool</td>
</tr>
</tbody>
</table>
## Thematic tool 6

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of people enrolled on ART who started TPT</td>
<td>Number of people who started TPT, expressed as a percentage of the total number of people on ART during the reporting period. This indicator should be disaggregated by people living with HIV newly enrolled on ART and all people currently on ART. This indicator is reported by the national AIDS programme to UNAIDS. Source: UNAIDS Online reporting tool</td>
</tr>
<tr>
<td>Percentage of people living with HIV initiating TPT and on ART who completed a course of TPT</td>
<td>Number of people on ART who completed TPT among those who initiated any course of TPT during the previous year (i.e. during 2023, outcomes for people starting TPT in 2021 should be reported). This indicator is reported by the national AIDS programme to UNAIDS. Source: UNAIDS Online reporting tool</td>
</tr>
<tr>
<td>Percentage of new and relapse TB patients assessed for known diabetes status or tested for diabetes by WHO diagnostic criteria at the time of TB diagnosis</td>
<td>Number of new and relapse TB patients assessed for known diabetes status or tested for diabetes by WHO diagnostic criteria at the time of TB diagnosis, expressed as a percentage of the number of notified new and relapse TB patients. Source: Adapted from the Collaborative framework for care and control of tuberculosis and diabetes</td>
</tr>
<tr>
<td>Percentage of new and relapse TB patients that have been assessed or tested for diabetes and have diabetes</td>
<td>Number of new and relapse TB patients assessed for known diabetes status or tested for diabetes, expressed as a percentage of the number of notified new and relapse TB patients who were assessed for known diabetes status or tested for diabetes by WHO diagnostic criteria at the time of TB diagnosis. Source: Adapted from the Collaborative framework for care and control of tuberculosis and diabetes</td>
</tr>
<tr>
<td>The percentage of new and relapse TB patients whose nutritional status is assessed</td>
<td>The number of new and relapse TB patients whose nutritional status is assessed, disaggregated according to age group (&lt;5 and ≥5 years).</td>
</tr>
<tr>
<td>The percentage of new and relapse TB patients who received a nutritional status assessment with SAM</td>
<td>The number of TB patients with SAM according to WHO diagnostic criteria for SAM, expressed as a percentage of the number of new and relapse TB patients whose nutritional status is assessed, disaggregated according to age group (&lt;5 and ≥5 years).</td>
</tr>
</tbody>
</table>


### Useful resources

Useful resources for this tool include:

- WHO's TB guidelines on screening, diagnosis, prevention and treatment on the WHO TB knowledge sharing platform:

- WHO guidelines on TB and comorbidities:
Thematic tool 6


WHO guidance on indicators for HIV-associated TB:


Thematic tool 7

Tuberculosis infection prevention and control

This tool covers assessment of tuberculosis (TB) infection prevention and control (IPC).

7.1 Objectives

At the end of the review, experts should be able to comment on how TB-IPC measures are implemented at different levels in the health services. The measures are:

- administrative controls;
- environmental controls;
- respiratory protection; and
- core components of IPC as they apply to TB.

TB laboratory biosafety is generally dealt with separately from TB-IPC, and assessment of biosafety should be coordinated with the experts reviewing the laboratory services.

7.2 Background

The World Health Organization (WHO) End TB Strategy calls for a 90% reduction in TB deaths and an 80% decrease in the TB incidence rate by 2030. The strategy emphasizes the need for prevention across all approaches, including TB-IPC at health care facilities and other settings where the risk of *Mycobacterium tuberculosis* transmission is high. TB-IPC measures and practices are vital to reduce the risk of transmission, by reducing the concentration of infectious particles in the air and the exposure of susceptible individuals to such particles.

7.3 Staff to be interviewed

The main personnel that have a role in implementation of TB-IPC and may be encountered as part of the programme review are:

- *managerial staff* – at national, subnational and health facility levels contributing to the national TB programme (NTP) and the national HIV/AIDS programme, and other individuals such as civil engineers, managers at hospitals and primary health care facilities and long-term residential facilities, prison health services, and migrant facilities; and
- *health workers and community health workers* – involved in TB and HIV care, household contact evaluations, infection control officers, and diagnostic services in health care facilities (in both public and private primary and secondary health sectors and other services).

7.4 Key questions to answer

The main questions to be answered in this assessment are given below; those marked by an asterisk are the most relevant nationally.

Policies and core components of IPC

- Are guidelines and institutional arrangements for infection control adequate in scope and do they focus sufficiently on airborne infection control (e.g. is there an IPC committee at the health facility level and does its mandate include airborne IPC)?
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➤ Are there infection control risk assessments and plans for selected high-risk settings?
➤ Have staff been trained or sensitized on airborne infection control in the past year?

**Administrative controls**

➤ Are administrative controls and measures in place to reduce the transmission of *M. tuberculosis* by patients with infectious TB at facilities?
  — Are staff designated to oversee IPC activities in the health facility?
  — Are staff designated to implement triage, separation and fast tracking of individuals with TB symptoms?
  — Are respiratory protection tools provided for staff and visitors (e.g. N95 masks for health care workers, and surgical masks)?
  — Is there a policy to ensure that TB treatment is started promptly among individuals diagnosed with TB?
  — Is patient education material provided (e.g. audiovisual aids in patient waiting areas giving information on cough etiquette and respiratory hygiene; and posters and pamphlets providing key messages to reduce airborne infections)?
  — Are health care workers offered annual TB screening (e.g. chest radiography and tests for TB infection) and provided with TB preventive treatment?

**Environmental controls**

➤ Is the infrastructure of health care facilities adequate for the implementation of TB-IPC?
➤ Is the patients’ waiting area well ventilated?
➤ Are the seating arrangements in the doctor or staff consulting rooms and hospital wards appropriate? Is there cross ventilation?
➤ Is any form of mechanical ventilation (e.g. exhaust fans and use of high-efficiency particulate air [HEPA] filters) used to ensure frequent air changes, or are upper-room ultraviolet germicidal irradiation (UVGI) systems employed?
➤ Is there a need for structural changes in the health facility to facilitate control of airborne infection? Who is responsible for health facility maintenance and renovation?

**Respiratory controls**

Do staff use respiratory protection equipment appropriately (e.g. N95 respirators and surgical masks)?
If respirators are used, are they fit tested when supplied to staff?

### 7.5 Indicators

Table 7.1 lists the indicators for TB-IPC and the source of information for each indicator.
Table 7.1  Indicators for TB-IPC

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Source of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of health facilities that have a valid (i.e. updated) TB-IPC plan</td>
<td>Policy document from the NTP, field visits and survey data</td>
</tr>
<tr>
<td>Proportion of health facilities that have an appointed TB infection control focal person as a part of the facility’s IPC committee</td>
<td>Policy document from the NTP, field visits and survey data</td>
</tr>
<tr>
<td>Rate of TB in health care workers per year compared with the TB notification rate in the general population</td>
<td>Surveillance data</td>
</tr>
<tr>
<td>Proportion of health care workers involved in the care of MDR-TB or in the collection of sputum samples who are provided with at least one N95 respirator per week</td>
<td>Field visits</td>
</tr>
</tbody>
</table>

IPC: infection prevention and control; MDR-TB: multidrug-resistant TB; NTP: national TB programme; TB: tuberculosis.

7.6 Useful resources

Useful resources for TB-IPC are the relevant publications from WHO on this topic and on laboratory biosafety:


Human resources

This tool covers the use of human resources (HR) for tuberculosis (TB) prevention, care and control activities.

8.1 Objectives
At the end of the review, experts should be able to comment on:
► existing staffing, in terms of distribution and organogram;
► capacity-building;
► implementation status as per the national strategic plan (NSP) for TB or the country’s HR for health (HRH) roadmap;
► gaps in HR in terms of the number of staff and their skills;
► actions that need to be taken to improve and strengthen HR management;
► policies for staff development for quality improvement; and
► staff retention.

8.2 Background
For TB prevention, care and control activities, HRH includes all staff who make each individual intervention and public health intervention happen. Without sufficient staff who are adequately trained, motivated, skilled, readily available (i.e. well distributed among facilities) and supported, it will not be possible to achieve global TB-control targets. In addition, a lack of HR often limits the capacity of countries to absorb resources from donor agencies.

8.3 Location
At the national level, the sites to be assessed will be the HR management unit, the continuous medical education unit, the national TB programme (NTP) management office, the national public health laboratory and the national TB reference laboratory.

At the subnational level, the sites will be subnational health offices, basic management units, TB clinics and TB laboratories.

8.4 Staff to be interviewed
In national and subnational health authorities, staff to be interviewed will be TB managers and the HR manager.

8.5 Documents to be reviewed
The documents to be reviewed will be HR documents related to health policy, organograms and organizational structures.
8.6 Key areas and sample questions

**Task analysis**
Given that HR requirements differ for the various tasks associated with the NTP, what are the implications of this for the workforce?

**NTPs’ HR**
- What is the current HR situation at all levels of the NTP?
- What are the strengths and gaps?
- Will more staff be needed as the programme expands and staff take on additional roles and responsibilities?

**Capacity-building activities**
- What capacity-building activities are currently undertaken (e.g. pre-service training, in-service training, regular training, development or updating of the training curriculum or plan)?
- Is there an annual training plan for the NTP? If so, is this plan being implemented?

**Quality management processes**
- What mechanisms are in place for quality management (e.g. incentives, performance management and supervision)?

**Addressing potential gaps**
- What types of solutions and activities to address potential gaps would be sustainable?

**Funding**
- What are the investment and budget sources for activities related to HR?

8.7 Indicators for assessing HR development

**Table 8.1 Indicators for assessing HR development**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Calculation</th>
<th>Source of information</th>
</tr>
</thead>
</table>
| Proportion of health facilities with at least one health worker trained in the national strategy for TB prevention, care and control | Numerator: number of health facilities with at least one health worker trained in the national TB prevention, care and control strategy in a specified geographical area  
Denominator: total number of health facilities in the same area | Periodic surveys          |
| Proportion of posts filled according to the development plan for HR        | Numerator: number of posts filled according to the development plan for HR  
Denominator: total number of posts that should be filled according to the development plan for HR | Periodic surveys          |

HR: human resources; TB: tuberculosis.

**Useful resources**
A useful resource for assessing HR and TB is the following World Health Organization publication:
- Tool to assess the impact of human resources for health investments on HIV, TB and malaria services and health outcomes. Geneva: World Health Organization; 2022  
  (https://apps.who.int/iris/handle/10665/352552).
Managing procurement and supply of anti-TB medicines and other health products

This tool covers the management of the procurement and supply of medicines against tuberculosis (TB) and other health products.

9.1 Objectives
At the end of the assessment, reviewers should be able to comment on:
► availability of anti-TB medicines – including those for children and for treating drug-sensitive TB (DS-TB) and drug-resistant TB (DR-TB), and for TB preventive treatment (TPT) – and TB diagnostic products;
► procurement processes and the quality assurance system;
► systems used for distribution and storage system;
► supply and management of pharmaceuticals and supplies;
► rational use of medicines; and
► any measures that need to be taken to improve the management of medicines and supplies.

9.2 Background
A good TB strategy requires adequate quantities of quality-assured medicines (Box 9.1) to be available whenever they are needed by patients and health workers. It also requires a good quality laboratory and an uninterrupted supply of materials needed for diagnosis and treatment monitoring. Managing the supply of anti-TB medicines includes taking essential steps to select, procure, distribute and ensure rational use of the medicines.

9.3 Location
The main sites to be assessed are the national, regional or provincial medicine and supply warehouses, and the basic management unit or pharmacies at TB clinics and private pharmacies.

9.4 Staff to be interviewed
Staff to be interviewed include TB coordinators, pharmacists, staff at the medicine and supply warehouses, and members of any procurement and supply management thematic working groups.

9.5 Key areas and sample questions
Selection
► Are medicines and other health products selected in line with the national guidelines and national essential medicines lists (nEMLs)? Are nEMLs and national guidelines promptly updated, based on the most recent guidance from the World Health Organization (WHO)?
► Are the selected medicines registered by the national regulatory agencies in the local market?
  — If the medicines are registered, are they quality assured?
  — If the medicines are not registered, what mechanism is being used to procure them?
Thematic tool 9

► Does the national legislation allow for access to international markets?
► Is domestic or donor funding available for the medicines and supplies listed below? If both domestic and donor funding is available, what is the contribution of each (as a percentage)? Is there a funding gap for procurement? Medicines and supplies for which information should be sought are as follows:
   — medicines for treatment of DS-TB (for adults and for children);
   — medicines for treatment of DR-TB (for adults and for children);
   — medicines for TPT (for adults and for children);
   — ancillary medicines for the management of adverse drug reactions; and
   — medical devices or diagnostics, and other health products.

Supply planning and procurement procedures
► What is the process for quantification and forecasting for anti-TB medicines?
► What tools are used for quantification and forecasting for anti-TB medicines?
► How accurate is demand forecasting of the need for anti-TB medicines?
► How often is the quantification (and re-quantification) done?
► What is the frequency of procurement and delivery for anti-TB medicines?
► Who is in charge of placing orders for procurement of medicines, medical devices, diagnostics and other health products?
► How are the medicines, medical devices, diagnostics and other health products procured – are they procured through donor funding or through domestic funding?
► Who is in charge and what is done to ensure that funds are disbursed and orders are placed in a timely fashion, so that products arrive as per delivery schedules?
► Who is in charge of ordering and receiving anti-TB medicines and supplies?
► What are the procedures used to verify and document the quantities of medicines received?
► Is procurement and supply management (including distribution and storage of medicines, diagnostics and other ancillary supplies) integrated with other programmes?
► Are pharmaceuticals and other health products available when needed?
► Are child-friendly formulations for DS-TB, DR-TB and TPT available?
► What mechanisms are used to ensure quality? Are stored medicines sampled and tested regularly? What is the procedure for handling expired anti-TB medicines?
► What are the mechanisms to ensure affordable prices for quality-assured products?

Distribution and storage
► What process is used for importation of medicines, including port and customs clearances, and registering of medicines?
► What is the distribution system for TB commodities (are there flowcharts of the system)?
   — How are products issued and distributed (e.g. which tools are used and what is the process for validation of orders)?
   — What is the frequency of stock replenishment (including transport) and how is it managed?
   — What is the average lead time for resupplying products?
— Are there any challenges related to the distribution of TB commodities and possible solutions?

► Are good storage practices being used (e.g. storage condition, temperature and humidity);
— Are the stocks well organized in the storage area (e.g. placed on shelves or pallets, and with adequate spacing)?
— Are storage conditions (e.g. cleanliness, security, temperature, humidity control and fire safety) adequate?

► Is there a logistics management information system (LMIS) in place? If so:
— What are the recommended LMIS tools?
— Are those tools updated?
— Is the LMIS integrated with or linked to the TB information system?
— Which TB information or data are collected from the LMIS, and how frequently?
— What is the current LMIS reporting rate and level of data quality (e.g. timeliness, completeness and accuracy)?

► Can the LMIS generate information that includes a safety stock and information for forecasting needs for medicines and supplies? How often are regular physical quality checks conducted and documented?

► Are medicine kits available for treating individual patients? If so, who organizes the availability of such kits and what duration of treatment do the kits cover?

► Is the rotation of stocks using the “first expiry, first out” (FEFO) principle in place? (If FEFO is in place, it is best to inspect a few packs of medicines and self-organized kits for patients to ensure that FEFO is being followed in practice).

► Is there a buffer or are there safety stocks of anti-TB medicines? If so, how long should the buffer stock last at different levels of the health service (e.g. national, provincial and health facilities); for example, would stocks last 3 months?

► Have there been any medicine stock-outs during the past year? If so, which medicines were affected, and for how long? (If stock-outs have occurred, explore the reasons for this; for example, determine whether incorrect amounts were ordered, deliveries arrived late from the regional or national store, or some medicines expired.)

► Have there been any excess stocks of anti-TB medicines during the past year? If so:
— What medicines were affected, and in what quantities?
— Did any medicines expire before they were used? (If medicines expired, explore the reasons for excess stock; for example, determine whether incorrect amounts were ordered or there were changes in the number of patients, regimens or formulas.)

► How are medicines that are near expiry or expired managed, to ensure that all medicines are consumed (to avoid wastage)?

► Are there procedures in place to dispose of expired medicines in the national warehouse?

► How are orders for anti-TB medicines calculated? How are quantities of buffer or safety stocks calculated?

► Are staff appropriately trained in forecasting, quantification, procurement, and supply planning and management? If yes, determine whether staff are trained in using tools for quantifications (e.g. QuanTB tool). Also, is training of trainers undertaken to ensure that sustainable procurement is not adversely affected by staff turnover?

► Are medicines and supplies regularly distributed from the national level to the regional and peripheral levels?
Thematic tool 9

► Is there an early warning system (EWS) in place? If yes:
  — At which levels does the EWS operate (e.g. national, regional or facility)?
  — What tools are used for the EWS?

Rational use

► In relation to regulations on prescribing and dispensing medicines:
  — What national regulations apply to over-the-counter sales?
  — Are the current regulations for over-the-counter sales implemented?

► What mechanisms are in place to enforce national regulations on prescribing and dispensing medicines?

► In relation to active drug safety monitoring and management (aDSM) and pharmacovigilance (PV) monitoring systems:
  — Is there a national PV system (e.g. PV centre and forms)? If so, what is the current reporting rate? How many of the notifications and reports are related to TB medicines?
  — Is there an aDSM system for TB medicines? If so, who manages the system, and what processes and approaches are used?
  — Are there any challenges related to aDSM and PV monitoring? If so, what are the possible solutions to these challenges?

► Are medicines (i.e. regimen and daily dosage) administered according to the national treatment guidelines and protocols? 9.6 Indicators

Table 9.1 lists the indicators to be used in assessing the management of pharmaceuticals. Box 9.1 provides suggestions for a quality assurance policy for anti-TB medicines.

Table 9.1  Indicators for management of pharmaceuticals

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Calculation</th>
<th>Source of information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of months that will be covered by the existing stock, including buffer or safety stock at a TB clinic or treatment centre</td>
<td>Quantities of anti-TB medicines available for the number of TB patients expected to be treated within the coming months Readily available months of stock in quantification files</td>
<td>TB treatment register and individual stock registers Reports from TB information systems or quantification files (e.g. QuanTB files)</td>
</tr>
<tr>
<td>Percentage of time anti-TB medicines (both first-line and second-line) and other health products were out of stock</td>
<td>Numerator: total number of stock-out days for a full set of anti-TB medicines of DS-TB treatment × 100 Denominator: 365 × number of anti-TB medicines usually in stock (Note: this calculation also applies to other health products)</td>
<td>TB treatment register and individual stock registers</td>
</tr>
<tr>
<td></td>
<td>Numerator: total number of stock-out days for a full set of core anti-TB medicines for DR-TB treatment × 100 Denominator: 365 × number of anti-TB medicines usually in stock (Note: this calculation also applies to other health products)</td>
<td>TB treatment register and individual stock registers</td>
</tr>
<tr>
<td>Value of expired anti-TB medicines during the most recent quarter</td>
<td>Sum of the number of units expired for each medicine × unit cost for each medicine</td>
<td>Order receipt</td>
</tr>
</tbody>
</table>

Box 9.1 Quality assurance policy for anti-TB medicines

Major international donors and agencies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), WHO, a United Nations Children’s Fund (UNICEF), United Nations Population Fund (UNFPA) and Stop TB/Global Drug Facility (GDF) have adopted a harmonized policy for quality assurance of supplied medicines. All medicines procured with Global Fund finances or supplied by the GDF follow this policy. Products are considered quality assured if they are approved by any of the following:

WHO Prequalification of Medicines Programme (PQP)

► The PQP prequalifies pharmaceutical and diagnostic products that are considered to be acceptable for procurement by the United Nations and specialized agencies. WHO regularly publishes the list of prequalified products (see https://extranet.who.int/pqweb/medicines/prequalified-lists).

Stringent regulatory authority (SRA)b

► SRAs are defined by WHO (see https://www.who.int/initiatives/who-listed-authority-reg-authorities)

Expert review panel (ERP)

► If no WHO-prequalified or SRA-approved products are available, countries may select a product recommended by an ERP for time-limited use (12 months) (see https://www.theglobalfund.org/media/4757/psm_productstb_list_en.pdf and https://extranet.who.int/prequal/sites/default/files/documents/73%20ERP_Feb2016_1.pdf).

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Thematic tool 10

Public–private mix approaches

This tool covers assessment of public–private mix (PPM) approaches to tuberculosis (TB).

10.1 Objectives
At the end of the review, experts should be able to comment on:
► the strength of collaborations among public–public and public–private providers;
► the impact of those collaborations;
► the implementation status as per the plan – either the country's national strategic plan for TB (NSP) or its PPM roadmap;
► any weaknesses and gaps in the collaborations;
► the scope and quality of the collaborations; and
► actions that need to be taken to improve and strengthen collaborations among the different providers.

10.2 Background
The delivery of care for TB patients through public-sector health services is generally the main focus of the national TB programme’s (NTP’s) activities. However, many patients with symptoms of TB, including patients who are very poor, seek and receive care from a variety of private and public health care providers outside the network of the NTP’s services.

10.3 Location
At the national level, the main sites for assessment are the NTP and ministerial departments.
At the field level, the main sites are basic management units, TB clinics, private health facilities and public-sector facilities not directly affiliated with the NTP that refer, diagnose or manage TB patients.

10.4 People to be interviewed
People to be interviewed for this assessment are TB managers, private and public care providers, and other relevant staff (e.g. health insurance officers).

10.5 Documents to be reviewed
Documents to be reviewed for this assessment are the NSP, the national PPM roadmap, relevant reports (e.g. patient pathway analysis, in published and unpublished studies) and annual reports.

10.6 Key areas and sample questions
This section gives examples of questions that could be asked in key areas.
Thematic tool 10

Rationale
Considering the rationale for engaging care providers, what are the patient’s preferences, what are the private-sector dynamics and what is the evidence?

Policy
Does the NSP include a PPM policy? Is there an operational guidance using local experiences?

Funding
Has funding been allocated for PPM activities? If so, is that funding adequate?

Partnerships
Have partnerships been established with different service providers (e.g. laboratories testing for drug-susceptible TB [DS-TB] and drug-resistant TB [DR-TB])? If so, what is their scope and strength?

Models of engagement
What models of engagement are being used? Does the NTP use incentives and enablers?

International TB standards
Do other sectors (i.e. outside the public health system) follow international standards of TB care?

Monitoring
What mechanism is used to monitor the PPM approach?

Digital technology
Is digital technology used in PPM-related surveillance? If so, how is it used?
10.7 Indicators for assessing PPM approaches to TB

Table 10.1 Indicators for assessing public–public and public–private mix approaches to TB

<table>
<thead>
<tr>
<th>Category</th>
<th>Indicator</th>
<th>Indicator definition</th>
</tr>
</thead>
</table>
| Outcome               | Successfully treated                | **Numerator**: number of notified (new and relapse) patients with DS-TB who are cured or completed treatment
|                       |                                     | **Denominator**: number of new and relapse patients with DS-TB notified to the national TB surveillance system                                           |
| Service coverage      | Initiated on TPT                    | Number of household contacts (or all close contacts) who were started on TPT, among those who were eligible                                              |
|                       | Received program drugs              | Number of notified patients who received government-procured anti-TB drugs as per the NTP protocol                                                    |
|                       | Bacteriologically confirmed         | Number of patients notified with bacteriologically confirmed pulmonary TB                                                                         |
|                       | Testing using WRD                   | Number of notified new and relapse TB cases tested initially with a WRD                                                                         |
|                       | Testing bacteriologically confirmed for drug resistance | Number of patients notified with bacteriologically confirmed pulmonary TB with DST results for rifampicin |
| Surveillance          | Presumptive TB patients             | Total number of individuals with presumptive TB                                                                                                   |
|                       | Notified TB patients                | Number of new and relapse TB patients notified to the national TB surveillance system                                                                |
| Provider coverage     | Providers active                    | Number of private and parastatal providers notifying at least one TB patient to the NTP during a calendar year                                         |


10.8 Useful resources

The World Health Organization and partners have produced a roadmap for PPM for TB:

Thematic tool 11

Multisectoral collaboration and accountability

This tool covers the assessment of multisectoral collaboration and accountability in the context of tuberculosis (TB).

11.1 Objectives
At the end of the review, experts should be able to comment on:
 ► the commitment of the government, ministry of health and sectors beyond the health sector;
 ► the accountability mechanism;
 ► the scope, strength and quality of the collaborations among various sectors;
 ► the impact of those collaborations, including definition of roles and responsibilities of other sectors and performance indicators;
 ► the implementation status as per the national strategic plan (NSP) for TB, or the country’s MAF framework or checklist;
 ► any weaknesses and gaps in the collaborations; and
 ► actions that need to be taken to improve and strengthen collaboration among the various sectors.

11.2 Background
TB is mainly concentrated in settings beset by poverty and other social and economic challenges, and among the most vulnerable populations. Factors such as poverty, undernourishment, and poor living and working conditions affect how people become infected, develop TB and cope with the demands of treatment; they also influence the health outcomes patients face. Thus, progress in fighting TB cannot be made by the health system alone. Progress requires firm political commitment at a higher level, strong multisectoral collaboration and an accountability system.

11.3 Location
At the national level, the main sites to be assessed are the national multisectoral coordination and review body or secretariat, and various ministries and sectors based on the country context (e.g. finance, planning, social welfare, labour, immigration, justice, defence and education).
At the field level, sites to be assessed are the subnational level multisectoral coordination secretariat and various sectors.

11.4 Staff to be interviewed
The main staff to be interviewed for this assessment are TB managers; staff of different ministries and sectors; and representatives of government, parliament, nongovernmental organizations (NGOs), civil society organizations (CSOs) and TB-affected communities.
11.5 Documents to be reviewed

The main documents to be assessed are the NSP, the national MAF, the completed MAF-TB baseline assessment checklist, recent mission reports, annual reports, TB legislation and policy (e.g. on labour and social support), reports (e.g. from NGOs, the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies operating in the country) and the national TB research plan.

11.6 Key areas and sample questions

**Commitment**
- Is the national level commitment in line with the global directions?
- What are the strengths and weaknesses of the commitments?

**Actions**
- Is there a multisectoral coordination mechanism; if so, by what modalities does it operate?
- Is there a multisectoral NSP or separate policy documents for national accountability?
- Which sectors within and beyond the health sector and stakeholders (e.g. private sector, CSO and affected communities, and United Nations agencies) are formally engaged, and what are the mechanisms of their engagement?
- Is the MAF baseline assessment checklist being used, and are the findings used for actions or planning?
- What is the status of implementation of the multisectoral actions on risk factors and social determinants of TB?
- Has an adequate and sustainable financing mechanism been defined? If so, does it involve a variety of sources of funding?

**Monitoring and reporting**
- Is there an established monitoring and reporting mechanism? If so, what is the status of its implementation?
- Is there an annual report (e.g. evaluations) identifying and monitoring the contribution of different sectors, based on predefined performance indicators?
- Does the annual national TB report include MAF-TB implementation?

**Review**
- Is there a formal national multisectoral and multistakeholder accountability and review mechanism, under high-level leadership?
- Are the reports of monitoring and reporting taken into consideration?
- What are the actions that need to be taken to improve and strengthen collaboration, and the actions of different sectors?
11.7 Indicators

Table 11.1 Basic indicators to monitor multisectoral collaboration and accountability

<table>
<thead>
<tr>
<th>Area</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Review mechanism</strong></td>
<td>Is there a national multisectoral and multistakeholder accountability and review mechanism, under high-level leadership, to monitor and review progress towards ending TB?</td>
</tr>
<tr>
<td></td>
<td>Do representatives of civil society and affected communities participate in the multisectoral accountability and review mechanism?</td>
</tr>
<tr>
<td><strong>Inter-ministerial</strong></td>
<td>To what extent are ministries (e.g. agriculture, defence, education, finance, justice, labour, social development and transport) or their equivalents engaged in the following aspects of the national TB response:</td>
</tr>
<tr>
<td><strong>collaboration</strong></td>
<td>► advocacy, information, education and communication;</td>
</tr>
<tr>
<td></td>
<td>► TB prevention and care;</td>
</tr>
<tr>
<td></td>
<td>► patient support including economic, social and nutritional benefits;</td>
</tr>
<tr>
<td></td>
<td>► not engaged; or</td>
</tr>
<tr>
<td></td>
<td>► not applicable.</td>
</tr>
<tr>
<td></td>
<td>In each case, briefly describe the ministry or sector and the area of collaboration, or leave empty if not applicable.</td>
</tr>
<tr>
<td><strong>Annual report</strong></td>
<td>Does the NTP (or equivalent) produce a publicly available annual report about the status of the TB epidemic and progress in response efforts?</td>
</tr>
</tbody>
</table>


11.8 Useful resources

Useful resources for MAF-TB are the following publications from the World Health Organization (WHO):


**Thematic tool 12**

**Social protection for people affected by tuberculosis**

This tool covers assessment of social protection for people affected by tuberculosis (TB).

### 12.1 Objectives

At the end of the review, experts should be able to comment on:

- the social protection needs of people affected by TB in the country;
- the policies and actions of the national TB programme (NTP) on social protection (including TB-specific programmes and TB-sensitive social protection schemes) available in the country;
- existing health and social care, and patient barriers hampering access to social protection for people affected by TB; and
- potential strategies to improve the delivery of and access to social protection to people affected by TB.

### 12.2 Background

Social protection is a fundamental human right and an integral component of people-centred care, which contributes to achieving the targets set in the End TB Strategy.

Social protection is commonly defined as a set of interventions that aim to reduce and eliminate poverty, vulnerability and risk. Such interventions may be carried out by the state, by nongovernmental actors (e.g. civil society organizations [CSOs] or religious organizations), by the private sector or through community initiatives and individuals. Annex 12.1 (below) provides examples of social protection schemes to consider during a situational assessment for a TB programme review.

During a TB programme review, the first step is to conduct a brief situational assessment and mapping of social protection initiatives (this is led by the NTP or other entities) with a particular focus on initiatives that are, or could be, supportive of the needs of people affected by TB along the continuum of care. This can be done as part of the desk review, then complemented and validated during the field review phase.

The second step is to identify barriers to accessing existing social protection mechanisms by TB patients – these barriers can be from the health and social care side (programmatic) and from the patient side.

Third step is undertaking an assessment to try to understand how existing schemes can be harnessed to increase coverage, adequacy of benefits, and quality of social care services among TB patients.

Lastly, reviewers should identify any potential need for new social protection schemes for TB patients and formulate suggestions for new social protection avenues within the overarching multisectoral policy dialogue to end TB.

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1 As defined in the World Health Organization (WHO) guidance on social protection for people affected by TB:
- TB-specific social protection: Interventions targeted at TB-affected households or individuals that aim to improve TB prevention, care and support (e.g. transport fees for patients with drug-resistant TB (DR-TB)).
- TB-sensitive social protection: Interventions that are not limited to TB-related issues but that can potentially affect TB prevention, care and control by targeting people who are at high risk of TB or are susceptible to the consequences of TB (e.g. a poverty reduction programme that is not designed specifically for TB patients but for which some TB patients may be eligible because they meet certain eligibility criteria such as place of residence or income level).
12.3 Location

At the national level, the main sites to be assessed are the central unit, ministerial departments (e.g. ministries of welfare, community and gender; development and poverty reduction; food security; employment; and health insurance), partner organizations (e.g. nongovernmental organizations [NGOs], community-based organizations [CBOs] and United Nations [UN] agencies), the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and CSOs.

At the subnational level, sites to be assessed are the basic management units, social care services, local NGOs and CBOs operating in social protection, and CSOs.

12.4 People to be interviewed

At the national level, the main people to be interviewed are NTP staff, social protection and welfare officers, health care staff, and staff of the Global Fund and CSOs.

At the subnational level, people to be interviewed are TB managers, health insurance managers, health care staff, social workers, TB patients and affected communities, including vulnerable populations (e.g. food insecure communities, people living in informal settings, people living with HIV and TB/HIV, internally displaced people, nomadic populations and cross-border populations).

Key areas and sample questions

**NTP’s social protection policies**
- Do NTP policies (e.g. the national strategic plan [NSP]) include social protection? If so, in what form?
- Has a nationally representative TB patient cost survey been conducted? If so, are the findings available?
  - Has a social protection mapping been undertaken as part of the development of the survey tool?
  - Has a dissemination event taken place or has a roadmap with recommendations for enhancing social protection been developed?

**Social protection needs**
- What are the key social determinants of health driving the TB epidemic in the country (Annex 12.2, below)?
- What are the TB-vulnerable populations in the country?
- Has a social protection needs assessment been conducted in the country?
- What form of social protection are TB patients likely to need throughout the continuum of care, and what is the best way to deliver such protection?

**Availability of social protection**
- Are TB-specific social protection schemes available to TB patients in the country? If so, what are the key features of these programmes:
  - eligibility criteria (i.e. are all TB patients eligible, or only those meeting specific criteria?);
  - targeting strategy (i.e. how are TB patients targeted and referred to this scheme?);
  - benefit type and size; and
  - benefit delivery strategy and duration of benefit (i.e. how do beneficiaries receive the benefit, how often and for how long?).
- Are TB-sensitive protection schemes available for TB patients in the country? If so, what are the key features of these programmes:
  - eligibility criteria (i.e. are all TB patients eligible, or only those meeting specific criteria?);
— targeting strategy (i.e. how are TB patients targeted and referred to this scheme?);
— benefit type and size; or
— benefit delivery strategy and duration of benefit (i.e. how do the beneficiaries receive the benefit, how often and for how long?).

**Social protection coverage**

► What is the estimated coverage of the identified TB-specific programme (or programmes) among TB patients?
► What is the estimated coverage of the identified TB-sensitive programme (or programmes) among TB patients?
► If these estimates are not immediately available, which stakeholders need to be engaged to generate these data?

**TB patient barriers to accessing social protection**

► What are the main barriers to accessing social protection experienced by TB patients:
  — *awareness and knowledge barriers* – patients are not aware of these services or their eligibility for them;
  — *stigma-related barriers* – patients are hesitant to seek help or are stigmatized by the social protection providers;
  — *administrative barriers* – patients do not have the minimum administrative requirements to access the benefits (e.g. bank account, permanent address or residency legal status); or
  — *socioeconomic barriers* – patients incur costs related to travel, administrative costs, waiting time and opportunity costs.

**Health and social care delivery system barriers to accessing social protection**

► What are the main barriers to accessing social protection from the health and social care delivery system side:
  — limited geographical coverage (i.e. the programme is not rolled out where most TB patients live);
  — eligibility criteria (i.e. TB patients do not meet, or only partially meet, the eligibility criteria for the programme);
  — limited financial and human resources that may limit the scope for expansion of the programme and may also make the benefits provided too small to effectively benefit TB patients; or
  — access and delivery points (e.g. offices may be located too far from patients).

**Impact of social protection**

► What is the estimated impact of existing social protection schemes on TB beneficiaries? Has this impact been documented?

**Monitoring, evaluation and research**

► What monitoring and evaluation (M&E) methods are being used (e.g. frequency of measurements and auditing)?
► What is the role of the NTP and other agencies in the M&E?
► Are there operational research studies evaluating the impact of social protection schemes in the country? If so, do any of these studies focus on TB?
Thematic tool 12

Stakeholder involvement and multisectoral action
► What sectors within and beyond health should be involved to implement new social protection schemes or to expand access to existing social protection for people with TB?

12.6 Useful resources
Useful resources for assessment of social protection for people with TB include the following:
► World Health Organization (WHO) guidance on social protection (upcoming).
► A report or publication from a nationally representative TB patient cost survey.
► The country’s NSP.
► National and subnational social protection reports from ministerial departments, NGOs, UN agencies, affected communities and CSOs.
► Documentation on TB social determinants in the country (including WHO’s global TB report).

Annex 12.1 Types of social protection schemes to consider during social protection mapping or situational assessment
The following types of social protection schemes may be identified and described:
► The country’s current TB-specific social protection schemes, such as:
  — cash transfers for TB patients (conditional or unconditional);
  — food support for TB patients (in kind, vouchers and cash allowance);
  — travel support for TB patients (in kind, vouchers and cash allowance);
  — housing support for TB patients;
  — vocational training, microcredit or enterprise support for TB patients; and
  — psychosocial support and management of drug use or addiction and other mental health problems for TB patients.
► General social protection schemes for which TB patients may be eligible:
  — social assistance:
    • cash or in-kind transfers (conditional or unconditional);
    • social security and pensions;
    • school feeding and support for intravenous nutrition;
    • subsidies (e.g. education and health);
  — social insurance:
    • health insurance;
    • unemployment insurance;
    • pensions (e.g. old age and disability);
  — labour market interventions:
    • vocational skills training programmes;
    • employment services; and
    • social services that facilitate mobility.
Thematic tool 12

- Rights-based country legislation:
  - right to employment protection;
  - right to social protection or services;
  - right to life; and
  - rights for those living with disability.


Annex 12.2 Key socioeconomic determinants of TB

WHO has developed a framework for monitoring the Sustainable Development Goals (SDGs) related to TB. The framework comprises 14 indicators for which a relationship with TB incidence could be established. Six of the 14 indicators are broader socioeconomic determinants:

- undernutrition;
- income equality;
- percentage of population living above the international poverty line;
- percentage of population covered by social protection and labour programmes;
- percentage of urban population not living in slums; and
- percentage of population with access to clean fuels and technologies for cooking.
Thematic tool 13

Research and innovation

This tool covers research and innovation in relation to tuberculosis (TB) prevention, diagnosis, treatment and care.

13.1 Objectives
At the end of the review, experts should be able to comment on the implementation and use of country-specific research in TB. The aim is to generate evidence that can support the national TB programme (NTP) to achieve the goals set in the national strategic plan (NSP) and the End TB Strategy.

13.2 Background
The full spectrum of research, from basic to implementation, is critical for developing new tools and strategies for better TB prevention, diagnosis, treatment and care.

In the Global Strategy for TB Research and Innovation, Member States agreed to accelerate research and innovation aligned to four objectives:

► create an enabling environment for high-quality TB research and innovation;
► increase financial investments;
► promote and improve approaches to data-sharing; and
► promote equitable access to the benefits of research and innovation.

The review will focus on the first three objectives, but include supplementary considerations for evaluating ongoing relevant research areas.

In implementing this assessment, it is best to establish a small multistakeholder working group under the ministry of health (MoH). The team should include staff from the MoH, academia, research institutes and civil society organizations (CSOs); it will map data sources, implement the assessment and draft recommendations.

13.3 Location
At the national level, the main sites to be assessed are the NTP, ministerial departments, academia and research institutions.

13.4 Staff to be interviewed
At the national level, the main staff to be interviewed are those in the NTP, ministerial departments, academia and research institutions.

13.5 Key areas, with indicators
There are three parts to the assessment of key areas:

► Part 1: Evaluate the TB research environment;
► Part 2: Assess epidemiological, operational, health system and social science research studies; and
► Part 3: Document research gaps during the review process.
**Part 1: Evaluate the TB research environment (as relevant)**

### Table 13.1 Indicators for assessing the research environment

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Examples of data and information to be reviewed (the list is not exhaustive)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Create an enabling environment for high-quality TB research and innovation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Potential (overall) measure (Indicator):</strong> Extent of government engagement in research networks and public-private partnerships for TB research and innovation, and time required for regulatory approval of clinical trial protocols and product evaluations</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Availability of a national TB research network or working group to guide a national research agenda setting and implementation</td>
</tr>
<tr>
<td></td>
<td>A country-specific TB research agenda (&lt;5 years) to guide country-specific action</td>
</tr>
<tr>
<td>1.2</td>
<td>Availability of local TB researchers and capacity-building opportunities for TB research</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Availability of international and local collaborative research initiatives (as necessary) to advance TB research and innovation</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Predictable regulatory processes for review of clinical trials and TB products</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Financial investments in TB research and innovation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Potential (overall) measure (Indicator):</strong> Nationally, proportion of gross domestic expenditure on research and development that is allocated to TB research</td>
<td></td>
</tr>
<tr>
<td>Checklist</td>
<td>Examples of data and information to be reviewed (the list is not exhaustive)</td>
</tr>
<tr>
<td>Funding allocated to TB research</td>
<td>Proportion of gross domestic spending on TB research and development</td>
</tr>
<tr>
<td></td>
<td>Numerical disaggregation of national budgeting and funding structures for TB research by discipline or research area (e.g. operational, clinical or epidemiological)</td>
</tr>
<tr>
<td></td>
<td>TB research expenditure from other sources (e.g. partnerships, private sector or philanthropy) as proportion of total funding for TB research</td>
</tr>
<tr>
<td><strong>Approaches to data-sharing</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Potential (overall) measure (Indicator):</strong> Extent of government efforts to establish or strengthen a well-resourced national open data initiative for TB research in various disciplines and sectors, and government contribution to timely, consistent, global data-sharing to guide global policy decision-making and development of new tools for TB</td>
<td></td>
</tr>
<tr>
<td>Checklist</td>
<td>Examples of data and information to be reviewed (the list is not exhaustive)</td>
</tr>
<tr>
<td>3.1</td>
<td>National health information and vital registration systems for the collection of high-quality data for reliable tracking of the TB epidemic</td>
</tr>
<tr>
<td></td>
<td>Other ways of measuring (periodically) TB disease burden (e.g. surveys of national TB prevalence, drug resistance, mortality and costs faced by TB patients and their households)</td>
</tr>
</tbody>
</table>
### Thematic tool 13

#### 3.2 Policies and practice for open access to and open data for scientific research financed by public funds

- National open access strategy
- Norms of open access for scientific data, including from programmes and censuses
- National policies and their effectiveness in ensuring the transparency of clinical trial data, including, for example, registration and disclosure of results in external registers and publications

MoH: ministry of health; NTP: national TB programme; TB: tuberculosis.

### Part 2: Assess epidemiological, operational, health system and social science research studies

- How many TB-specific epidemiological, operational, health system and social science research studies are ongoing? How are the achievements or gaps in this area affecting the country's progress towards targets set in the NSP?
- Do the ongoing studies address the needs of vulnerable populations or address issues perceived to be important by affected communities? Such studies include those that assess structural, social, behavioural and cultural barriers to TB services.
- Is there a culture of dissemination of research findings with the NTP or in scientific journals? If possible, in advance of the review, implement a literature review to identify the number of country-specific manuscripts on TB, published in local and international journals over the past 1–5 years.
- How useful were the results of the studies, either to the NTP or for achieving goals set in the NSP? For example, did studies assess the feasibility, acceptability, effectiveness and impact of new interventions on health outcomes, and broader benefits to communities, health care systems and economies to support rapid uptake and integration of TB tools? Also, did studies stimulate programme quality improvements, including in the design and implementation of health systems, and more efficient methods of service delivery?
- Has the NTP taken actions based on the results of these studies?

### Part 3: Document research gaps during the review process

The research review team may also request other thematic review leads to document research gaps they note during the course of their review.

### 13.6 Useful resources

Useful resources for assessment of research include the following publications from the World Health Organization (WHO):

Thematic tool 14

Engagement of communities and civil society in the national tuberculosis response

This tool covers the engagement of communities and civil society organizations (CSOs) in the national response to tuberculosis (TB).

14.1 Objectives
At the end of the review, experts should be able to comment on:

► the effectiveness of the current engagement of communities and CSOs to end TB;
► to what extent this engagement contributes to key TB outcomes and targets of the national strategic plan (NSP), including:
  — meaningful engagement of communities and CSOs in efforts to end TB, planning for the national TB programme (NTP), decision-making, implementation, and monitoring and evaluation (M&E);
  — the role played by communities and CSOs in efforts to end TB; and
  — recommendations on how the involvement of communities and CSOs can be improved.

14.2 Background
The engagement of communities and CSOs to end TB is anchored in a person-centred approach that builds on existing global health commitments. Viewing community and health care as a single system means that the health and community components complement each other and represent a continuum of roles and actions. Meaningful engagement of community and CSO stakeholders is key for ending TB at local, subnational and national levels, because of their expertise in community needs and solutions, with an emphasis on community leadership, government-supported integrated care and multisectoral action. Communities and CSOs are context specific; thus, health systems need to collaborate with community leaders and representatives to define the stakeholders who can meaningfully engage in the TB response, and to identify their strengths, capacities and specific roles.

14.3 Location
The main sites to assess are the network or coordinating body for community and CSO engagement at national and subnational levels; the ministry of health’s (MoH’s) community health worker programme (or similar); institutions whose work focuses on TB determinants (e.g. poverty reduction and social protection); the NTP at the national, intermediate and local levels; and the grassroots community.

14.4 People to be interviewed
People to be interviewed are the community; networks of CSOs and other major organizations; managers and staff at national and subnational levels; the NTP manager or community focal point; managers and staff of the community health worker programme; health service managers at the subnational level; staff at health facilities; community, opinion and religious leaders; community health workers and their supervisors; advocates; individuals undergoing TB treatment and their families; and local community representatives and people within their structures.
14.5 Key areas and sample questions

Policies and governance

▶ Is there an established legal or policy framework for engaging communities and CSOs in ending TB? If so, please specify the document.
▶ Are there up-to-date national guidelines for engagement of communities and CSOs to end TB?
▶ Is there a functional national coordinating body (or similar) for community and CSO stakeholders for ending TB? Is there a similar coordinating body at subnational level? Do the meetings of these bodies or networks take place regularly; also, are notes taken at the meetings available?
▶ Is there available funding for community and CSO engagement to end TB? If so, is this through external or donor funding sources, or through domestic funding sources?

Monitoring and evaluation

▶ Are tools and guidelines for M&E of community involvement in place?
▶ What data on community engagement are being captured in the national surveillance system? Are the data complete and of high quality?

Activities at service delivery level

▶ Do the implemented community engagement activities for ending TB include:
  — provision of TB preventive treatment;
  — facilitation of access to diagnosis (e.g. community-based referral);
  — treatment adherence support;
  — treatment literacy;
  — screening and referral of household contacts;
  — screening, care and support for TB comorbidities (e.g. HIV or diabetes) or social determinants (e.g. loss of income and social protection schemes);
  — demand creation and resource mobilization;
  — community engagement for monitoring the availability and quality of TB services;
  — TB-associated disability support;
  — health promotion; and
  — other (specify).
▶ Is there an established community health worker programme (or other community engagement initiative for health) as part of the MoH? If so, are TB services being delivered as part of this programme?
▶ Are there any unaddressed needs for capacity-building for meaningful community and CSO engagement?

Collaboration and synergies

▶ How strong is the collaboration between the MoH or NTP and communities or CSOs in the areas of planning, decision-making, implementation and M&E?
▶ What are the opportunities to foster synergies with existing initiatives targeting communities and CSOs (e.g. those addressing TB determinants or comorbidities)?
14.6 Indicators

Table 14.1 shows the indicators for assessing the engagement of communities and CSOs in the national response to TB.

### Table 14.1 Indicators for engagement of communities and CSOs

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Calculation</th>
<th>Source of information</th>
</tr>
</thead>
</table>
| Percentage of newly notified TB patients who were referred by community health workers (in a basic management unit during the same period) | **Numerator:** number of new TB patients referred for diagnosis by community-based health workers or volunteers and notified in a basic management unit during a specified period  
**Denominator:** total number of new TB patients notified in the basic management unit during the same period | TB suspect register, treatment cards, and TB laboratory or treatment register |
| Proportion of new TB patients successfully treated who benefited from any form of community-based treatment adherence support | **Numerator:** number of new TB patients successfully treated and provided with support for treatment adherence from community-based health workers in the basic management unit during a specified period  
**Denominator:** total number of new patients given treatment support by community health workers during the same period | TB treatment register |
| Persons affected by TB or CSO representatives have actively participated in the development or review of the NSP and key documents | Community representatives or persons affected by TB have actively participated during the past year in:  
► development of the NSP  
► programme review  
► annual report  
► guidelines development (e.g. standard-setting documents of the NTP, such as guidance documents for different technical areas in the TB response, training modules, and primers for TB care at the service delivery level)  
This yes/no response will be supplemented by a qualitative description of the level of involvement as a case study | Meeting reports, acknowledgements section of the NSP and key strategic documents for the TB response |
| Percentage of overall funding for TB response available for community engagement activities | **Numerator:** Amount of committed NSP funds for community engagement activities that are in addition to service delivery (defined as funding specifically for “advocacy and communications” and “community engagement”), expressed in US dollars  
**Denominator:** Total amount of committed NSP funds, expressed in US dollars | Annual NSP committed funds, including breakdown of spending on “advocacy and communications” and “community engagement”; MoH budget and expenditure on the community health worker programme (or similar), where relevant |

CSO: civil society organization; MoH: ministry of health; NSP: national strategic plan; NTP: national TB programme; TB: tuberculosis.

14.7 Useful resources

A useful resource to assess the engagement of communities and civil society organizations (CSOs) in the national response to TB is the following WHO publication:

► Guidance on engagement of communities and civil society to end tuberculosis, Geneva: World Health Organization; 2023  
https://www.who.int/publications/i/item/9789240080294
Thematic tool 15

Tuberculosis in vulnerable populations

This tool covers assessment of tuberculosis (TB) in vulnerable populations.

15.1 Objectives

At the end of the review, experts should be able to comment on:

► whether people who are particularly vulnerable to developing tuberculosis (TB) infection or TB disease, or have poor access to health services or a higher likelihood of poor outcomes (including impairment and disability) are identified within the national strategic plan (NSP) for TB and in the activities implemented by the national TB programme (NTP); also, if this is the case, experts should be able to comment on how these people were identified and who they are;

► specific interventions or actions to engage these groups in TB care and retain them in it, using a people-centred, human-rights-based approach;

► the effectiveness of these interventions in reaching vulnerable and marginalized populations; and

► any gaps in the NTP’s response in reaching vulnerable and marginalized populations.

15.2 Background

At the first United Nations (UN) General Assembly high-level meeting on TB, held in 2018, heads of state and governments adopted the political declaration on the fight against TB. The declaration includes a commitment to ambitious targets for TB treatment and prevention through universal access to quality diagnosis, treatment, care and support, without suffering financial hardship; it also includes a special focus on vulnerable and marginalized populations.

Strategic planning for TB, therefore, should respond to the needs of all affected populations, including the most vulnerable, as informed by a comprehensive analysis of the epidemiological, health system and socioeconomic situation.

Defining what is meant by TB-related vulnerability is important, and a number of definitions have been proposed. The World Health Organization (WHO), in their consolidated guidelines on systematic screening for TB disease, states that “TB disproportionately affects individuals who are already disadvantaged due to disease, their socioeconomic situation or legal status, among other disadvantages, and these individuals are regarded as being vulnerable to TB” (1). A recent narrative review commissioned by WHO defined vulnerable populations as “people whose context leads to disadvantaged socioeconomic positions that put them at systematically higher risks for TB with limited access to health systems, thus experiencing health inequalities and adverse TB outcomes” (Wu S et al., unpublished, 2022).

A number of population groups have been documented as having a higher risk of developing TB or having poor TB treatment outcomes. WHO’s Guidance for national strategic planning for tuberculosis (2) notes that populations vulnerable to TB vary depending on local epidemiology, but that common populations include children, health care workers, indigenous peoples, people living with HIV, people who use drugs, people in prisons and other closed settings, miners, mobile and migrant populations, women, and the urban and rural poor. Whatever criteria are used to define TB vulnerability, it is important to bear in mind that these population groups are often context specific; thus, an understanding of local data and the epidemiological, sociocultural and legal context is required to define who these populations are. Further, the definition of population groups with TB-related vulnerability should never be used to stigmatize population groups who may already experience difficulties in accessing health care.
TB-related vulnerability can be addressed with increased efforts from all partners involved in the TB response, including affected communities and civil society organizations (CSOs). Upstream and multisectoral interventions to address the main determinants and drivers of the TB epidemic are important, as emphasized in WHO’s multisectoral accountability framework for TB. Such interventions might include addressing poverty, overcrowded living and working conditions, food insecurity, gender disparities, restrictive laws and practices, stigma, discrimination and human rights, social protection, catastrophic health expenditure, catastrophic costs and broader societal inequities. More specific actions within the health sector to be actioned by ministries of health (MoHs) and NTPs might include reducing health care access barriers, universal health coverage, active TB case finding, systematic screening for TB disease and TB infection, contact investigation, provision of TB preventive treatment (TPT), well-functioning infection prevention and control services, access to bacillus Calmette-Guérin (BCG) vaccination, decentralized care (including for TB diagnosis and treatment), treatment support, training of health care workers, and the provision of integrated, decentralized or collaborative care.

15.3 People to meet

► Within the NTP, assessors should meet the focal points for:
  — vulnerable populations (e.g. TB in children and adolescents, people living with HIV, refugees and migrants, or people in prisons);
  — TB screening, active case finding and contact investigation;
  — TPT; and
  — work on multisectoral accountability.

► Outside the NTP (e.g. MoH, other ministries, other governmental and nongovernmental partners, communities and affected persons), assessors should meet:
  — people working in prison or justice health services, refugee and migrant services, nongovernmental organizations (NGOs), those providing services for people with drug and alcohol use disorders, and community-based or faith-based organizations active in this area;
  — technical partner organizations such as Médecins Sans Frontières (MSF), KNCV and the International Union Against Tuberculosis and Lung Disease (the Union); and UN organizations such as the UN Development Programme (UNDP), the UN Agency for Refugees (UNHCR), the International Organization for Migration (IOM), the World Food Programme (WFP), the UN Office on Drugs and Crime (UNODC) and the
    — International Labour Organization (ILO);
  — advocacy groups, affected populations and community leaders; and
  — relevant staff in other ministries.

15.4 Key areas and sample questions

This section lists key areas that may be relevant to particular levels of the health system, depending on the country context.

Identifying populations in the country vulnerable to TB

► Who are the persons or population groups who are vulnerable to TB in this particular context?

► How have these vulnerable populations been identified (e.g. through the epidemiological review, as part of routine surveillance or through surveys or studies)?
Thematic tool 15

Policies and TB services

► Does the NSP identify vulnerable populations?
► Is there representation of vulnerable population constituencies during the process of planning, monitoring and evaluation of the NTP (including on the Country Co-ordinating Mechanism of the Global Fund to Fight AIDS, Tuberculosis and Malaria)?
► Are there specific interventions for people who are vulnerable to developing TB infection or TB disease? If so, what are these mechanisms (e.g. contact investigation, testing or screening for TB infection, screening or testing for TB disease [sometimes called systematic screening or active case finding], and outreach services)?
► If there are activities or interventions to reach vulnerable populations with TB services, are these activities coordinated at national and subnational levels?
► Do the interventions reach the intended target population? If so, how effective are they (if they have been evaluated)?
► Are TB services people-centred? If so, in what way?
► What are the barriers (e.g. legal, regulatory, stigma based, human-rights based and discrimination) that patients face in accessing TB services and how can these barriers be mitigated or removed?
► What are the most pressing implementation gaps or needs with regards to TB and vulnerable populations?

Recording and reporting

► Does the national surveillance system capture data on the identified vulnerable populations; if so, how well does it capture the data?
► Are there specific indicators for TB among vulnerable groups?

Stakeholder and multisectoral engagement

► Has there been any mapping of stakeholders or community structures supporting vulnerable populations?
► Is the NTP building partnerships within and beyond the health sector (including with affected communities and CSOs) to reach people who are vulnerable or marginalized?

15.5 Indicators

Suggested indicators are listed in Table 15.1; they include routine indicators that could be disaggregated by population group to determine differences and points for intervention.
Thematic tool 15

Table 15.1 Indicators for TB in vulnerable populations

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Source of indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in number of TB deaths</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>Reduction in TB incidence rate</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>Percentage of TB patients and their households experiencing catastrophic costs due to TB</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>TB treatment success rate</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>HIV status among TB patients</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>Case fatality ratio</td>
<td>End TB Strategy indicator</td>
</tr>
<tr>
<td>Proportion of TB cases attributable to vulnerabilities or social determinants, dependent on the country context</td>
<td>Programmatic data</td>
</tr>
</tbody>
</table>

HIV: human immunodeficiency virus; TB: tuberculosis.

15.6 Useful resources

Useful resources for assessing populations vulnerable to TB include:

- the guidelines on screening, diagnosis, prevention, treatment and management of TB in children and adolescents on the WHO TB knowledge sharing platform:

- Guidelines relating to TB and comorbidities:

References


Thematic tool 16

Social determinants of tuberculosis

This tool covers assessment of the social determinants of tuberculosis (TB).

16.1 Objectives
At the end of the review, experts should be able to comment on:
► the key social determinants of health influencing the tuberculosis (TB) epidemic in the country;
► the policies and legislation that address TB social determinants;
► the recording, reporting and monitoring of data on the social determinants of TB; and
► the use of data on TB social determinants to inform policy and multisectoral action.

16.2 Background
The TB epidemic is strongly influenced by health-related risk factors, and by social and economic determinants. Social determinants of TB are defined as nonmedical factors that influence TB and its outcomes. Examples include food security, housing and basic amenities, structural conflict, income and social protection, and access to affordable health services of decent quality. Social determinants can be more important than health care or lifestyle choices in influencing health.

Actions on the determinants of ill health through “health-in-all-policies” approaches will have an immense benefit on TB care and prevention. The necessary social, economic and public health policies and actions include those that:
► pursue overarching poverty reduction strategies and expanding social protection;
► reduce food insecurity;
► improve living and working conditions;
► improve environmental and living conditions in prisons and other congregate settings;
► address the social, financial and health situation of migrants; and
► promote healthy diets and lifestyles, including reduction of smoking and harmful use of alcohol and drugs.

Addressing the social determinants of TB (and health in general) is a shared responsibility across disease programmes and other stakeholders within and beyond the health sector.

16.3 Location
At national level, the main sites to be assessed are the national TB programme (NTP), ministry of health (MoH) and other ministerial departments, and technical partners such as United Nations agencies and nongovernmental organizations (NGOs).

At subnational level, the sites to be assessed include basic management units and relevant health facilities, and local NGOs providing social support to TB-affected communities.
16.4 People to meet

► At national level, the main people to meet are the TB manager, social protection and welfare managers, and health and social care staff.

► At subnational level, the people to meet include TB managers, health insurance managers, health care staff, social workers, TB patients and affected communities, including vulnerable populations such as food insecure communities, people living in informal settings, people living with HIV and TB/HIV, internally displaced people, nomadic populations and cross-border populations.

16.5 Key areas and sample questions

Burden

► What are the social determinants of health driving TB incidence, morbidity and mortality in the country?

► What is the proportion of TB patients exposed to these risk factors (see Table 16.1)?

Policies

► Are there national or subnational policies and interventions addressing the social determinants of health and TB (e.g. legislation to promote affordable housing and labour rights [including those for TB patients and their care givers])?

► Does the national strategic plan (NSP) include interventions and activities to address the social determinants of TB?

Recording, reporting and monitoring

► Are data on the social determinants of TB routinely collected and monitored (see Table 16.1)?

Use of data for policy action

► Are data used to inform policy development and implementation, and multisectoral action?

16.6 Indicators

Table 16.1 lists the various indicators used to assess social determinants of TB.
<table>
<thead>
<tr>
<th>Social determinant</th>
<th>Indicator</th>
<th>Source of data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living in poverty, and catastrophic health spending</td>
<td>1. Proportion of people living below the international national poverty line (SDG target indicator 1.1.1)</td>
<td><a href="https://unstats.un.org/sdgs/dataportal/database">https://unstats.un.org/sdgs/dataportal/database</a></td>
</tr>
<tr>
<td></td>
<td>2. Proportion of people living below the national poverty line (by age and sex) (SDG target indicator 1.2.1)</td>
<td>Local demographic health surveys</td>
</tr>
<tr>
<td></td>
<td>3. Proportion of people living below 50% of median income, by sex, age and disability</td>
<td>National census</td>
</tr>
<tr>
<td></td>
<td>4. Proportion of TB patients living below the international poverty line</td>
<td>National TB prevalence surveys and TB patient cost surveys</td>
</tr>
<tr>
<td></td>
<td>5. Proportion of TB patients facing catastrophic costs (overall and by income level, age and sex)</td>
<td>Local scientific literature (e.g. operational and implementation research studies)</td>
</tr>
<tr>
<td></td>
<td>2. Prevalence of moderate or severe food insecurity in the population, based on the Food Insecurity Experience Scale (SDG target indicator 2.1.2)</td>
<td>Surveillance and programmatic data</td>
</tr>
<tr>
<td></td>
<td>3. Prevalence of undernourishment among TB patients</td>
<td>National TB prevalence surveys, TB patient cost surveys</td>
</tr>
<tr>
<td></td>
<td>4. Prevalence of moderate or severe food insecurity among TB-affected households</td>
<td>Local demographic health surveys</td>
</tr>
<tr>
<td>Housing and indoor air pollution</td>
<td>1. Proportion of population living in households with access to basic services (SDG target indicator 1.4.1)</td>
<td><a href="https://unstats.un.org/sdgs/dataportal/database">https://unstats.un.org/sdgs/dataportal/database</a></td>
</tr>
<tr>
<td></td>
<td>2. Proportion of urban population living in slums, informal settlements or inadequate housing (SDG target indicator 11.1.1)</td>
<td>Local demographic health surveys</td>
</tr>
<tr>
<td></td>
<td>3. Size of homeless population in the country</td>
<td>National census</td>
</tr>
<tr>
<td></td>
<td>4. Proportion of TB patients living in households with access to basic services</td>
<td>National TB prevalence surveys and TB patient cost surveys</td>
</tr>
<tr>
<td></td>
<td>5. Proportion of TB patients who are homeless</td>
<td>Local scientific literature (e.g. operational and implementation research studies)</td>
</tr>
<tr>
<td></td>
<td>6. Proportion of population with primary reliance on clean fuels and technology (SDG target indicator 7.2.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Mortality rate attributed to household and ambient air pollution (SDG target indicator 3.8.2)</td>
<td></td>
</tr>
<tr>
<td>Labour security, unemployment</td>
<td>1. Unemployment rate, by sex, age and disability (SDG target indicator 8.5.2)</td>
<td><a href="https://unstats.un.org/sdgs/dataportal/database">https://unstats.un.org/sdgs/dataportal/database</a></td>
</tr>
<tr>
<td></td>
<td>2. Unemployment rate among TB patients (or level of employment before TB occurrence)</td>
<td>Demographic health surveys</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National census</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National TB prevalence surveys and TB patient cost surveys</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Local scientific literature (e.g. operational and implementation research studies)</td>
</tr>
</tbody>
</table>
### Thematic tool 16

<table>
<thead>
<tr>
<th>Social determinant</th>
<th>Indicator</th>
<th>Source of data</th>
</tr>
</thead>
</table>
| Social protection  | 1. Access to social protection:  
                     2. Percentage of population covered by social protection and labour programmes (SDG target indicators 1.3 and 3.8)  
| Migration and IDP  | 1. Proportion of people affected by TB among migrant populations and IDP | Surveillance and programmatic data Assessments |

IDP: internally displaced people; SDG: Sustainable Development Goal; TB: tuberculosis.

#### 16.7 Useful resources

Useful resources for the assessment of social determinants of TB include the following:

- national and subnational reports and publications on the social determinants of TB;
- key informant interviews (e.g. with social protection implementers, social workers, TB care staff and TB patients); and
- a WHO publication on social determinants of health:
- data from the Sustainable Development Goals data portal:
Thematic tool 17

Governance of the national tuberculosis programme

This tool covers assessment of the governance of the national tuberculosis (TB) programme.

17.1 Objectives
At the end of the review, experts should be able to comment on:

► the architecture and hierarchy of the TB programme and its placement within the overall health system architecture;
► distribution of health facilities at national and subnational levels, including their accessibility in both rural and urban settings;
► health care providers beyond the public sector;
► the community system network for TB services;
► how TB services are structured within the health and social care system;
► how TB policies are developed, disseminated and implemented to ensure quality of TB services;
► mechanisms and platforms for coordination with other ministry of health (MoH) departments and programmes; and
► mechanisms and platforms for engagement with other sectors and stakeholders

17.2 Background
The national TB programme (NTP) is part of a country’s overall health system. In most countries, TB services are organized within an NTP, which is usually housed within the MoH. The programme’s activities are implemented at different levels: national, subnational, health facility and community.

17.3 Location
Sites to be assessed include relevant MoH departments and programmes, the central unit of the NTP and subnational level authorities.

17.4 Staff to be interviewed
The main staff to be interviewed for the assessment are national and subnational management staff and health authorities, and key technical and development partners and stakeholders.

17.5 Documents to be consulted
The main documents to be consulted are:

► national development plans;
► health sector strategic plan, policies and reports;
► the national strategic plan (NSP) for TB; and
► other relevant reports and documents (e.g. the government’s manifesto and health human resources strategic plans).
## 17.6 Key areas and sample questions

Table 17.1 summarizes key areas to be reviewed at different levels of the health service.

### Table 17.1 Areas to be reviewed, by level of health service

<table>
<thead>
<tr>
<th>Level of the health system</th>
<th>Key areas to be reviewed</th>
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| National and federal level                 | ► Organization of TB services within the national health system at all levels  
► Processes and procedures for development and dissemination of policies on TB  
► Interprogramme and multisectoral coordination at national level  
► Key opportunities, threats and challenges related to the provision of health and TB services at national level |
| State, county, provincial and regional levels | ► Roles and responsibilities of the state, country, provincial and regional levels in health and TB services  
► Interprogramme and multisectoral coordination at each level  
► Key opportunities, threats and challenges related to the provision of health and TB services at each level |
| District level                             | ► Roles and responsibilities of the district level in health and TB services  
► Interprogramme and multisectoral coordination at district level  
► Key (managerial) opportunities, threats and challenges related to the provision of health and TB services at district level |

TB: tuberculosis.

**Architecture of the national TB programme within the health system**

► What is the placement and structure of the NTP within the overall health system architecture?

**Health and TB services delivery model**

► How are health services delivered in the country?
  — How are health facilities distributed at national and subnational level, including their accessibility in both rural and urban settings?
  
► How is the delivery of TB services organized within the national health care system at all levels (including national and subnational structures) and along the TB care cascade (integration into public health care)?
  — How is TB services delivery linked to the social care delivery system?
  — What is the community system network for TB services?

**Processes and procedures for development, implementation and dissemination of TB policies**

► How are policies on TB (including the NSP and guidelines) developed, disseminated and implemented to ensure quality of TB services?
17.7 Useful resources

Useful resources for assessment of the governance of TB include the following publications from the World Health Organization:

Ethics, equity, human rights and gender

This tool covers assessment of policies and guidelines on ethics, equity, human rights and gender in relation to tuberculosis (TB).

18.1 Objectives
At the end of the review, experts should be able to comment on how the national TB programme (NTP) has adopted and is implementing World Health Organization (WHO) policies and guidelines on ethics, equity, human rights and gender.

18.2 Background
“Protecting human rights, ethics and equity” is one of the four key principles of the WHO End TB Strategy. This approach is fully aligned with the 2030 Agenda for Sustainable Development and its focus on human rights, ethics and equity. To this end, the Sustainable Development Goals (SDGs) monitoring framework emphasizes disaggregated analysis and reporting of data to measure equity of health and health care, and to monitor progress towards achieving universal health coverage.

18.3 People to be interviewed
The main people to be interviewed for the assessment are the NTP manager or ethics, equity and human rights focal point; health service managers at the subnational level; staff at health facilities; community representatives and their organizations; people affected by TB; and leaders of civil society organizations (CSOs).

18.4 Key areas and sample questions

Integrated, patient-centred care and prevention

Information
Are all individuals diagnosed with TB being informed about the following human rights relevant to TB:

► informed consent;
► privacy;
► access to TB health services according to WHO recommendations (e.g. Xpert TB diagnosis and recommended treatment regimens free of injectables);
► access to social protection;
► access to the internet; and
► access to rehabilitation services?

Human rights
Is information about the human rights listed above provided in verbal form or in writing, and is it recorded in the clinical record?

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1 Informed consent refers to the process of engaging patients as partners in the delivery of health services by giving them sufficient and relevant information to enable them to make decisions for themselves (WHO, 2017).
Thematic tool 18

Tests
According to WHO guidance for the implementation of the End TB Strategy, although countries continue the process of scaling up their capacity to provide diagnosis and treatment for multidrug-resistant TB or rifampicin-resistant TB (MDR/RR-TB), the use of tests that provide information on drug susceptibility can be appropriate, even when no effective treatment is available:

- Are drug-resistant TB (DR-TB) diagnostic tests offered even in the absence of adequate treatment to inform decisions on personal and institutional level (e.g. infection prevention and control)?

Contact tracing
Is contact tracing conducted with the consent of the person diagnosed with TB?

- Is this consent provided verbally or in writing, and is it recorded in the patient’s clinical record?
- Are there instances of contact tracing being conducted without informed consent?

Communication
Does communication with vulnerable people during follow-ups comply with the patient’s preferences in terms of:

- means (e.g. by telephone, text messaging or home visits);
- privacy;
- autonomy;
- gender; and
- language (e.g. considering linguistic barriers for minorities or migrants)?

Adherence to treatment
Do health care providers support patients in adhering to treatment by:

- offering supervision of treatment (directly observed therapy [DOT]), but not enforcing it if the patient chooses otherwise;
- informing patients about the risks that poor adherence to treatment poses for themselves, their families and the community;
- informing patients about the benefits of having such adherence monitored;
- identifying barriers to completion of treatment, in conjunction with the patient;
- developing and implementing a consensual plan by health care workers and patients that takes into account a patient’s preferences for adhering to treatment;
- offering all possibilities to make patient-centred DOT a feasible option; that is:
  - community-based DOT;
  - digital tools (e.g. video-observed therapy [VOT]); and
  - the right for the patient to choose the place and person responsible for having their adherence monitored via DOT.

Social support
Is social support or social protection systematically offered to all patients with TB, in the form of:

- education or information;
- psychological support; and
- material support in cash, in kind or as services.
Non-voluntary isolation

Respiratory isolation in TB management can take the form of physical isolation in a hospital or household or the use of masks worn by patients, and it is almost always voluntary.

- Has non-voluntary isolation of a case or cases been enforced in the district, province, region or country? If so:
  - Was the patient listened to about their needs?
  - Was the patient offered social support?
  - Was the patient known to be contagious, did they refuse effective treatment, and had all reasonable measures to ensure adherence been attempted but been unsuccessful?
  - Was the patient known to be contagious, and had they agreed to ambulatory treatment but lacked the capacity to institute infection control at home; in this case, was the patient refused inpatient care?
  - Was the patient highly likely to be contagious (based on laboratory evidence), but refused to undergo an assessment of their infectious status; in this case, was every effort made to work with the patient to establish a treatment plan that met their needs?
  - Was non-voluntary isolation the last resort to be considered only after every other attempt had failed?

Palliative care

Palliative care is defined as an approach used to improve the quality of life of patients facing a life-threatening illness. It prevents and relieves suffering through the early identification and correct assessment and treatment of pain and other problems (e.g. physical, psychological, social and spiritual).

- Is proper access to care and to the management of adverse drug reactions provided?
- Is relief from suffering provided according to patient needs?
- Is the management of the following physical symptoms taken into account:
  - dyspnoea (is oxygen being provided to patients either at their home or at the health care facility?);
  - fatigue; and
  - pain (are painkillers, including opioids, offered as needed)?
- When planning for palliative care, have the patient’s preferences been considered in regard to:
  - the spiritual and emotional challenges; and
  - the quality of dying (e.g. preparation of death, family and community nearness).

Children

Has hospitalization of children with TB happened in the country in the absence of medical justification for treatment and care (e.g. either a hospital or hospice)?

Continued access

Is there a protocol to ensure continued access to treatment for people deprived of freedom after they are released? If yes, are the following in place:
- identification of a facility for continued treatment;
- provision of patient records to that facility; and
- follow-up mechanisms to ensure proper access and retention to care?
Thematic tool 18

Communities and CSOs
Are communities and CSOs engaged in activities to strengthen:
► health education;
► health literacy;
► collaboration across sectors; and
► ethics, equity, human rights and gender?

Policy and supportive systems
Information systems, data and surveillance
► Are the information systems and surveillance able to capture, disaggregated data by factors such as sex, gender, age, geographical location, income, race and ethnicity, disability and any other factors relevant in local contexts (please specify these other factors)?
► Are reports produced using these disaggregated data?

Barrier assessments
► Has the NTP conducted barrier assessments on ethics, equity, human rights and gender?
► If so, has the NTP used findings to inform the national strategic plan (NSP) for TB, programme reviews, inclusion of ethics and human rights in all technical guidelines, and education of people affected by TB and TB stakeholders?

Training
Does the health workforce receive training on:
► national guidelines and updates on TB prevention, diagnosis and treatment; and
► awareness of stigma and discriminatory behaviours based on age, gender and disability?

Health care workers
Health care workers are at increased risk of acquiring TB infection or disease.
► Is testing for latent TB infection (LTBI) offered to health care workers?
► Is treatment for LTBI offered to health care workers?

Borders
► Is mandatory TB screening at borders done with the intention of providing appropriate medical care, never to exclude or preclude entry?
► Is a person’s status (e.g. tested positive for LTBI or receiving treatment for LTBI) affecting the process, procedure and status of immigration or entry, or work permit?
► Are migrants receiving access equal to their host country’s citizens to quality TB prevention, diagnosis, care and treatment?

TB research in the country (question for the national level or NTP)
Protocols for TB research
Do the protocols for TB research in the country ensure that it is conducted according to the following sound ethics considerations:
► Do all stakeholders (including local investigators) and the community participate in the generation of research questions and the design and implementation of studies?
Thematic tool 18

► Are participants kept informed of research findings and the application of these findings?
► Is research designed so that the populations in which it is carried out benefit from the results?
► Do research results lead to technology transfer, whenever applicable, for the benefit of the affected population?
► Is collaborative international research conducted in a way that ensures or promotes capacity-building in the low- and middle-income countries involved?
► Do research ethics committees determine that the risks of the research are reasonable in relation to the anticipated benefits?
► Is there an adequate process in place for obtaining informed consent from participants?
► Do research protocols specify how findings would be translated into public health policy, as applicable?

Useful resources

Useful resources for this topic include the following publications from WHO:
Financing for health and TB services

This tool covers assessment of financing for services for health and tuberculosis (TB).

19.1 Objectives
At the end of the review, experts should be able to comment on:
► the health financing landscape, including key indicators for universal health coverage (UHC) and health financing;
► how the current financing mechanisms for health and TB services are implemented at the national and subnational level; and
► whether current health financing mechanisms and reforms (e.g. health insurance, provider payment and purchasing arrangements) ensure affordability, and progress towards the End TB targets and UHC.

19.2 Background
Progress in reducing the burden of TB disease requires adequate funding, sustained over many years. Increases in domestic funding for TB, coupled with international funding, are required to ensure sustainability of resources and quality of care. Policies and health financing mechanisms need to ensure quality and affordability of care, thus accelerating a country’s progress towards UHC.

19.3 Location
At the national level, the main sites to be assessed are the national TB programme (NTP), ministerial departments (e.g. finance unit of the ministry of health [MoH] and the ministry of finance) and the national health insurance authority. At the subnational level, sites include health insurance offices and health facilities.

19.4 Staff to be interviewed
At the national level, the main staff to be interviewed are those from the NTP, ministerial departments and the national health insurance authority. At the subnational level, staff to be interviewed include TB managers, health insurance managers and patients with TB.

19.5 Key areas and sample questions
TB financing landscape
► What funding mechanisms does the country have for TB?
► What government funding is available for health services, in particular for TB services (including funding through other sectors such as local government and municipalities)?
► What funding is available from the local non-state sector (e.g. private sector and philanthropic organizations)?
► What external funding is available?
► What mechanisms in place for covering health expenditure focus on TB services (e.g. health insurance and out-of-pocket payments)?
Thematic tool 19

The national strategic plan

► What information is available about the budget needed to support the TB national strategic plan (NSP):
  — Has the NSP for TB been costed? If so, what is the total estimated budget needed for the period covered by the NSP, and what is the yearly budget for each year included in the NSP?
  — Have the sources of funding been clearly identified in the present NSP?
  — What was the total budget mobilized for TB prevention and care over the past year? What financial contribution was made by the government? What financial contribution was made by other stakeholders, and who were those stakeholders? Was there a funding gap over the past year?

► Has the NTP developed a strategy to mobilize financial resources to implement the NSP? If so, what actions have been taken to mobilize these resources, and how proactive has the programme been in undertaking these actions?

Affordability of health and TB care (progress towards End TB targets and UHC)

► What is the level of out-of-pocket expenditure incurred by the general population? (This is a broad indication of whether there are major financial barriers to accessing health care)

► What is the level of TB-related costs and catastrophic costs incurred by patients with TB and their households? Has a nationally representative survey of costs of patients with TB been undertaken?

► Does the country have an essential or basic package of care? If so, what TB services are included in this package?

► To what extent do co-payment and exemption systems affect access to health care for patients with TB?

19.6 Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition or computation</th>
<th>Source</th>
</tr>
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| Percentage of NTP budget that is funded | **Numerator:** received funds (including NTP costs) for TB prevention, diagnosis and treatment (latest year with data)  
**Denominator:** total budget needed (including NTP costs) for TB prevention, diagnosis and treatment (same year as the numerator) | WHO Global Tuberculosis Database, annual TB report and health reports |
| Percentage of available funding for TB prevention, diagnosis and treatment that is spent | **Numerator:** Total expenditure (including NTP costs) on TB prevention, diagnosis and treatment from all sources  
**Denominator:** Received funds (including NTP costs) for TB prevention, diagnosis and treatment from all sources. | WHO Global Tuberculosis Database |
| Percentage of health expenditure that is out-of-pocket (general population) | Share of out-of-pocket payments of total current health expenditures | WHO’s national health accounts database and WHO Global Health Expenditure Atlas |
| Percentage of TB patients and their households facing catastrophic costs due to TB | Percentage of TB patients and their families facing total TB-related costs exceeding 20% of household annual income | WHO Global Tuberculosis Database, national TB patient cost survey and subnational level studies |

NTP: national TB programme; TB: tuberculosis.
19.7 Useful resources

Useful resources for this tool include:

► the following publications from WHO:


  (https://www.who.int/publications/iitem/9789240017405).

  (https://www.who.int/publications/iitem/9789240065536).

► National TB spending over the past 10 years by sources of funding and line item, which can be synthesized from the TB country profiles and financing profiles available here:

GUIDANCE ON CONDUCTING REVIEWS OF TUBERCULOSIS PROGRAMMES