Guidance on conducting reviews of tuberculosis programmes

Web annex C.

Tuberculosis epidemiological reviews and assessments of tuberculosis surveillance and vital registration systems: implementation guide and terms of reference
Guidance on conducting reviews of tuberculosis programmes

Web Annex C. Tuberculosis epidemiological reviews and assessments of tuberculosis surveillance and vital registration systems: implementation guide and terms of reference
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>CDC</td>
<td>centres for disease control</td>
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<td>CRVS</td>
<td>civil registration and vital statistics</td>
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<tr>
<td>DHIS2</td>
<td>District Health Information Software 2</td>
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<td>DR-TB</td>
<td>drug-resistant TB</td>
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<td>DST</td>
<td>drug susceptibility testing</td>
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<tr>
<td>EMR</td>
<td>electronic medical records</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>GP</td>
<td>general practitioner</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HMIS</td>
<td>health management information system</td>
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<tr>
<td>LIS</td>
<td>laboratory information system</td>
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<tr>
<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<tr>
<td>MDR-TB</td>
<td>multidrug-resistant TB</td>
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<tr>
<td>MoH</td>
<td>ministry of health</td>
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<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
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<td>NPO</td>
<td>national professional officer</td>
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<td>NRL</td>
<td>national reference laboratory</td>
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<td>NSP</td>
<td>national strategic plan</td>
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<td>NTP</td>
<td>national TB control programme</td>
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<tr>
<td>OPD</td>
<td>outpatient department</td>
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<tr>
<td>PLHIV</td>
<td>people living with HIV</td>
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<tr>
<td>PMTPT</td>
<td>programmatic management of TB preventive treatment</td>
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<tr>
<td>RR-TB</td>
<td>rifampicin-resistant TB</td>
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<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<td>ToR</td>
<td>terms of reference</td>
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<tr>
<td>TPT</td>
<td>TB preventive treatment</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO/GTB</td>
<td>WHO Global TB Programme</td>
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<tr>
<td>WRD</td>
<td>WHO-recommended rapid diagnostic</td>
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1.1 Rationale for tuberculosis epidemiological reviews

A major goal of tuberculosis (TB) surveillance is to provide an accurate measure of the number of new episodes of TB (and related deaths) and to monitor trends in the number of new episodes. Currently, there are important gaps in country-level TB surveillance, which prevent the accurate measurement and monitoring of TB burden. By strengthening routine TB surveillance, in terms of coverage and quality, national TB control programmes (NTPs) can more effectively monitor changes in the local TB epidemic, visualize programmatic successes and shortfalls, and target resources to areas and populations most at need.

1.2 Goal of conducting a TB epidemiological review

A TB epidemiological review includes assessment of the TB surveillance and vital registration system; it is a country-level systematic and standardized assessment of a country’s TB surveillance system, monitoring and evaluation (M&E) activities and TB epidemiological situation. Such a review is undertaken for the entire system – from the central to operational level – to better understand best practices in the country, and the TB epidemiological situation and how this is changing with programmatic and external factors. The review also provides information on how to better strengthen surveillance, M&E and data use, based on gaps identified during the assessment.

An epidemiological review should be integrated into a country's routine process for TB strategic planning. The review could help to guide the development of subsequent NTP reviews, a national strategic plan (NSP) for TB, and requests for funding (both domestic and international).

The conduct of the review is based on a set of standardized terms of reference (ToR) that outline the main objectives and tasks to be carried out (Appendix 1). Those ToR should be considered in conjunction with this implementation guide.

Objectives of the review

The standardized ToR for TB epidemiological review include five main objectives:

- **Objective 1.** Describe and assess the current national TB surveillance and vital registration systems, with particular attention to their capacity to measure the level of, and trends in, TB disease burden (incidence and mortality) using the standards and benchmarks checklist (1).

- **Objective 2.** Assess the level of, and trends in, TB disease burden (incidence, prevalence and mortality) and programmatic indicators using available surveillance, survey, programmatic and other data. Assess whether recent trends in TB disease burden and programmatic indicators are plausibly related to changes in TB-specific interventions and programmatic factors, taking into account external factors, including economic or demographic trends.

- **Objective 3.** Define a comprehensive set of recommendations to strengthen the surveillance system to directly measure trends in TB disease burden, strengthen M&E processes and address programmatic gaps, including, where feasible, an indication of what type of technical assistance or additional funding would be required.

- **Objective 4.** Provide feedback to the NTP, the WHO regional and country offices, WHO headquarters, relevant funding agencies and technical partners on key findings, recommendations and prioritization, following approval by the NTP.
Objective 5. Build local capacity for epidemiological reviews and assessments of surveillance systems by involving members of the NTP to actively participate in Objectives 1–4.

Benefits of a review and dissemination

Potential benefits of conducting a TB epidemiological review include:

- Enhanced understanding of the TB epidemic and its characteristics at national and subnational levels;
- Clear scientific evidence to support the development and implementation of interventions targeted at areas and populations most in need;
- Strengthened technical capacity in the country for the analysis and interpretation of TB data;
- Improved development and implementation of the NSP, by taking a multisectoral approach and engaging local and international stakeholders; and
- Increased confidence in the priorities outlined in a funding proposal and the NSP, and the potential impact of suggested activities.

The utility of a review extends beyond supporting the NTP and providing findings and recommendations. Therefore, the review should be disseminated to relevant partners; for example, to:

- Help domestic and international funders to track the impact of investments and guide the allocation of funding for key activities;
- Inform the WHO country office and local technical partners on how to better support the NTP;
- Provide key information to WHO headquarters to strengthen burden estimation (at country level and globally); and
- Help to guide the prioritization of activities at WHO regional and global levels.

1.3 Overview of this document

The purpose of this document is to serve as a guide to conducting TB epidemiological reviews following the standardized ToR. This document is predominantly aimed at individuals who are involved in the organization and implementation (as leaders or participants) of TB epidemiological reviews, including external consultant epidemiologists, NTP, and staff from WHO country and regional offices; it may also be useful for funders and technical partners – providing an overview of how epidemiological reviews are carried out. Finally, the document can be used by people developing data-driven NSP and funding requests.

The rest of this document is structured as follows:

- Chapter 2 provides an overview of the planning and organization of a TB epidemiological review, including a discussion on the optimal timing for carrying out the activity.
- Chapter 3 explains the steps that need to be carried out ahead of the in-country mission, to organize and prepare for an upcoming TB epidemiological review.
- Chapter 4 outlines the typical activities to be carried out during the in-country mission, to complete the tasks and meet the objectives in the standardized ToR.
- Chapter 5 covers the steps that follow the in-country mission, particularly the dissemination of the report and the need for follow-up on the agreed recommendations.
CHAPTER 2
Planning and organization

2.1 Optimal timing for a TB epidemiological review

TB epidemiological reviews generate important evidence to support data-driven decision-making; they also provide specific recommendations that need to be planned for and funded, to strengthen the country’s TB surveillance system and M&E activities. The activity must be coordinated by the NTP, with support from WHO and local and international partners, as required. The TB epidemiological review should be integrated into the national health programme’s strategic planning cycle. It should be viewed as the initial step in the process of developing or revising the NSP for TB, or developing domestic or international funding requests (e.g. the funding request that is submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria [Global Fund]). TB epidemiological reviews are generally carried out every 3–5 years, in line with the country’s process for health programme planning for TB. It is best practice for the review to be carried out 2–3 months ahead of the field assessment phase of the NTP review, to help guide the organization, focus and implementation of that review.

A TB epidemiological review should also be considered if major changes to programme planning or TB surveillance are anticipated, or if gaps have been identified and would require a systematic investigation. Similarly, a review could also be considered if a thorough epidemiological analysis is needed; for example, if changes to the local TB epidemiological situation have been observed or if new insights to the TB epidemic have become available.

2.2 Key steps in the TB epidemiological review process

Fig. 2.1 summarizes the key steps in planning and organizing a TB epidemiological review in a country. Significant investment in time and effort are required for the organization and preparation of the review; therefore, the activity should be planned well in advance of when it is needed. It is strongly recommended to integrate the planning for a TB epidemiological review directly in the wider programme planning process, so that any needs for technical assistance and funding can be identified early and the organization of the review can start in a timely manner. With proper strategic planning, any needs should be identified and planned for a year in advance, even before the exact dates of the activity have been confirmed.

Once the needs for technical assistance have been identified, the NTP submits a formal request for support to the WHO country office; this request is then transmitted to the WHO regional office or WHO headquarters, as required. Bilateral discussions between WHO and the NTP are offered, to understand the specific needs of
the NTP and to guide development of the mission-specific ToR and organization of the review, ensuring that funding is secured and consultants can be mobilized.

A call for support is then released to the relevant consultant roster (global or regional), to identify the availability of consultants for undertaking the activity on the proposed dates. Consultants should be matched based on seniority and skillset.

Fig. 2.2 Summary of the steps for preparing, implementing and concluding a TB epidemiological review

A briefing with the consultants is held; at that meeting, context for the review and any relevant information that the consultants should consider is discussed (e.g. any additional objectives or tasks that may have been included in the mission-specific ToR, any specific areas that may require extra focus or investigation, and any queries the consultants may have about the context or the review process). With support from WHO, the consultants are then put into contact with the NTP, to start preparing activities.

2.3 Developing a mission-specific ToR

The core objectives of a national TB epidemiological review are listed in Section 1.2. These objectives and their associated tasks, as outlined in the standardized ToR, are required for a complete TB epidemiological review. It is best not to make any major modifications to the core objectives and tasks, so that the reviews can be implemented in a standardized fashion and results can be comparable across reviews, to measure progress and identify gaps in a systematic way.

Removal of core objectives should only be considered when a similar activity has recently been carried out and would meet the objectives that have been removed. For example, a country that received external technical assistance to carry out a detailed epidemiological analysis in line with the tasks related to Objective 2 of the ToR might consider removing this objective if the analytical report could provide sufficient information to the external consultants contracted to carry out the remaining objectives to allow them to complete the review. This situation should only be considered in special circumstances, and if the two assessments are carried out in the same year and are based on the same sources and years of data.

Depending on the country context, and the context of the review, additional objectives and tasks may be added. These should be based on specific questions the NTP may have that require specific investigation. These needs should be identified during the planning and organization phase (Section 2.2) and planned for in advance, to ensure that the external consultants with the appropriate skills and expertise can be identified. The types of additional objectives or tasks included would be specific to the situation but may include, for example, a detailed review of some functional components of a digital system that the NTP is currently facing challenges with and is therefore requesting specific guidance on. Similarly, an NTP may be interested in carrying out an inventory study and would like to include an objective on assessing the feasibility of carrying out such a study, receive guidance on the methodology or receive support in identifying potential sources for record linkage.
Other activities that are complementary to TB epidemiological reviews may be considered for inclusion and carried out as one integrated activity. In such cases, specific objectives from the ToR of the complementary activity should be integrated; alternatively, the ToR from the complementary activity can be linked to the ToR of the TB epidemiological review. Some complementary activities are in the development or pilot stage, with specific ToR still to be drafted or validated; such activities include:

- integrating epidemiological review components for TB and noncommunicable diseases;
- reviewing public–private or public–public mix M&E;
- implementing a data optimization framework for NTP planning;
- implementing a readiness assessment for the transition to digital case-based surveillance; and
- reviewing TB elimination M&E and undertaking a situational assessment.

Before considering the integration of the above activities, it is best to contact the WHO Global TB Programme (WHO/GTB) for an update on the status of maturity of the activity and the associated ToR.

Integrating complementary activities into a TB epidemiological review may require the contracting of an additional external consultant; this would need to be planned for accordingly, with the appropriate additional funding in place.
CHAPTER 3
Preparing for an epidemiological review

3.1 Composition of the review team and respective roles of its members

The TB epidemiological review is usually led by two external (international) consultant epidemiologists who can bring an objective perspective to the review; the aim is to avoid the potential introduction of bias in the assessment. In addition, the epidemiologists can bring invaluable experience from other country contexts that they are familiar with, or from other epidemiological reviews that they have carried out. The external team may comprise independent consultants or epidemiologists attached to a technical organization such as WHO, the United States Centers for Disease Control and Prevention, KNCV or the International Union Against Tuberculosis and Lung Disease.

It is recommended to contract two external consultants (rather than one) so that the workload can be shared and the objectives met at a high quality and within the given timeframe. The consultants should generally complement each other, taking into consideration their level of experience and comparative skills, providing a collective expertise in epidemiology and surveillance. Of the two consultants, one will generally be identified as the lead, and will be responsible for guiding the preparations and implementation to ensure a successful review.

With guidance from the consultants and WHO, the NTP will establish an in-country team to support the review. At least one M&E officer from the NTP should be appointed for the entire duration of the mission; however, where feasible, the NTP manager should also be involved. The NTP staff will support the preparation of the mission by contributing to the development of the agenda, facilitating the organization of site visits, and providing the necessary data and documentation ahead of the review. During the review, relevant NTP staff (e.g. the NTP manager and an epidemiologist) should be available to participate in the review, analysis and interpretation of the data.

The WHO country office can help to ensure a successful review; for example, the office may support preparations for the review by facilitating links with the NTP and beyond. It is common that the WHO country office will assign at least one national professional officer (NPO) to be part of the national team for the duration of the mission.

Depending on the context, the national team might include academics from local universities, national epidemiologists from the ministry of health (MoH) (other than the NTP), and staff from country offices of development and technical partners (e.g. nongovernmental organizations [NGOs]). These partners can support the review by providing additional information and data. They may also be able to assist in advocating for additional funds to support the implementation of recommendations from the review.

Other international staff, such as those from bilateral and multilateral agencies that provide technical support to the NTP or MoH, may be included in the team, because they can offer technical expertise to support the implementation and subsequent follow-up on recommendations that stem from the review (Section 4.12).

3.2 Setting the review agenda

The agenda for the TB epidemiological review should be developed in close consultation with the NTP, with guidance provided by the external consultants and WHO. The agenda usually covers a 2-week in-country assessment period. It should cover all the activities that need to be carried out to meet the objectives as outlined in the standardized ToR, including any expanded or additional objectives and tasks based on the needs of the country.
It is important to budget the time for the following core activities, which are explained in more detail in Chapter 4:

▶ briefings with the WHO representative, NTP and stakeholders;
▶ finalization of any outstanding preparations for the review;
▶ visits to health facilities, laboratories and partners;
▶ completion of Parts A and B of the standards and benchmarks checklist for TB surveillance (1);
▶ epidemiological analyses and interpretation of findings with the NTP;
▶ validation of findings and recommendations; and
▶ debriefings with NTP staff, the WHO representative and stakeholders.

The briefing and debriefing sessions will normally take at least half a day, and may require a full day in some settings. Depending on the country, an additional security briefing with the WHO country office may be needed and should be scheduled in the agenda.

A large part of the in-country mission is spent visiting a variety of health facilities and partners. The selection of the specific site visits and the partners to interview should be guided by the NTP and should consider the country context. The NTP and WHO country office should ensure that the appointments are made in advance of the in-country mission. At a minimum these should include:

▶ health facilities and associated sources of laboratories:
  — rural or low TB notification facility;
  — urban or high TB notification facility;
  — primary, secondary and tertiary level facilities;
  — public and private facilities;
▶ health facilities providing:
  — TB/HIV services;
  — paediatric TB services;
  — multidrug-resistant TB (MDR-TB) services;
▶ national reference laboratory (NRL);
▶ key NGOs and partners who support the NTP to implement TB services;
▶ division responsible for:
  — vital statistics;
  — population statistics;
  — central health management information system (HMIS) or integrated disease surveillance; and
  — national health insurance (or universal health coverage) and primary health care.

About 2 hours should be scheduled for each site visit, or longer for the first facility to be visited. About 1 hour should be scheduled for each interview.

Usually, more than one health facility and laboratory can be reached in a day, but it is important to factor in travel time and road conditions (e.g. traffic, checkpoints, potential roadblocks and weather) when planning the agenda. The NTP and NPO will be familiar with the setting and their guidance should be followed when selecting health facilities or zones to visit. In selecting a rural facility, this should be somewhere that can be reached and returned from in 1 day during daylight, unless accommodation is planned for near the site and can be reached before dark. United Nations (UN) staff and consultants employed by WHO may need formal clearance before entering some zones, or may need additional security training (Safe and Secure Approaches in Field Environments [SSAFE] for Surge Deployment) for other zones if required by the UN Department of
Safety and Security. These additional clearance procedures should be planned for in advance, or such zones should be avoided altogether. For external consultants from other organizations, there may be additional clearance procedures that need to be followed before visiting some zones; this should be discussed with the consultant’s organization in advance of the review.

Planning for interviews with stakeholders should follow the same considerations as for site visits regarding travel times and safety considerations.

If a previous epidemiological review was carried out in the country, then the agenda for the current review can be based on the agenda from the previous review, adjusted as necessary.

3.3 Preparing the documents for desk review

The external consultants should request access to key documents to support the TB epidemiological review, and the NTP should share these ahead of the in-country mission. It is good practice for the external consultants to start the desk review during the preparation phase because it provides useful information on the context of the setting and guides the initial discussions when completing the standards and benchmarks assessment. The consultants should provide a detailed list of the types of documents requested as early as possible, because it may take time for the NTP to collate them. It is likely that the NTP will not have access to all the documents that are requested – a fact that may be a useful finding for the review and could be considered when making recommendations. It is also common to identify additional useful documents (i.e. beyond those requested) during the in-country mission.

Box 3.1 provides an example list of the types of documents that should be requested during preparations for the review and, where available, should be included in the desk review.

3.4 Preparing the data

The data should be compiled by the NTP and shared with the external consultants ahead of the review. This is often the most difficult task for the NTP in preparing for the review; hence, the NTP should be encouraged to start preparing the data as soon as possible. Once the external consultants receive the data, they should check them for completeness and ideally should start on the initial analysis.

With the advancement in digitization of TB recording and reporting systems in recent years, this process is somewhat more straightforward than it was when most systems were paper based. However, some countries continue to rely on paper-based systems, keeping the data on numerous Microsoft Excel sheets; also, some countries with digital systems cannot easily extract the data or extract them in a format that allows the data to be analysed. In such cases, this process should be planned for far in advance, assuming that it will be necessary to invest a significant amount of time in data cleaning and transformation before analysis.

A TB module in District Health Information Software 2 (DHIS2) – named tbhistoric – has been developed by WHO to support the safeguarding of TB data for countries without a functional digital system, and to support data visualization and analysis in the context of TB epidemiological reviews (2). When requesting data from the NTP, the external consultants should discuss the possibility of using the tbhistoric DHIS2 module. If the NTP agrees, then a standardized template can be provided to the NTP to help in collating the data, which are then uploaded into tbhistoric DHIS2.

Box 3.2 lists some of the strengths and limitations that should be considered when using tbhistoric DHIS2 for epidemiological reviews.

A wide variety of data are needed to complete the epidemiological review, some of which are routinely collected by the NTP and should therefore be made available by the programme. Other data may be collated from open-access sources online. The type of data required are described below.
BOX 3.1

**Types of documents to be requested from NTP**

The types of documents to be requested from the NTP are as follows:

- TB care and prevention manual or guidelines, including for TB/HIV, MDR-TB and paediatric TB;
- documents related to TB surveillance and M&E:
  - all standard operating procedures (SOPs) (e.g. data recording, reporting, data quality checks and validation);
  - case definitions and data dictionary;
  - analytical plan;
  - SOPs for supervision of health facilities and feedback procedures (e.g. checklists);
  - confidentiality policy, law or procedures;
- policy statement or law for mandatory reporting of TB cases;
- blank documents related to recording and reporting of TB data; for example:
  - treatment registers;
  - treatment cards;
  - quarterly report forms;
  - laboratory register (including the NRL);
  - HIV register;
- most recent annual report;
- documents related to training on TB surveillance and M&E:
  - training plan;
  - training material;
- list of all health facilities in the country (e.g. public, private and NGO);
- latest NSP;
- reports from programme review or any other type of review conducted that is relevant to TB;
- report from the most recent TB epidemiological review;
- reports from surveys or studies undertaken in the past 10 years; for example:
  - prevalence survey;
  - drug resistance survey;
  - inventory study;
  - patient cost survey;
  - mortality survey;
  - TB/HIV coinfection survey;
- reports from any audits of TB surveillance, studies or evaluation of data quality (especially any that were nationally representative);
- document describing the overview of the HMIS structure in the country, digital health strategic plan or e-health plan
- documents related to human resources (staffing and structure) for TB surveillance or M&E; and
- documents related to civil registration and vital statistics (CRVS).
All available national and subnational TB data along the pathway of prevention and care

These data should be collected routinely by NTPs and should include data on screening, presumptive TB, TB preventive treatment (TPT), notifications, treatment outcomes, HIV-associated TB and drug-resistant TB (DR-TB). In some contexts, some programmatic activities at some stages of the pathway of prevention and care will still be nascent, and therefore data on those activities may be limited.

Data should be provided for a minimum of 5 years, ideally at a quarterly interval (where feasible), and at least two administrative units below the national level (e.g. district level). The data should be provided in a way that allows disaggregation by age, sex, site of disease and previous history of treatment, in line with global guidance on routine recording and reporting of TB data. If the recording and reporting system allows for additional analyses (e.g. tracking referrals from the community or tracking the performance of the private sector), then these should also be considered. It is common for additional data to be made available throughout the review.

Census data and updated population estimates

To calculate rates, the latest available census information and estimates should be collated for the same period for which TB surveillance data are available. These data should also be made available for the same subnational levels for which the TB surveillance data are available (e.g. at least two administrative units below national) and disaggregated by age and sex, where possible.

All available known TB determinant data

These data can be accessed from open-access sources such as the World Bank database, Global Health Observatory or Sustainable Development Goals (SDGs) database. They should include the prevalence of health-related risk factors for TB (HIV, diabetes, smoking, harmful use of alcohol and undernutrition) and socioeconomic data. Time trends for these data should be extracted, where available. In addition to open-access sources, data on health-related risk factors may be available from the MoH, other ministries, or partners that could be useful for the TB epidemiological review; therefore, it is advised to review these data with the NTP.

3.5 Summary of logistical considerations

The contracting office will support the external consultants in booking flights and will provide a per diem to cover living expenses during the in-country part of the contract. Hotels can be recommended by the NTP or WHO country office and should be booked by the external consultant, with assistance from the WHO country office.
office or contracting office if necessary. The external consultants are responsible for acquiring travel visas if needed. Finally, the external consultants should ensure that transport from the airport to the hotel is organized.

The NTP and WHO country office will ensure that all expected visits are organized in advance in alignment with the agenda and that transport is available for movement between locations.

The external consultants and in-country review team should demonstrate flexibility and adaptability during the review, in the case that plans change due to unforeseen circumstances. The risk of last-minute changes can be minimized with proper planning.

3. Preparing for an epidemiological review
CHAPTER 4

Carrying out in-country activities

4.1 Summary of core activities

The five core activities carried out during the in-country mission are:

▶ characterizing the surveillance system using Part A of the standards and benchmarks checklist (1);
▶ assessing the capacity of the surveillance system using Part B of the standards and benchmarks checklist (1);
▶ analyzing TB surveillance and other relevant data to characterize the TB epidemiological situation and identify programmatic gaps;
▶ carrying out site visits to health facilities and laboratories, including undertaking interviews with personnel and checking the recording and reporting tools; and
▶ interviewing key stakeholders and partners.

An in-country mission will always start on the first day with briefing sessions and end with debriefing on the final day. Table 4.1 shows the key activities and how they are generally structured during the mission. Details are provided throughout this chapter.

Table 4.1 Key activities and the suggested order in which they should be carried out

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<thead>
<tr>
<th>First day</th>
<th>Briefing with WHO representative and NPO</th>
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<tr>
<td></td>
<td>Briefing with NTP staff and key national stakeholders</td>
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<td></td>
<td>Finalization of the agenda and review of any missing documentation or data</td>
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<tr>
<td>Week 1</td>
<td>Part A of the standards and benchmarks checklist (1)</td>
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<td>Desk review, interviews with NTP staff and stakeholders</td>
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<td></td>
<td>Visits to health facilities and laboratories, interviews with staff</td>
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<tr>
<td>Week 2</td>
<td>Part B of the standards and benchmarks assessment checklist (1)</td>
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<td></td>
<td>Data analysis and interpretation based on findings from week 1</td>
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<td></td>
<td>Validation of findings, definition of and agreement on recommendations</td>
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<tr>
<td>Last day</td>
<td>Debriefing with WHO representative and NPO</td>
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<td></td>
<td>Debriefing with NTP staff and key national stakeholders</td>
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<td></td>
<td>Definition of and agreement on next steps and follow-up</td>
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NPO: national professional officer; NTP: national tuberculosis control programme; WHO: World Health Organization.
4.2 Briefing meetings

At the start of the mission, the external consultants should meet with the WHO country office, particularly the WHO representative and the NPO assigned to the team. This briefing should cover the key objectives and high-level activities of the mission, to ensure that the country office can help to facilitate field visits, and ensure that essential data and documentation are obtained in a timely manner. The country office will also be able to provide relevant information about the current situation on TB prevention, care and control activities in the country in terms of challenges and priorities, or any other relevant information that may be important to keep in mind in terms of the context (e.g. multisectoral relationships that should inform the consultants’ diplomatic approach during the discussions with agencies and stakeholders).

A second, more detailed, briefing is then held with the entire review team. This briefing is normally hosted by the NTP, and should include relevant stakeholders. The NTP should send out invitations in advance to all those who will participate in the review and may be able to assist in the implementation of recommendations. For this briefing, the external consultants are required to give a presentation (with slides) on the purpose of the review, its methodology, the activities that will be carried out and the key deliverables. During the same meeting, the NTP is expected to brief the external consultants on the TB situation in the country, major interventions and activities that are carried out, a high-level overview of the recording and reporting system with mention of any milestones, and a discussion of any challenges the country is facing with the TB surveillance system that the review should investigate. Where it is not possible to address all requests in the given time frame or with the existing data, the external consultants should manage expectations and work with the NTP to provide solutions on how to best answer these questions in the future; these solutions could then be incorporated into the recommendations. Stakeholders may also prepare relevant briefing presentations for the review team.

Finally, where multiple reviews have been carried out in the country, there should be a systematic discussion on the progress made since the last epidemiological review, through a review of the results from the standards and benchmarks and the status of implementation of the recommendations. Any challenges that the country has faced in implementing the recommendations (including a lack of priority) should be discussed. This process may be integrated into the briefing presentation that the NTP will deliver to the team, or it could be a separate discussion led by the external consultants. Any recommendations that were not implemented should be kept in mind by the review team during the investigation and should be re-evaluated at the end of the mission to determine whether they are still relevant and, if so, whether there is new evidence that can support their implementation.

Depending on the country, the briefings are likely to take half to a full day.

4.3 Finalizing the agenda and review of any missing documentation or data

The agenda that was prepared in consultation with the country team in advance of the mission should be reviewed with the NTP, NPO and any other members of the review team. Depending on the country, this could be done after the briefing session, with all stakeholders present. This discussion is important because it creates a common understanding of the sites and personnel that need to be visited. It also provides an opportunity for the in-country team responsible for booking appointments to comment on which appointments are confirmed and which are tentative, and any changes to the visits that were previously captured on the original agenda.

As discussed above, a degree of flexibility is required, and the external consultants should be prepared to regularly revise the agenda throughout the mission to accommodate changes (often, these are due to competing priorities of those who will be interviewed). Also, it may become apparent during the review that some key stakeholders were missing from the original agenda, or initial findings may indicate that a specific health facility or zone may benefit from a more detailed review.

During the meeting, timelines related to finalization and distribution of the epidemiological review report should be discussed. The external consultants should also receive agreement from the NTP that the results can be shared with stakeholders and donors, and that a copy of the final report will be held in the epidemiological review repository at WHO headquarters (Section 5.2).
The documentation and data that were previously shared with the external consultants should be reviewed in consultation with the NTP and NPO. Hence, it is important for the external consultants to come to the meeting with a clear list of questions and requests from having earlier reviewed the documentation and data for completeness and quality. Any outstanding items should be highlighted and, if they are available, should be requested. It is useful to try to understand the barriers and challenges that the NTP might be facing in retrieving the documentation and data. This discussion may uncover some key findings that should be addressed in the recommendations.

4.4 Desk review of key documents

It is recommended to start the desk review in advance of the in-country mission; however, where possible, the desk review should be completed at the beginning of the mission, because it can provide a strong outline of the context; that is, an overview of the TB surveillance system and associated M&E activities, and the chronological order of past TB events and other pertinent health-related events in the country. This information is necessary to complete Part A of the standards and benchmarks checklist (Section 4.5) \(^1\). Also, it can help guide interviews with stakeholders and partners (Section 4.6), and investigations at health facilities and laboratories (Section 4.7), and will be useful in supporting interpretation of findings from Part B of the standards and benchmarks checklist (Section 4.8) and the analysis of surveillance data (Section 4.9).

An important part of the epidemiological review is to identify documents that are missing or out of date. Missing documents should be confirmed as not available through the review of completeness of documentation that was carried out with the NTP (Section 4.3). Where documents are identified as missing or outdated, this finding can be used to ensure that relevant technical assistance is provided in the future to fill the gaps.

It is important to keep in mind the accessibility of the documents in the country. For example, documents that should be available at the health facility should be made available to the review team during health facility visits, to ensure that the most up-to-date versions of key documents have been distributed accordingly. These documents may include guidelines, standard operating procedures (SOPs), and standardized recording and reporting tools. Some of the relevant documents may be available online; if so, this availability should be verified to ensure that the most up-to-date documents are uploaded and that the website is accessible to those who may need it.

4.5 Part A of the standards and benchmarks checklist

Part A of the standards and benchmarks checklist \(^1\) comprises 18 questions, with associated categorical responses, to help the external consultants characterize the surveillance system for TB and related M&E activities.

During an epidemiological review, it is best to first fill this in using information from the documentation that was provided to the external consultants ahead of the review. A session with the NTP should be planned for at the beginning of the review (on day 1 or the morning of day 2) for a high-level response to the questions; this can also help to provide more context for the rest of the assessment.

Filling in Part A of the checklist is an iterative process because more information will be revealed during the review. Therefore, it is important to return to the checklist and update it when new information arises. The information that is provided in the documentation and by the interview with the national level should be verified through interviews with people at the subnational level (e.g. provincial and district level staff) and at health facilities and laboratories during the site visits. Observations from reviewing the completeness and quality of relevant registers, and from other data recording and reporting tools, will help in refining the answers. For example, aspects of TB surveillance quality assurance that are discussed in Part A (e.g. frequency of training, supervision, data quality review meetings and standardization of forms) should be verified during the field visits. Interviews with stakeholders and partners will also provide relevant information to consider, particularly when they are related to TB data recording and reporting tools (paper based or digital) that are not managed by the NTP.
The goal when completing Part A of the checklist is to provide as much detail as possible, to understand the characteristics of the surveillance system, including the patient and data flow, and any gaps in recording and reporting of TB cases. Part A will also help in understanding potential factors that may be the root causes of poor data quality.

By completing Part A of the checklist, the external consultants should have mapped out the various tools that are used for recording and reporting of TB data at different service delivery points, how these tools are linked, and how data flow from the health facility to the national level. It is good practice to develop a data flow diagram to be included in the report (an example is provided in Fig. 4.1). Box 4.1 provides a more detailed list of the expected outputs from completing Part A of the checklist as listed in the ToR for epidemiological reviews.

**Fig 4.1 Example diagram depicting the flow of information between tools and administrative levels in a country**

HMIS: health management information system; MTB: Mycobacterium tuberculosis; NRL: national reference laboratory; NTP: national tuberculosis control programme; PMDT: programmatic management of drug-resistant TB; RIF: rifampicin; RRL: regional reference laboratory.
## Expected outputs from completing Part A of the standards and benchmarks checklist (1)

- Mapping of agencies, organizations and sectors that are providing TB services and collecting or reporting TB data, with a discussion of data governance, ownership and data sharing agreements. The mapping should consider and describe the existing multisectoral collaboration and integration of the NTP with these entities; for example, private sector (for-profit and not-for-profit organizations), correctional services, military, mining and indigenous people’s associations.

- A review of the existing objectives of the surveillance system.

- Description of the policies, guidelines or strategies that are in place for M&E, recording and reporting or surveillance, including the national strategy for digital health.

- Description of the recording and reporting tools (paper based or digital) used by the NTP, and their availability at different health care levels and sectors.

- In the case of a digital system, a description and review of the system (e.g. stages, data entry forms, analytics and dashboards) and a discussion of challenges faced by users of the system.

- Description of NTP data that are captured on recording and reporting tools (paper based or digital), and at what levels.

- Description of the NTP data flow from the health facility to the national level.

- Description of non-NTP systems (paper based or digital) managed by other agencies or sectors that are also collecting TB data. Description of how systems collecting TB data are related to, or linked with, other health information systems (e.g. from other disease programmes, health insurance, electronic medical records, and HMIS or DHIS2).

- Description of TB data that are captured at the laboratory and how these are shared with the NTP.

- Description of all system linkages (paper based or digital) and mechanisms for data sharing across systems or agencies collecting relevant data.

- Whether there are investments and a long-term plan for implementing or strengthening other digital systems that capture TB data in the country (e.g. CRVS, HIV or HMIS), and whether the NTP is included in these plans.

- Types of data that are available at the national level (e.g. aggregate reports versus case-based data).

- Description of the existing master health facility list that the NTP is using to collect data from, and any gaps when compared to the total number of facilities offering TB services in the country. Commentary on whether the master health facility list is up to date and exhaustive.

- The availability and quality of a unique identifier that can be used to confidently link data from the different sources.

- Description of mechanisms for ensuring that high-quality data are recorded and reported, including a detailed description of any evidence of issues with data quality or underreporting.

- Timing and timeliness of reporting, including lag times that may hamper the capacity to monitor the trends routinely or in real time and take timely action.

- Availability and quality of data analysis plans, dissemination of reports and use of data for action.

- Staffing assigned to TB M&E tasks with, if available, the inclusion of an organigram highlighting occupied and vacant posts.

- Description of training plans and mechanisms for TB recording and reporting, M&E and analysis.
4.6 Interviews with stakeholders

Interviews with stakeholders should be conducted to gain a more holistic understanding of TB surveillance, M&E, and related challenges that extends beyond the scope or visibility of the NTP. The stakeholders may be different departments within the MoH with whom the NTP should be collaborating, or other ministries who may be providing related services (e.g. social security). They can also be institutions outside the local government, such as partner organizations supporting the NTP with the rollout of planned activities or the response to the TB epidemic (e.g. by implementing TB prevention and care programmes for specific areas or populations). Each setting is different; hence, the key stakeholders should be identified beforehand, in consultation with in-country colleagues. It is also advisable to gain an understanding of the relationship dynamics between the stakeholder and the NTP, because these can sometimes be delicate, making the interview at times difficult to manoeuvre; it is important to always act in a respectful and diplomatic manner.

Interviews with stakeholders should be used to support generating a narrative around the responses to the questions included in Part A of the standards and benchmarks checklist (1). Also, stakeholders may reveal key information that can support the responses in Part B of the standards and benchmarks checklist (Section 4.8), and may hold additional key data that can support the epidemiological analysis (Section 4.9).

Many of the individuals who will be interviewed during the mission will not have been present at the initial briefing meeting. Therefore, context needs to be provided to explain that the NTP is carrying out an epidemiological review – including a short overview of the activity and how the interview fits within the objectives of the review. This process may start with either the NTP or another member of the in-country team providing a short introduction, followed by the external consultant giving a summary of the support that is being provided to the NTP to carry out an epidemiological review with a specific goal (e.g. to inform an upcoming national programme review and the development of a new NSP for TB). It is important to make clear that this review is not an evaluation of the performance of the stakeholder, and to invite the interviewee to speak openly and share any challenges they may face, because these can then inform the recommendations where appropriate. The stakeholders should be given the opportunity to share opening remarks during the briefing process, before the official interview begins.

The interview should open with a leading question on what the role of the stakeholder is, and any process or activities related to TB prevention and care and associated M&E or surveillance. Allowing staff to talk with limited interruptions will usually reveal many interesting aspects of the TB programme that can then be followed up with more targeted questions. It is also important to have considered specific questions ahead of time, to ensure that all relevant information is obtained for an adequate assessment and correct interpretation, and to keep the interview focused on the topic at hand. The specific questions asked will depend on which stakeholder is being interviewed. Towards the end of the interview, the interviewee should be invited to raise any other issues that they feel are important to discuss. Before closing, permission to contact the stakeholder again should be requested, in case any further questions arise or to provide feedback once the epidemiological review has been finalized.

Box 4.2 provides a non-exhaustive list of key stakeholders that should always be considered for interviews during a TB epidemiological review, including some guidance on what information should be sought. Other stakeholders may be identified, depending on the country and context of the review.

About 1 hour is generally needed for each meeting.
**BOX 4.2**

**List of key stakeholders for TB epidemiological review**

**HMIS department, or equivalent, within the MoH**

This entity is responsible for health-related data, and for the development and rollout of digital tools to support the provision of health services or surveillance. This is an important entity that the NTP should have a close link with. Any digital system the NTP is developing or strengthening for M&E, surveillance and clinical management should be discussed with the HMIS department and should be part of the national digital health system structure or plan. For example, if the country is planning to develop and roll out electronic medical records, the NTP should be involved with the development of the TB relevant content. If the NTP already has a TB surveillance system in place, this should be linked, be interoperable with, or report data to the overall HMIS architecture (this typically involves reporting a couple of high-level TB indicators to HMIS).

The balance of the relationship between HMIS and disease programmes is often a delicate one; for example, there might be pressure from HMIS to integrate the TB surveillance system into a centralized and integrated surveillance system. Although system integration, mechanisms for data collection and centralization of resources are useful to help leverage funds, the NTP’s needs and interests should also be supported by the review so that the programme can collect and access all the data that are needed to address all objectives of their surveillance system and support programme planning.

Another discussion item with this team could be around master health facility lists. These lists are vital for understanding where TB services are offered in the countries and any gaps. Such lists should be exhaustive, should include both the public and private sector, and should be kept up to date. Where available, lists should be accessible to the NTP and should form the backbone of the surveillance system (paper based or digital).

The indicators should be reviewed to ensure that they are consistent with NTP and global guidelines. Also, it may be possible for TB data for relevant indicators to be compared between the NTP system and HMIS system, to see how well they match.

**National centres for disease control (CDCs) or other entities responsible for the surveillance of notifiable diseases or outbreak detection and response**

In most countries, TB is a notifiable disease. This will be confirmed through standard B1.8 in Part B of the standards and benchmarks assessment (1). If TB is not a notifiable disease in the country, then the recommendations should advocate for its inclusion in the list of such diseases.

The relationship between the national CDC and the NTP is often complex or strained. The national CDC is typically responsible for collection and analysis of key TB indicators (e.g. TB notifications), but also typically promotes its system (paper based or digital) for use by disease programmes. Frontline workers at the health facility often have to report the same information to both the CDC system and the NTP system. During the interview, it is advisable to discuss (where appropriate) the simplification of processes; for example, through interoperability of systems and data sharing agreements, so that reporting of TB data at the health facility only needs to happen once but the data can be used by both entities. This may not be an easy discussion to have and, depending on the systems being used in the country, there may not be an easy solution. However, this situation needs to be highlighted and addressed, to promote efficiency and overall improvement of data quality.

It may be possible for TB data for relevant indicators to be compared between the NTP system and CDC system, to see how well they match.
Bureau or office of national statistics or other entity responsible for population estimates or population-based surveys

The aim of this interview is to understand whether there are any reports on findings from population- or household-based surveys that collected data on TB, and whether there are plans to conduct such surveys in the future. For example, these may be demographic health surveys (DHS) or other household-based surveys collecting information on people’s behaviour towards TB and their understanding of the disease. Surveys may also measure the prevalence of some broader determinants or risk factors for TB. The NTP may be unaware of these data or may not be considering them in programme planning; however, such data are useful to support the interpretation of the findings from the epidemiological analysis (e.g. to explain any changes or differences to observed trends). If such data are lacking, it is worth discussing including TB relevant indicators in future surveys.

This entity may also be responsible for carrying out census surveys and estimating the population of the country at national and subnational levels. Therefore, it is particularly important to ensure that the NTP is using the most up-to-date census data available, and that the data source is consistent across administrative units and over time. It is also important to try to obtain population data disaggregated by age and sex, ideally at the district level. If these data exist, then their use by the NTP should be promoted so that subnational notification rates can be calculated per population. Finally, depending on when the last census was carried out, any plans for a future census should be discussed.

Entity responsible for CRVS, if available, or sample vital registration system

This interview aims to gain an understanding of the quality and coverage of the CRVS system and corresponding mortality data. The interview should reveal whether a national CRVS system is in place or whether there is a sample registration system that is representative of the country (and if not, whether there are plans to implement such a system).

Implementing and maintaining a functional CRVS system extends beyond the purview of the NTP, because the benefits support the understanding of disease burden and health risk overall, to guide action by decision-makers at the health system level rather than just for TB. Therefore, advocating for such a system requires a multisectoral approach, which in turn requires political buy-in and investment beyond TB (e.g. other disease programmes, other departments within the MoH and other ministries).

Where a functional CRVS system is in place, then it is important to ensure that the NTP (and other disease programmes) have an established link with the entity responsible for CRVS, to ensure that CRVS data can be used systematically to guide programmatic and planning action. If a system is in place, it would be useful to discuss data sharing agreements, data analysis and use of TB-related data, where available, and how these data could be important for the NTP.

Where a functional CRVS system is not in place, then it is advisable to discuss what would be required to implement such a system in a measured way according to existing resources; for example, holding a national consultation to review the need for mortality data to guide burden estimates and consider a pilot for a sample registration.

Implementing partners

This is a broad category of stakeholders that may be offering TB services or supporting the NTP in implementing planned interventions. For example, these partners could be public, private or parastatal NGOs that support the implementation of provider-initiated screening and case-finding activities that take place in health facilities, households, the wider community, correctional facilities or mines and para-mining communities.

In countries that have many implementing partners, it is a good idea to prioritize and visit the most important ones, or those that cover different subpopulations. The selection of implementing partners should be done in consultation with the NTP. In advance of the meeting, a request should be sent to the implementing partner to ask them to prepare some slides that describe the TB activities they carry out, including any associated M&E findings of the activities, if available.
The interview should be centred around understanding what data are recorded, how they are recorded and whether they are reported into the official NTP surveillance system (and, if so, how that reporting is done). It is important to look for opportunities for integration and collaboration.

Implementing partners often carry out activities or interventions that are part of a contract with a limited duration that they have signed with a funding agency, and may not have evaluated how well these interventions work – this is a missed opportunity and should be identified. Therefore, any plans for measuring impact should be discussed. In the context of the “finding the missing TB cases” priority of the Global Fund, it is advisable that national and global partners have impact frameworks built into implementation plans and guiding future investments.

A copy of the presentation slides and data should be requested during the interview, because implementing partners often collect and have access to data on vulnerable groups, provider-initiated case-finding interventions, and implementation of new technologies for screening, diagnosis and treatment of people with TB infection and disease.

**Private sector coordinating entities**

These entities may be an association of private providers; for example, hospitals, general practitioners (GPs) and paediatricians. Engagement of the NTP with the private sector is a priority area of the End TB Strategy, and one that the TB community has embraced for many years. Some of the priority areas of engagement from the private sector include:

- participation from the private sector during the development of national clinical guidelines for screening, prevention, diagnosis and treatment of people with TB infection and disease;
- promoting alignment of TB services offered by the private sector according to national guidelines;
- access to the latest TB treatment options, as well as other technologies and tools; and
- reporting of TB data.

With the support of the NTP and WHO country office, it is important to first identify the priority private stakeholders for interview based on the country context (e.g. related to the share of the private sector offering TB services). The interview should cover the type of TB services offered, a description of the engagement activities they are carrying out with the NTP, availability of data sharing agreements, and what data are reported and how.

Some of the most typical problems identified within this group of stakeholders are non-adherence to national clinical guidelines; this could lead to underdiagnosis of people with TB disease or inadequate patient management, and the underreporting of diagnosed TB cases into the official surveillance systems. A private sector facility providing TB services should be visited during the epidemiological review (Section 4.7).
4.7 Site visits to health facilities and laboratories

Visits to health facilities that provide TB services and associated TB laboratories are central to an epidemiological review. During a review, it is expected that the team will visit a variety of service delivery sites. At a minimum, these sites should include the following – noting that some are not necessarily mutually exclusive sites; for example, some facilities may be providing multiple services covering TB/HIV, paediatric TB or MDR-TB:

- health facilities and associated sources of laboratories:
  - rural or low TB notification facility;
  - urban or high TB notification facility;
  - primary, secondary and tertiary level facilities;
  - public and private facilities;
- health facility providing TB/HIV services;
- health facility providing paediatric TB services;
- health facility providing MDR-TB services; and
- NRL.

The information gained during the discussions at the national level or through the desk review may not hold true at the peripheral level (where policies and practices may not be well implemented or adhered to). Visits to such facilities provide a rich source of information to refine the narrative for Part A of the standards and benchmarks checklist (1); therefore, information previously received should be validated at the peripheral level.

Each visit should be scheduled for at least 2 hours, but a visit could last longer if the site is the first to be visited during the review.

Before reaching the site, a courtesy visit and briefing is generally provided to the district level officer (or provincial or state officer) with whom the review team will be working. The district health officer will then join the team for all visits that take place under their jurisdiction.

At the health facility, the visit will open with a briefing with the health facility staff. Depending on the size of the facility, this may first be done with the hospital director and the TB team (tertiary level facility), the TB service coordinator (secondary level facility) or the TB nurse directly (primary level facility). As with the briefings with stakeholders, the session should cover the purpose of the epidemiological review and its specific context (e.g. to inform the development of a new NSP for TB). The importance of frontline workers in the recording and reporting of TB data, and therefore in TB surveillance, should be highlighted. It should also be made clear that the visit is not a review of facility staff performance, but rather is an assessment of the system as a whole; facility staff should feel comfortable to speak openly about any challenges they are facing with the system so that these can be factored into the recommendations. The objectives and process of the visit should be explained; that is, to understand how patients flow through the system, what data are collected during the process, how these data flow to the national level, and that the discussion will be followed by a review of the paper-based forms and registers. During the discussions, it is important to not use overly technical language because the health facility worker will likely not have received formal training in data science or epidemiology.

Visits to health facilities need to be approached with care because facility staff can feel intimidated by being visited by a large external team that include their superiors (the district level officer). During the interview, it is important to be mindful of the influence that having the superiors present may have on the flow of the conversation. Depending on the setting, this situation may facilitate the conversation whereas at other times it may act as a barrier (e.g. if the facility staff are worried about revealing the challenges they face).

The interview should begin with a broad focus and then narrow down into the specifics, to ensure that the review team gathers the information they are seeking and can investigate any additional relevant points revealed by the facility staff during the discussion. Therefore, the interview should open by inviting the staff to talk about the facility they work in. Staff may describe the different services provided, their specific work in
the facility and the human resource capacity for TB services. The conversation may then evolve to a more specific discussion on the TB services provided. This can be achieved, for example, by asking the staff to describe the pathway the patients take, including how and where patients are screened; how they are referred to the TB services; sample collection and testing, including where the associated laboratory is located; what happens when a positive or negative laboratory result is reported; and the process for treatment initiation and follow-up to ensure adherence. This should also include a demonstration of where data are recorded at the different stages. Any community outreach activities that may be linked to the health facility should also be covered, such as referrals from community health workers and community treatment support initiatives, and how and where this information is recorded. During this discussion, it is important to try to identify gaps in the pathway or any challenges that the staff face in the pathway of TB care. Any challenges that were highlighted in the discussions with the national level should be investigated at the health facility level and can help to guide the interview. A tour of the facility is a useful way to map out the locations where the different stages may take place, understand the distances that patients may have to travel within a facility and identify any opportunities to reduce loss to follow-up in the pathway. At the health facility, it is also important to understand the connection with the TB laboratory network. If laboratory services are provided at the facility, then this department should be visited. It may be that a microscope is available at the health facility that is used for follow-up microscopy, whereas diagnosis by GeneXpert or other WHO-recommended rapid diagnostic test (WRD) is done at another site; in such cases, the sample transport mechanism should be described.

By the end of the interview, the review team should have a clear understanding of the pathway that patients take, any gaps and challenges faced, and where data are being recorded.

When the interview concludes, the review team should ask to see the TB recording and reporting tools, to assess the following:

- availability of the recording and reporting tools (e.g. paper-based registers, patient cards, forms or digital tools);
- whether the tools are up to date and capturing the relevant information;
- timeliness of recording data in the tools;
- whether data are complete and consistent within the tool; and
- whether data are consistent across tools.

The following checks should be carried out:

- trace of information for all (or a select number of) patients across registers (e.g. presumptive register, case register and laboratory register);
- whether the number of cases recorded in the case register matches the aggregate numbers captured on quarterly reporting forms (if relevant) and the number of patient cards available at the facility; and
- where a digital system is in place and data are still captured on paper-based registers in parallel, then whether the data from the digital system match the data captured on the paper-based tools (this can be facilitated by the M&E team, who may be able to generate summary reports of the data from the facility that is under review).

Reviewing the registers should reveal challenges with TB prevention and care (e.g. diagnostic delays or poor treatment outcomes), and issues in the recording and reporting of TB data (e.g. evidence of delayed reporting or underreporting). This information will help the review team to understand the completeness and quality of the source data, and how this might influence what is observed at higher administrative units; however, this is not a nationally representative sample. Although reviewing the registers might shed some light on the assessment of Standard B1.4 (Section 4.8), it will not be sufficient to fully assess the standard.

Box 4.3 describes some particular considerations that should be kept in mind for certain types of sites visited (e.g. different levels and sectors of the facility and laboratories, and different service delivery points). The considerations provided should be deemed as guidance and are not meant to be prescriptive because they will differ for each setting.
BOX 4.3

Special considerations for different types (level and sector) of health facilities, laboratories and services

Primary level facility

Depending on the setting (even within the same country), primary level facilities can differ in their size and their capacity to offer health services. These facilities may have a laboratory on site (either microscopy or WRD, or both) or may rely on an external laboratory for testing samples.

It is not possible to provide all TB services at the primary level facility (e.g. management of DR-TB may not be possible at this level, so it is important to understand the referral process when a case of DR-TB is detected). Also, the capacity for clinical diagnosis of pulmonary TB or the diagnosis of extrapulmonary TB may not be available at the facility. Again, these referral processes should also be reviewed.

Some rural primary level facilities may be managed by only one or two nurses, with no medical doctor present. Access to TB diagnostics may be limited because of the large distance to the nearest TB laboratory. Therefore, the sample transport mechanism should be discussed in detail. Similarly, patients may have to travel long distances to reach the facility, creating issues with patient management and follow-up. These challenges should also be discussed in detail, including efforts that are made to ensure treatment adherence and success.

Urban primary level facilities are usually better equipped to provide TB services and may have multiple outpatient departments (OPD). In such cases it is important to understand the integration of TB services with other services provided and the different points of entry into TB services.

Secondary level facility

Secondary level facilities will have a stronger capacity for the diagnosis of TB than primary level facilities. There may be a dedicated TB clinic within the secondary level facility, or TB services may be integrated into other services. There will usually be a laboratory on site that is equipped with a WRD. Similarly, the capacity for clinical diagnosis will usually be available and may be supported by the availability of radiography services. Therefore, patients may be referred from the primary level for diagnosis, then referred back to the primary level for treatment initiation. The referral process with the primary level facility should be described during the visit.

Secondary level facilities may provide services for the diagnosis and treatment initiation of DR-TB cases. In this case, the drug resistance register should be available and reviewed. These facilities may also have the capacity to diagnose TB in children, and can therefore also serve as the facility to visit for paediatric TB. Where this is the case, the relevant service delivery point should be visited if it is not directly integrated into the TB service delivery point. Particular attention should be paid to ensuring that children diagnosed with TB are recorded in the TB case register.

There will be multiple OPDs within the secondary level facility, and some facilities may also have inpatient departments or wards. The team should review any integration of services; for example, where screening activities are taking place in other OPDs or on inpatient wards, the team should review the process for testing and diagnosis, and how data are captured in the standardized tools. Where there is a dedicated TB service delivery point, the team should review how the referral mechanism works and how data are shared with the dedicated departments.
### Tertiary level facility
These are often large hospitals with a variety of OPDs and inpatient departments providing services for issues requiring advanced medical intervention. Briefing with the hospital director and relevant team members may be required, before holding discussions with the TB service staff.

As with secondary level facilities, the integration of TB services with other departments should be reviewed; this includes the different entry points and data sharing with the TB department. Large tertiary level hospitals are complex systems; hence, it is easy for TB data to be lost along the way. Inventory studies have shown that such facilities are often a source of underreporting of TB cases. It is also important to discuss the digital tools that are being used in the tertiary level facility because they often rely on a separate electronic medical records (EMR) system. The NTP’s recording and reporting system is often underused and lacks interoperability with the hospital’s EMR, which may be one of the contributing factors to underreporting of TB cases.

Finally, although tertiary level facilities are still part of the public system within the NTP network, they often act with a higher degree of autonomy and may not adhere closely to national TB guidelines, favouring the diagnosis of TB clinically rather than bacteriologically. This should be kept in mind by the review team and investigated as necessary, to assess any evidence of potential overdiagnosis of TB in both adults and children.

### Community level
TB services are usually also being provided outside of health facilities. Community-based initiatives may include, for example, screening for TB or treatment adherence support at household level. These initiatives may be carried out by health care workers or community outreach workers. It is important to discuss these initiatives with the NTP and health facility workers during visits to health facilities. Community outreach workers may be relying on specific tools (paper based or digital) to capture TB data, which should then be linked to the NTP’s core recording and reporting system.

Depending on the type of community-based initiative in place, it may be relevant to have a specific discussion about how the work in the community is linked with the health facility. This would include referrals from the community to the health facility for screening, testing, diagnosis, treatment initiation or evaluation at the end of treatment, and the associated data recording and reporting mechanism (e.g. are these individuals captured directly in the health facility’s registers and, if so, what mechanisms are in place to track the contribution of community efforts).

### TB/HIV service providers
TB/HIV integrated services will be provided at both the TB service delivery points and the service delivery points for HIV and antiretroviral therapy (ART), and should be integrated into primary care. Both service delivery points should be visited during an epidemiological review.

On the TB programme side, testing for HIV should be done systematically at TB diagnosis if the patient’s HIV status is not known or if a current HIV-negative result is outdated. HIV testing coverage, status and ART status are generally captured in TB case registers because these are routinely monitored by NTPs.

On the HIV programme side, screening for TB should be done systematically among people living with HIV (PLHIV). The provision of TPT among PLHIV is managed by the HIV programme. TB screening and TPT data are captured in HIV registers, which should be reviewed for completeness and consistency, including the possibility to link with TB registers as necessary. These data should also be shared routinely with the NTP because they form part of the core indicators for the programmatic management of TPT (PMTPT) to be monitored routinely by the NTP.
Private providers of TB services

Private providers often operate independently outside of the NTP network, with little known about what is happening in this sector. As mentioned in Section 4.6, engagement with private providers is a priority initiative within the End TB Strategy. The size of the private sector in providing health services and the level of engagement the NTP has with the private sector will vary, depending on the setting. The private sector can be a major source of underreporting of TB cases and may not be adhering to the most up-to-date clinical guidelines. This is being addressed by setting up memoranda of understanding with private providers, and by training private health care providers and equipping them with NTP clinical guidelines and recording and reporting tools. However, this is only successful if the private provider is willing to collaborate.

At private facilities, it is important to review the level of engagement with the NTP and gain an understanding of the types of TB services that are available and whether these are aligned with the most up-to-date national and global guidelines. It is also important to understand how TB data are being shared with the NTP. This mechanism will differ from country to country. In some instances, the NTP will hire staff to be stationed at the private provider to register the information on behalf of the private provider. In others, the private provider will be equipped with the necessary NTP recording and reporting tools. In the case of a digital system, a lighter version of the NTP’s digital recording and reporting system may be offered, to capture the minimum amount of data required. In the case of a paper-based system, the registers and reporting forms should be checked for completeness and consistency of the data. It is sometimes observed that the quality of the data being recorded is not as high as in the public sector.

TB laboratories

Like health facilities, TB laboratories can vary in size and in capacity for TB testing. They may be located within a health facility or serve as an independent entity (e.g. the NRL). In its simplest form, a TB laboratory may contain only a microscope within a health facility, which the nurse uses for reading smear slides. More complex and larger laboratories will be able to offer more advanced techniques, such as testing samples using a WRD (e.g. GeneXpert) or culture. These more advanced laboratories may also have the capacity to perform drug susceptibility testing (DST), either for first-line drugs alone or for fluoroquinolones as well.

When visiting a laboratory, it is first important to understand the capacity the laboratory has for TB diagnosis. Normally, a tour of the laboratory is provided, where the review team will be able to understand the type of diagnostic tools present, in what number, and the functionality of the tools (e.g. whether all modules in the GeneXpert machine are currently functional). A discussion around recently reported down time of the equipment and any stockouts should be covered.

Even if the laboratory is attached to a health facility, it may serve as the testing site for a number of facilities in the area. The number of facilities that the laboratory serves and what type of tests it undertakes should be discussed and documented, including the mechanisms for sputum transport, reception and processing.

As with visits to the health facility, the review team should aim to understand the path the sputum sample will take from reception to testing, including what data are collected along the way, what tools are being used to record the information and how results are communicated back. It is important to look for any gaps in the pathway that may be leading to underdiagnosis (e.g. barriers to testing samples) or underreporting (e.g. barriers to communicating positive results).

The recording and reporting system of the laboratory may be paper based, with a series of registers depending on the test conducted (e.g. for microscopy, GeneXpert, or culture and DST). In this case, data may then be entered and stored in Microsoft Excel. The registers should be reviewed to assess the consistency and completeness of information. It is important to also try to understand how a link is made with the TB case register in the health facility (e.g. by including respective identification codes from the registers), because this is often not done systematically. If possible, the review team should try to assess
Guidance on conducting reviews of tuberculosis programmes. Web Annex C

The visit to health facilities and associated laboratories should be a rich source of information to support the narrative for Part A of the standards and benchmarks checklist (1), by revealing new information or validating information previously received. It is important to revisit and update Part A of the standards and benchmarks checklist throughout the series of site visits, as needed.

4.8 Part B of the standards and benchmarks checklist

Part B of the standards and benchmarks checklist (1) is used to assess the capacity of the TB surveillance and the country’s vital registration system to measure TB incidence and mortality. The first edition of the checklist was published in 2014 with a comprehensive user guide (3). The checklist was updated in 2023 and is now in its second edition; the latest edition is the one that should be used for TB epidemiological reviews from now on (1). Where applicable, benchmarks have been updated to be better aligned with the SDGs and M&E indicators for updated WHO TB guidelines. The scope of the second edition of the checklist has been widened to cover more of the pathway of prevention and care, with the addition of two new standards related to programmatic management of TPT (PMTPT) and treatment outcomes.

The second edition of Part B of the standards and benchmarks checklist comprises 17 standards (i.e. general statements about the criteria for a high-performing TB surveillance system) and associated benchmarks, across four sections:

- **Section 1** – Core standards related to TB surveillance and vital registration systems, nine of which are related to the measurement of TB cases (e.g. data quality and system coverage) and one of which is related to the measurement of TB deaths (using TB mortality data from vital registration systems).
- **Section 2** – Three supplementary standards for surveillance on specific populations (TB and HIV coinfection, DR-TB and childhood TB); the responses can be used to assess whether a national TB surveillance system can be certified as providing a direct measure of the number of cases of rifampicin-resistant TB (RR-TB), HIV-positive TB or childhood TB.
- **Section 3** – Two standards that can be used to assess the quality of treatment outcome data.
- **Section 4** – Two standards related to contact tracing and prevention; the responses can be used to assess the availability and quality of M&E data on PMTPT.

A list of the standards from Part B of the standards and benchmarks checklist (1) is shown in Box 4.4.

To ensure that the most complete data are available for review, the assessments are designed to use data from the most recent complete calendar year, unless otherwise stated. Depending on the timeliness of the reporting and finalization of data validation procedures in the system, the lag time may range from no delay...
to up to 1 year. In some instances, data from additional years are needed to assess trends over time; alternatively, data from a single quarter can be used, to reduce the burden of data collection.

Part B of the standards and benchmarks checklist (1) is largely analytical, and most of the standards can be assessed through the analysis of the routine data that have been provided by the NTP. Therefore, Part B of the checklist can be completed in parallel to the data analysis (Section 4.9). However, the desk review, stakeholder interviews and site visits are required for a complete and comprehensive assessment.

When carrying out Part B of the standards and benchmarks checklist, evidence should be provided that justifies the assessment of the standard, and any gaps identified should be linked to recommendations.

Although the full narrative should be included in the TB epidemiological review report, the findings from the assessment should be summarized in a table that includes results from previous assessments (if available), to highlight progress that has been made in strengthening TB surveillance and any systematic gaps that remain, as shown in Fig. 4.2.

**BOX 4.4**

**List of standards from Part B of the standards and benchmarks checklist (1)**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1.1</td>
<td>Case definitions are consistent with WHO guidelines.</td>
</tr>
<tr>
<td>B1.2</td>
<td>The TB surveillance system is designed to capture a minimum set of variables for reported TB cases.</td>
</tr>
<tr>
<td>B1.3</td>
<td>All scheduled periodic data submissions have been received and processed at the national level.</td>
</tr>
<tr>
<td>B1.4</td>
<td>Data in quarterly reports (or equivalent) are accurate, complete and internally consistent (for paper-based systems only).</td>
</tr>
<tr>
<td>B1.5</td>
<td>Data in national database are accurate, complete, internally consistent and free of duplicates (for digital case-based or patient-based systems only).</td>
</tr>
<tr>
<td>B1.6</td>
<td>TB surveillance data are externally consistent.</td>
</tr>
<tr>
<td>B1.7</td>
<td>Number of reported TB cases is internally consistent.</td>
</tr>
<tr>
<td>B1.8</td>
<td>All diagnosed cases of TB are reported.</td>
</tr>
<tr>
<td>B1.9</td>
<td>Population has good access to health care.</td>
</tr>
<tr>
<td>B1.10</td>
<td>Vital registration system has high national coverage and is of high quality.</td>
</tr>
<tr>
<td>B2.1</td>
<td>Surveillance data provide a direct measure of RR-TB in bacteriologically confirmed pulmonary TB cases.</td>
</tr>
<tr>
<td>B2.2</td>
<td>Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases.</td>
</tr>
<tr>
<td>B2.3</td>
<td>Surveillance data for children reported with TB (defined as ages 0–14 years) are reliable and accurate AND all diagnosed childhood TB cases are reported.</td>
</tr>
<tr>
<td>B3.1</td>
<td>Monitoring of treatment outcomes is consistent with WHO guidelines.</td>
</tr>
<tr>
<td>B3.2</td>
<td>Recording and reporting of TB treatment outcomes are accurate, complete and consistent.</td>
</tr>
<tr>
<td>B4.1</td>
<td>Monitoring indicators for PMTPT is consistent with WHO guidelines.</td>
</tr>
<tr>
<td>B4.2</td>
<td>PMTPT data are accurate, complete and consistent.</td>
</tr>
</tbody>
</table>
4.9 Data analysis

The data analysis aims to provide an updated assessment of the level of, and trends in, TB burden and programmatic indicators in the country. This entails the review and compilation of published estimates of TB morbidity and mortality, plus a review of TB notification and related service delivery data. Examples of sources of data are:

- WHO Global tuberculosis database (for incidence and mortality estimates);
- the NTP’s aggregate or case-based surveillance dataset;
- census and population estimates from the responsible agency (e.g. national bureau of statistics);
- records from national or sample CRVS for cause of death data, or results from mortality surveys and mortality review reports;
- demographic or other health survey reports, including facility level service readiness assessment surveys;
- other published literature from important research studies carried out in the country; and
- data from active disease surveillance sites.

The core set of analyses are carried out using the NTP’s routinely collected data along the pathway of prevention and care; however, they may need to be complemented by other data that are not routinely collected by the NTP. The analysis should be carried out by time (time-series for at least 5 years of data), geography (sub-national analysis) and population (e.g. age and sex), where data permit. Additional dimensions related to the level and type of health service provider should be considered, where feasible. The analysis should be carried out as outlined in the ToR for TB epidemiological reviews. A summary of the key programmatic indicators is provided in Box 4.5. Additional analyses can be carried out at the discretion of the epidemiologist to support the review.
### BOX 4.5

**Summary of key indicators for analysis as outlined in the ToR**

The following should be included for the analysis of *notifications and outcomes data*:

- **TB case notifications (absolute numbers and rates), all cases and by different case types;**
- **proportions and ratios of notified cases:**
  - proportion of notified cases who were bacteriologically confirmed, by treatment history;
  - proportion of notified cases who were diagnosed with extrapulmonary TB;
  - proportion of notified cases who were aged less than 15 years;
  - proportion of notified cases who were previously treated;
  - rate ratio of 0–4:5–14;
  - male-to-female ratio;
  - ratio of presumptive-to-bacteriologically confirmed cases, if data are available and quality of the data allows;
- **distribution of notified TB cases by age and sex, and the average age of newly notified cases;**
- **age- and sex-specific case notification rates, if population data are available;**
- **trends in the number of TB patients being referred and/or notified by different types of providers, levels of health system and case-finding approaches, where data are available:**
  - public, private;
  - community health worker, pharmacist, GP, secondary/tertiary hospital;
  - HIV centres, diabetes clinics, other outpatient services or OPDs;
  - patient-initiated, provider-initiated;
- **linkage to care: number of TB patients treated with appropriate TB regimen divided by the number of notified patients eligible for treatment, expressed as a percentage;**
- **consistency of number of recorded outcomes with reported treatment cohort and number of notified TB cases;**
- **TB treatment success rate: percentage of notified TB patients who were successfully treated (cured or completed treatment) for drug-susceptible TB and DR-TB (combined and separately);**
- **trends in all TB treatment outcome categories to investigate contribution of unfavourable outcomes:**
  - percentage cured;
  - percentage treatment completed;
  - percentage died;
  - percentage failed;
  - percentage lost to follow-up; and
  - percentage not evaluated.

The following should be included for the analysis of *DR-TB notifications and outcomes data*:

- **care cascade for DR-TB:**
  - number of pulmonary bacteriologically confirmed TB cases;
  - number and percentage of cases tested for resistance to rifampicin;
  - number and percentage of cases with RR-TB;
  - number of cases started on second-line regimen, and number successfully treated;
- **care cascade for other levels of drug resistance (e.g. pre-extensively drug-resistant TB [pre-XDR] and XDR), if data are available;**
- DR-TB notifications, by level of drug resistance;
- DR-TB treatment outcomes.

The following should be included for the analysis of *HIV-associated TB notifications and outcomes data*:
- care cascade for HIV-associated TB:
  - number of new episodes of TB;
  - number and percentage tested for HIV;
  - number and percentage with TB-HIV coinfection;
  - number and percentage started on ART;
- TB-HIV coinfected TB notifications; and
- HIV-associated TB treatment outcomes.

The following should be included for the analysis of *programmatic management of TPT data*:
- contact investigation coverage: number and percentage of contacts of patients with bacteriologically confirmed TB who completed an evaluation for TB disease and TB infection;
- TPT coverage: number and percentage of people eligible for TPT who initiated treatment out of those eligible – if data are available, then this could be disaggregated by:
  - PLHIV (newly or currently enrolled on ART);
  - contacts aged below 5 years;
  - contacts aged 5 years and above;
  - TPT regimen (e.g. 3HP [3 months isoniazid and rifapentine regimen], 3HR [3 months isoniazid and rifampicin regimen] or 6H [6 months isoniazid regimen]);
- TPT completion: number and percentage of people who completed TPT out of those who initiated treatment – if data are available, then this could be disaggregated by:
  - regimens lasting less than 6 months; and
  - regimens lasting 6 months or more.

The following should be included for the analysis of *TB laboratory data*:
- trends in the introduction of more sensitive diagnostic tests (e.g. Xpert) and the impact of rollout on case detection;
- percentage of new episodes of TB who were tested using a WRD at the time of diagnosis;
- review of laboratory testing practices in the country, including the diagnostic algorithm implemented and the eligibility for testing using different methods;
- number of smear microscopy slides read and the smear positivity rate;
- number of Xpert MTB/RIF tests conducted, the *Mycobacterium tuberculosis* (Mtbc) and RR-TB positivity rate (including error, invalid or no result); include trace results and “rifampicin (Rif) indeterminate” where Xpert Ultra is used; and
- Xpert MTB/RIF utilization rate; that is, number of tests in a given period divided by the capacity of the machine, expressed as a percentage.

The following should be included for the review of other relevant data to support interpretation of findings from the above analyses and provide more context:
- summarize and describe the level of, and ideally the trends in, underreporting from a national inventory study if these data are available before the assessment, or from alternative sources of TB patient quantification or estimation (e.g. health insurance claims data);
- any data or findings available from special studies or surveys of TB in high-risk groups, such as PLHIV, older people, people with diabetes, people with compromised immune systems, prisoners, miners, migrants and homeless people;
If agreed by the NTP, the data analysis can be facilitated by using the WHO tbhistoric DHIS2 platform (2). However, the system captures only a limited number of indicators; therefore, additional analyses will need to be carried out using tools other than tbhistoric (the external consultants may use any statistical programmes that they are proficient in).

Typically 4–5 days is required to complete the data analysis. It is recommended that the analysis is split between the two external consultants and the M&E team of the NTP, where possible.

Interpretation of the findings must be done in close collaboration with the NTP. It is also important to draw from the characteristics of the TB surveillance system (Part A of the standards and benchmarks checklist (1)), as well as findings from the site visits and interviews with stakeholders. This approach will bring in factors related to the overall system architecture that may influence what is observed in the data, before drawing any conclusions related to TB burden.

Some resources are available to help the review team in the interpretation of TB data. These include the handbook *Understanding and using tuberculosis data* (4) and the e-learning course *Harnessing the power of routine health facility data: tuberculosis* (5), which was developed by the WHO/GTB in collaboration with the WHO Academy.

### 4.10 Synthesizing and validating findings and recommendations

Findings from each of the core activities carried out during a TB epidemiological review (as summarized in Section 4.1) should be synthesized into a logical narrative, highlighting the strengths and weaknesses of the TB surveillance in the country, as well as programmatic successes and gaps.

The synthesis should form the basis for developing a set of coherent and actionable recommendations for the NTP and partners for strengthening TB surveillance, M&E and programmatic activities in the country. The feasibility of implementing a recommendation and its utility should be carefully considered. For example, before making a recommendation, the level of effort required to implement that recommendation needs to be assessed against the level of impact that the recommendation is expected to bring. Furthermore, it is important to consider the appropriateness of the potential recommendation for the setting, particularly for activities that have defined eligibility criteria (e.g. prevalence surveys). It is helpful to explain the context of the recommendation and the rationale for why it was made, drawing from evidence gathered from the epidemiological review.

It is useful for the external consultants to be aware of global resources and activities that are available to support NTPs, with an understanding of the context of when they should or should not be considered.

The external consultants should also keep in mind that official recommendations can serve as a tool for advocacy (e.g. to mobilize funds for an activity or serve as a starting point for a multisectoral engagement that might be needed for addressing an issue that extends beyond the scope of the NTP).

Recommendations can be presented in different ways but providing timelines (e.g. a short-term versus long-term vision) and estimating the level of impact a recommendation can bring can be useful later, when determining priorities for implementing the recommendations.

Recommendations should be made related to the following areas:

- strengthening routine surveillance, M&E and data use in the country;
- improving understanding of the TB burden through the generation of new data from priority periodic studies;
- addressing programmatic gaps and improving performance of TB services in the country;
- identifying:
  - further analyses to be carried out by the NTP that were not feasible to carry out during the TB epidemiological review because the required data were not readily available;
  - aspects that require further investigation (e.g. by the NTP review team or through NTP supervisory visits); and
- determining research priorities for filling any important data gaps in the country.

It is also important to think about what additional technical assistance might be needed for implementation of the recommendations, how to access the technical assistance, and if this would require additional funds. Such assistance can then be included in the discussions with the NTP, and in the debriefing presentations and final report.

The findings and recommendations need to be discussed in detail with the NTP before any official debriefings, so that NTP staff have the opportunity to provide comments, validate the findings and agree on the recommendations, which may require some negotiation. This should be done through an informal debriefing with the NTP.

Presenting findings, particularly weaknesses and gaps, and discussing recommendations with the NTP may be a sensitive task; hence, it should be approached in a diplomatic and tactful manner. For example, the external consultants should be aware that some recommendations that may be requested for inclusion may be political rather than based on scientific evidence. The team should be open to discussing and changing the recommendations, but should not feel pressured to recommend something that is not achievable in the current context, does not follow the evidence from the review or is contrary to practices recommended in global guidelines.

Recommendations should also be synthesized using the recommendations synthesis checklist provided in Appendix 2. Appendix 2 also provides the definitions of the high-level recommendations. Specific recommendations that have been made to the country can be mapped onto the framework and fit within one of the high-level recommendations. The recommendations synthesis checklist serves as a tool to help synthesize and monitor recommendations in a standardized way across reviews and is not meant to replace the specific recommendations that are made to the country. The completed checklist does not necessarily need to be presented to the country but is required to include in the final report; therefore, it may be completed after the conclusion of the in-country mission, during the drafting of the report.

Once the findings have been validated and the recommendations agreed with the NTP, preparations for the official debriefing sessions can start. The NTP will be able to inform the external consultants on the scope of the debriefing meetings, who will be present and the level of detail that should be provided in the debriefing presentation. If the external consultants feel that any particular individual or entity should be present for the debriefing, then this request should be made to the NTP.

### 4.11 Debriefing meetings

As with the briefings, the debriefing sessions can take different forms. The external consultants should be aware of the audience who will be present at the meeting and prepare accordingly. The debriefing presentation should be fit for purpose; that is, it should provide the key messages and recommendations at the level of detail that is relevant for the audience (as guided by the NTP).

Typically, the external consultants will have to plan for at least two debriefing meetings. Depending on the setting, the debriefing process can take up to a full day and should be planned for accordingly in the agenda for the review.

Following the validation of the findings and agreement on recommendations (Section 4.10) an official debriefing, covering in detail the findings from the core activities from the review, would be scheduled with the full NTP team, including the programme manager. This debriefing session may also include key stakeholders, including technical and funding agencies.
In some situations, the external consultants may be asked to provide the high-level findings and recommendations only, in a separate debriefing to the programme manager or stakeholders.

A debriefing with the WHO representative and NPO will also be scheduled. This meeting is usually internal to WHO, without the presence of the NTP or stakeholders. However, in some rare cases the M&E staff from the NTP who were assigned to the review may join this meeting. Given the limited time that the WHO representative will have available, these meetings usually need to be short but effective. It is important for the external consultants to have prepared some talking points on the major findings and recommendations from the review, to focus the discussion, which should include the high-level findings and recommendations that may be beyond the scope of the NTP. These findings and recommendations may require a multisectoral approach or intervention at a health system level, which the WHO country office may be recommended to support, or which the WHO representative may take up directly with the minister of health.

### 4.12 Defining next steps and planning for follow-up

Before the in-country mission concludes, it is important to have a discussion on the next steps and plan for follow-up on the recommendations. This is usually done in consultation with the NTP and WHO country office, or with local partners providing technical support for the NTP. Immediate next steps may include finalizing any outstanding analyses or making corrections remotely. A timeline on providing a full draft of the report, as well as turnaround time for comments, should be agreed upon.

As discussed in Section 4.10, when presenting the recommendations, the external consultants should try to identify any technical assistance or funding that may be required for implementing the recommendations; these requirements should be communicated to the NTP, WHO country office and local technical partners (where relevant). The NTP will be responsible for planning for and implementing the recommendations; however, follow-up and support should be provided by the WHO country office and local technical partners (where relevant). It is important to define these roles through in-person discussions. Further follow-up and support can be provided by the WHO regional office and WHO headquarters, who may provide guidance or technical assistance, or facilitate links with relevant partners.
CHAPTER 5

Reporting on the epidemiological review

5.1 Drafting the report

The main deliverable from the epidemiological review as set out in the standardized ToR is a comprehensive report addressing all of the objectives of the assignment, which should be shared with the NTP, WHO country and regional offices, WHO headquarters, donors who financed the review and other stakeholders as authorized by the NTP.

The report is used to inform the NTP review, the development of domestic and international funding requests (e.g. to the Global Fund), and the development of national strategic plans or other strategic documents. Therefore, the report should follow a standard template for epidemiological reviews as show in Box 5.1.

Parts A and B of the standards and benchmarks checklist (I) should include as much detail as possible, so that they are sufficient to serve as a core section of the report. This can be written during the in-country mission, reducing the workload that needs to be carried out afterwards. To further expedite the process, some sections of the report may be drafted before the review (e.g. the introduction, objectives and part of the methods).

A full draft of the report should be shared with the NTP and WHO country or regional office no later than 2 weeks after the conclusion of the in-country mission, for comment and review. If relevant, WHO headquarters may also provide guidance and feedback on the report to ensure a high-quality output. The final draft of the report, which should incorporate the feedback from the reviewers, should be submitted to the WHO country office and NTP no later than 4 weeks after the conclusion of the in-country mission. The NTP will validate the final report and sign off when appropriate.

5.2 Ownership, dissemination and use of the review findings and report

The NTP and MoH own the TB epidemiological review outputs and report. Expectations on report dissemination are included in the TB epidemiological review ToR (Objective 4) and should be clarified with the NTP for final agreement. However, countries should be encouraged to share findings widely because they can inform stakeholders on how to tailor their support and can serve as a resource that other countries can make use of.

Beyond the NTP and MoH, the report is also expected to be shared with the three levels of WHO, to help in coordinating and implementing appropriate support to the NTP.

At WHO headquarters, WHO/GTB holds a repository of reports from TB epidemiological reviews carried out globally, and manages a database of findings and recommendations from standards and benchmarks assessments. These findings and recommendations are synthesized and used to track improvements in strengthening TB surveillance globally; they are also used to help guide priorities for the development of guidance and tools to support the NTP in this initiative. Furthermore, findings from the epidemiological review can be used to support burden estimation.

The NTP and MoH should also consider the relevant funding agencies and technical partners with whom the report should be shared. Donors (e.g. the United States Agency for International Development [USAID]) and technical partners may use the report to direct investments and technical assistance resources to support the implementation of the recommendations.

The final report should be submitted by the external consultants to the NTP, MoH and contracting office as a deliverable requirement to conclude the contract. The external consultants should not, under any circumstances, use the findings in the report for any purposes outside of the contract (e.g. for peer reviewed publication) unless this is agreed by the NTP and MoH.
**BOX 5.1**

**Standardized structure for TB epidemiological review reports**

**Executive summary**
- Summarize the main components of the report in one or two pages

**Introduction**
- Briefly introduce the country-specific context, including an overview of the TB situation in the country and recent achievements of the NTP
- Describe the context of the TB epidemiological review

**Objectives**
- List the objectives of the review (as stated in the country-specific ToR) and associated expected outcomes

**Methods**
- Describe the methods used to collect, collate and analyse the data
- Describe the desk review, site visits and interviews that were carried out
- Summarize the data that were available (and their sources) and that informed the TB surveillance checklist and analyses
- Summarize the analyses that were conducted

**Results: standards and benchmarks checklist**
- Include Part A and Part B of the standards and benchmarks checklist (1)
- Provide a summary table for Part B of the standards and benchmarks checklist (1), including results from previous assessments
- Provide a written summary to interpret the current status for each standard, highlighting any changes since previous assessments and where gaps still remain

**Results: epidemiological analysis**
- Present the results and associated interpretations from the analysis from Objective 2 in the ToR

**Discussion**
- Synthesize the findings and provide a summary
- Describe the strengths and gaps, weaknesses or challenges with the TB epidemiological situation, TB surveillance system, M&E, data use and TB programmatic response
- Describe any limitations (e.g. the availability or quality of data) and any reason for not being able to complete any section

**Recommendations**
- List the agreed recommendations, providing the rationale and evidence as needed
- Include the recommendations synthesis checklist

**Annexes**
- Provide additional documents as annexes, including the agenda for the review and a list of the people interviewed
References


Appendix 1.

Terms of reference for national TB epidemiological reviews and assessments of TB surveillance and vital registration systems

The following terms of reference (ToR) include technical details about what should be assessed for the core objectives and tasks to be carried out during a full national tuberculosis (TB) epidemiological review and assessment of TB surveillance and vital registration systems. For contracting purposes, a shorter version of the ToR can be used, by removing the technical details and focusing on the objectives and tasks outlined (in such cases, the full ToR should be appended, to provide additional information to the contracted epidemiologists). The ToR should be consulted alongside the implementation guide (Chapters 1–8) to manage the planning, implementation and follow-up of the activity.

A1.1 Background

A major goal of TB surveillance is to provide an accurate measure of the number of new episodes of TB (and related deaths), and to monitor how these trends change over time. Important gaps in country-level TB surveillance are currently preventing the accurate measurement and monitoring of TB burden. By strengthening routine TB surveillance, in terms of coverage and quality, national TB programmes (NTPs) can more effectively monitor changes in the local TB epidemic, visualize programmatic successes and shortfalls, and plan for action by targeting resources to areas and populations most at need.

Epidemiological reviews are a country-level systematic and standardized assessment of a country’s TB surveillance system, monitoring and evaluation (M&E) activities, and TB epidemiological situation. Such a review is undertaken for the entire system – from the central to operational level – to better understand best practices carried out in the country; understand the TB epidemiological situation and how this is changing with programmatic and external factors; and provide information on how to strengthen surveillance, M&E and data use based on gaps identified during the assessment.

This activity is generally integrated into a country’s TB strategic planning process; for example, to help guide the organization of the process and focus of subsequent reviews of TB programmes, the development of national strategic plans (NSPs) for TB, and the development of domestic and international funding requests.

The utility of the reviews extends beyond supporting the NTP; therefore, findings and recommendations should be disseminated to relevant partners. For example, epidemiological reviews can help domestic and international funders to track the impact of investments, provide key information to strengthen country-level and global burden estimation, inform the World Health Organization (WHO) country office on how to better support the NTP, and guide the prioritization of activities at regional and global levels.

These ToR outline the main objectives and tasks to be carried out, which should be considered in conjunction with the activity’s implementation guide.

A1.2 Objectives

**Objective 1.** Describe and assess the current national TB surveillance and vital registration systems, with particular attention to their capacity to measure the level of, and trends in, TB disease burden (incidence and mortality) using the standards and benchmarks checklist (1).

**Objective 2.** Assess the level of, and trends in, TB disease burden (incidence, prevalence and mortality) and programmatic indicators using available surveillance, survey, programmatic and other data. Assess whether recent trends in TB disease burden and programmatic indicators are plausibly related to changes in TB-specific interventions and programmatic factors, taking into account external factors, including economic or demographic trends.
**Objective 3.** Define a comprehensive set of recommendations to strengthen the surveillance system to directly measure trends in TB disease burden, strengthen M&E processes and address programmatic gaps, including, where feasible, an indication of what type of technical assistance or additional funding would be required.

**Objective 4.** Provide feedback to the NTP, the WHO regional and country offices, WHO headquarters, relevant funding agencies and technical partners on key findings, recommendations and prioritization, following approval by the NTP.

**Objective 5.** Build local capacity for epidemiological reviews and assessments of surveillance systems by involving members of the NTP to actively participate in Objectives 1–4.

### A1.3 Tasks by objective

**Objective 1.** Describe and assess the current national TB surveillance and vital registration systems, with particular attention to their capacity to measure the level of, and trends in, TB disease burden (incidence and mortality) using the standards and benchmarks checklist (1).

**Task 1.A.** Using Part A of checklist, provide a written description and explanation of the main features of the current systems for national TB surveillance and vital registration.

This should include:

- mapping of agencies, organizations and sectors that are providing TB services and collecting or reporting TB data, with a discussion of data governance, ownership and data sharing agreements; it should also consider and describe the existing multisectoral collaboration and integration of the NTP with these entities, such as the private sector (for-profit and not-for-profit), correctional services, military, mining and indigenous people’s associations;
- review of the existing objectives of the surveillance system;
- description of the policies, guidelines or strategies that are in place for M&E, recording and reporting or surveillance, including the national strategy for digital health;
- description of NTP recording and reporting tools (paper or digital) and their availability at different health care levels and in different sectors;
- in the case of a digital system, description and review of the system (e.g. stages, data entry forms, analytics and dashboards) and discussion of challenges faced by users of the system;
- description of NTP data that are captured on recording and reporting tools (paper or digital) and at what levels;
- description of the NTP data flow from the health facility to the national level;
- description of other non-NTP systems (paper or digital) managed by other agencies or sectors that are also collecting TB data, and of how systems collecting TB data are related to, or linked with, other health information systems (e.g. from other disease programmes, health insurance, electronic medical records or health management information system [HMIS] or district health information system [DHIS2]);
- description of laboratory TB data that are captured at the laboratory and how these are shared with the NTP;
- description of all system linkages (paper or digital) and mechanisms for data sharing across systems or agencies collecting relevant data;
- whether there are investments and a long-term plan for implementing or strengthening other digital systems that capture TB data in the country (e.g. civil registration and vital statistics [CRVS], HIV and HMIS), and whether the NTP is included in these plans;
- types of data that are available at the national level (e.g. aggregate reports versus case-based data);
description of the master health facility list that the NTP is using to collect data from, and any gaps when that list is compared with the total number of facilities offering TB services in the country; the description should include commentary on whether the master health facility list is up to date and exhaustive;

availability and quality of a unique identifier to confidently link data from different sources;

description of mechanisms for ensuring that high-quality data are recorded and reported, including a detailed description of any evidence of issues with data quality or underreporting;

timing and timeliness of reporting, including lag times that may hamper the capacity to monitor the trends routinely or in real time, and take timely action;

availability and quality of data analysis plans, dissemination of reports and use of data for action;

staffing assigned to TB M&E tasks, including an organigram highlighting occupied and vacant posts (where possible); and

description of training plans and mechanisms for TB recording and reporting, M&E and analysis.

Note: To help characterize the TB surveillance system, Part A of the WHO TB surveillance checklist (18 questions) should be completed. It is based on a desk review of all existing documents and interviews with relevant TB programme staff at all administrative levels and relevant partner agencies.

Task 1.B. Using Part B of the standards and benchmarks checklist, assess the current capacity of the TB surveillance system to provide a direct measure of TB disease burden and provide the opportunity to effectively monitor programmatic efforts, including high-quality monitoring of programmatic management of TB preventive treatment (TPT) and treatment outcomes.

This should include assessment of:

- the TB notification system against standards related to system coverage and quality;
- the availability and quality of TB mortality data against the standard related to vital registration;
- the supplementary standards focused on paediatric TB, HIV-associated TB and drug-resistant TB (DR-TB);
- the standards related to the M&E of programmatic management of TPT; and
- the standards related to treatment outcomes.

Note: To help assess the TB surveillance and vital registration system, Part B of the WHO TB surveillance checklist (17 standards and associated benchmarks) should be completed. The assessment is based on the review of recording and reporting tools (digital or paper), analysis of TB surveillance data for the assessment of analytical standards, and interviews with relevant TB programme staff at all administrative levels and relevant partner agencies.

Task 1.C. Describe the availability, quality and use of population estimates (e.g. census).

This should include:

- when the last time the population estimates were directly measured and plans for the next census;
- any specific limitations or gaps in population estimates, particularly at the subnational level (e.g. migrants, displaced populations and highly mobile populations); and
- whether the NTP is using the most up-to-date estimates, and whether the source is consistent across administrative units.

Task 1.D. Describe the availability, quality and use of mortality data.

This should include:

- whether a vital registration system using standard coding of cause of death is in place;
- if a vital registration system is in place, a description of that system (national or sample), including its coverage and quality; and
- if no vital registration system is in place, a description of the current situation and any plans to develop one.
Task 1.E. Summarize the main strengths of the current surveillance system and the weaknesses or gaps that need to be addressed, based on the findings from Objective 1.

Potential data sources for Objective 1

Potential data sources include:

▶ interviews with relevant staff at the NTP (national and subnational), civil or vital registry departments and bureau of statistics, nongovernmental organizations (NGOs) or other partners supporting the NTP and the HIV department;
▶ national and subnational case-based or aggregated TB notification data;
▶ national or sample vital registration data;
▶ data quality results from facility audits (e.g. service availability and readiness assessment [SARA] or harmonized health facility assessment [HHFA]) or reviews of the quality of recorded data;
▶ results from drug resistance surveillance including drug resistance surveys; and
▶ published literature.

Note: A comprehensive list of data sources is provided in the standards and benchmarks user guide that accompanies the checklist (2).

Objective 2. Assess the level of, and trends in, TB disease burden (incidence, prevalence and mortality) and programmatic indicators using available surveillance, survey, programmatic and other data. Assess whether recent trends in TB disease burden and programmatic indicators are plausibly related to changes in TB-specific interventions and programmatic factors, taking into account external factors, including economic or demographic trends.

Note: This objective includes the review and compilation of published estimates of TB morbidity and mortality that are already available to assess the level of, and trends in, TB disease burden (at least nationally and, when feasible, subnationally and among subpopulations); and the analysis and interpretation of TB surveillance, programmatic and other available data. Interventions implemented by NTPs should result in the detection of people with TB disease or infection, and the provision of curative or preventive treatment. These efforts should have a direct impact of TB mortality and eventually TB incidence if transmission can be reduced sufficiently. The successes and gaps in the programmatic response to the epidemic can be monitored and investigated through the routine analysis of trends in programmatic TB data. At the same time, a range of factors besides TB-specific interventions can influence the trends observed in the data because they favour an increase or decrease in burden; hence, these factors should also be taken into consideration. Having considered trends in disease burden and programmatic data, it is important to assess whether these trends can partly be related to changes in TB-specific interventions (and associated funding), considering external factors, such as the broader determinants of TB.

Task 2.A. Summarize and describe the level of, and trends in, TB mortality, by HIV status.

This should include:

▶ description of trends in TB mortality from global TB mortality estimates, by HIV status, including a commentary of the quality of the estimates depending on the source of data that informed them (e.g. estimated from a high-quality national or sample vital registration system versus other methods as described in the annual global TB report);
▶ analysis of the trends in the distribution of contributory causes of AIDS deaths (with an emphasis on TB), if data are available;
▶ calculation of the percentage reduction in the absolute number of TB deaths compared with 2015 and assessed against the End TB Strategy global indicator;
▶ calculation and description of the trend in the case fatality ratio (CFR), obtained by dividing the number of TB deaths by the number of estimated incident cases; if high-quality vital registration data are not available, then mortality estimates from the global TB database can be used; and
review of data from special study sites (e.g. demographic surveillance systems) to identify similarities and differences in estimates, where available.

Note: Deaths from TB among HIV-negative people are classified as TB deaths in the most recent version of the International classification of diseases (ICD-11) (3). When an HIV-positive person dies from TB, the underlying cause is classified as HIV; therefore, the analysis should make a clear distinction between TB deaths in HIV-negative people and TB deaths in HIV-positive people. In most countries, numbers of TB deaths in HIV-positive people are only available from the TB treatment outcome data.

Task 2.B. Summarize and describe the level of, and trends in, TB incidence, by HIV status.

This should include:

- description of trends in TB incidence from global TB report incidence estimates, by HIV status, including a commentary of the quality of the estimates, which depends on the quality of available data in the country and the methods used to generate the estimates as described in the annual global TB report;
- calculation and description of the trend in treatment coverage, obtained by dividing the number of TB notified cases (new episodes) who initiated TB treatment by the estimated incidence; and
- description of trends in the incidence of rifampicin-resistant TB (RR-TB), by treatment history or discussion of drug resistance survey results.

Task 2.C. Summarize and describe the level of, and trends in, data from priority studies for TB, including prevalence surveys and patient cost surveys.

This should include:

- if one or more prevalence surveys have been carried out, description of the burden of TB in terms of TB prevalence (as estimated by the survey), and how this may have changed over time with repeat surveys; also, description of other key survey findings that can help in characterizing the TB burden in the country, which should be reflected in NTP data (e.g. male-to-female ratio, geographical distribution of TB cases) (4); and
- if one or more patient cost surveys have been carried out, description of the level of catastrophic costs that households face, and how this may have changed over time with repeat surveys; also, description of other key survey findings that can help in characterizing the TB burden in the country in terms of catastrophic costs, which may influence the trends in NTP data (5).

The results from one or more surveys can be used to assess the current level of TB disease burden and may also provide important evidence about the effectiveness of current TB programmatic efforts and actions needed to improve TB care and control. If comparative survey methodology allows, evidence about trends in disease burden can be obtained from repeat national surveys conducted about 10 years apart.

Task 2.D. Analyse and interpret the level of, and trends in, all available TB programmatic and M&E data (e.g. related to screening, prevention, laboratory, notifications and outcomes) – by time (time-series), by geography (subnational analysis) and by population (e.g. age and sex) – where data permit. Additional dimensions related to level and type of health service provider should be considered, where feasible. The analysis should follow the standard analytical plan for epidemiological reviews, which can be modified depending on data availability. Where relevant, assessment of progress to reaching national targets in the existing NSP should be carried out with commentary provided. Additional analyses to support the review can be carried out at the discretion of the epidemiologist. To support the interpretation of TB programmatic and M&E data and provide a more comprehensive context, other data for additional analysis and findings from other studies or surveys may be considered.

Analysis of notifications and outcomes data should include:

- TB case notifications (absolute numbers and rates), all cases and differentiated by case type;
- proportions and ratios of notified cases:
  - proportion of notified cases who were bacteriologically confirmed, by treatment history;
  - proportion of notified cases who were diagnosed with extrapulmonary TB;
— proportion of notified cases who were aged below 15 years;
— proportion of notified cases who were previously treated;
— rate ratio of notified cases aged 0–4:5–14;
— male-to-female ratio;
— ratio of presumptive-to-bacteriologically confirmed cases, if the availability and quality of data allow;
▶ distribution of notified TB cases by age and sex, and the average age of newly notified cases;
▶ age- and sex-specific case notification rates, if population data are available;
▶ trends in the number of TB patients being referred or notified by different types of providers, levels of health system and case-finding approaches, where data are available:
   — public and private;
   — community health worker, pharmacist, general practitioner (GP) and secondary or tertiary hospital;
   — HIV centres, diabetes clinics, and other outpatient services or departments;
   — patient-initiated and provider-initiated;
▶ linkage to care: number of TB patients treated with appropriate TB regimen divided by the number of notified patients eligible for treatment, expressed as a percentage;
▶ consistency of number of recorded outcomes with reported treatment cohort and number of notified TB cases;
▶ TB treatment success rate: percentage of notified TB patients who were successfully treated (cured or completed treatment) for drug-susceptible TB and DR-TB, both combined and separately;
▶ trends in all TB treatment outcomes categories to investigate contribution of unfavourable outcomes:
   — percentage cured;
   — percentage treatment completed;
   — percentage died;
   — percentage failed;
   — percentage lost to follow-up; and
   — percentage not evaluated.
Analysis of DR-TB notifications and outcomes data should include:
▶ care cascade for DR-TB:
   — number of pulmonary bacteriologically confirmed TB cases;
   — number and percentage tested for resistance to rifampicin;
   — number and percentage with RR-TB;
   — number started on second-line regimen and number successfully treated;
▶ care cascade for other levels of drug resistance (e.g. pre-extensively drug-resistant TB [pre-XDR] and XDR), if data are available;
▶ DR-TB notifications, by level of drug resistance; and
▶ DR-TB treatment outcomes.
Analysis of HIV-associated TB notifications and outcomes data should include:
▶ care cascade for HIV-associated TB:
   — number of new episodes of TB;
— number and percentage tested for HIV;
— number and percentage with TB-HIV coinfection;
— number and percentage started on antiretroviral therapy (ART);
▶ TB-HIV coinfected TB notifications; and
▶ HIV-associated TB treatment outcomes.

Analysis of programmatic management of TPT data should include:
▶ contact investigation coverage: number and percentage of contacts of bacteriologically confirmed TB patients who completed an evaluation for TB disease and TB infection;
▶ TPT coverage: number and percentage of individuals eligible for TPT who initiated treatment out of those eligible; where data are available, data could be disaggregated by:
  — people living with HIV (newly or currently enrolled on ART);
  — contacts aged below 5 years;
  — contacts aged 5 years and above;
  — TPT regimen (e.g. 3HP, 3HR or 6H);
▶ TPT completion: number and percentage of individuals who completed TPT out of those who initiated treated; where data are available, date could be disaggregated by:
  — regimens lasting less than 6 months; and
  — regimens lasting 6 months or more.

Analysis of TB laboratory data should include:
▶ trends in the introduction of more sensitive diagnostic tests (e.g. Xpert) and the impact of rollout on case detection;
▶ percentage of new TB patients who were tested using a WHO-recommended rapid diagnostic test at the time of diagnosis;
▶ review of laboratory testing practices in the country, including the diagnostic algorithm implemented and the eligibility for testing using different methods;
▶ number of smear microscopy slides read and the smear positivity rate;
▶ number of Xpert MTB/RIF test conducted, and the Mycobacterium tuberculosis (Mtb) and RR-TB positivity rate (including the error, invalid or no result, and including trace results and “Rif indeterminate” where Xpert Ultra is used); and
▶ rate of use of Xpert MTB/RIF: number of tests in a given period divided by the capacity of the machine, expressed as a percentage.

Review of other relevant data to support interpretation of findings from the above analyses and providing more context should include:
▶ summary and description of the level of (and ideally the trends in) underreporting from a national inventory study, and whether these data are available before the assessment or from alternative sources of TB patient quantification or estimation (e.g. health insurance claims data);
▶ any data or findings available from special studies or surveys of TB in high-risk groups (e.g. people living with HIV, older people, people with diabetes, people with compromised immune systems, prisoners, miners, migrants and homeless people);
▶ review of the pathway to diagnosis, if a patient pathway analysis has been carried out, to quantify:
  — where people with symptoms consistent with TB seek care;
  — where people diagnosed with TB first sought care;
▶ other miscellaneous analyses that may be relevant in specific settings (to be determined by the epidemiologist undertaking the assessment).

**Task 2.E.** Define and compile data that are relevant to assess the extent to which changes in TB disease burden and programmatic data in recent years (e.g. 5–10 years) can be explained by TB-specific interventions or programmatic efforts.

This should include at least:

▶ government and international donor funding for TB care and control;
▶ number and location of health facilities providing TB diagnostic services per 100 000 population, if available;
▶ number and location of health facilities providing TB treatment services per 100 000 population, if available;
▶ number and location of health facilities providing TB prevention services per 100 000 population, if available;
▶ performance of community-based intervention for case detection and treatment support (e.g. number of people referred from the community or numbers supported by community-based treatment support initiatives and its impact on unfavourable treatment outcomes);
▶ performance and coverage of public–public and public–private mix initiatives in the country; and
▶ data related to stock-out of essential commodities for TB services.

**Task 2.F.** Define and compile data that are relevant to assess the extent to which changes in TB disease burden in recent years can be explained by factors that are not specifically related to TB-specific interventions or programmatic efforts.

This should include at least:

▶ prevalence of HIV among the general population and ART coverage;
▶ prevalence of diabetes, smoking, harmful use of alcohol and undernutrition;
▶ gross national income (GNI) per capita;
▶ percentage of the population living below the poverty line;
▶ Gini coefficient;¹
▶ the impact of economic crises;
▶ coverage of financial protection for health care costs (by government health budget or health insurances) and social potential programmes;
▶ the percentage of health care expenditures accounted for by out-of-pocket payments;
▶ the percentage of TB-affected households that experience catastrophic costs due to TB;
▶ demographic changes: percentage of the population who are aged below 15 years, and those aged above 65 years, cross-referenced to the age demographics of the country’s TB epidemic;
▶ the under-5 mortality rate, as a proxy indicator of the overall performance of the health care system; and
▶ the universal health coverage index (Sustainable Development Goal [SDG] 3.8.1).

¹ The Gini coefficient is an index for the degree of inequality in the distribution of income or wealth.
Potential data sources for Objective 2

Potential data sources include:

- global TB database;
- annual global TB report;
- prevalence survey reports;
- drug resistance survey reports;
- reports and datasets from the office or department responsible for population estimates;
- national and subnational case-based or aggregated data from the routine TB surveillance system;
- laboratory data;
- inventory study reports;
- national databases with information about overall health system characteristics and determinants or risk factors related to TB;
- geographic specific data such as sites funded by the United States President’s Emergency Plan for AIDS Relief (PEPFAR);
- SARA or HHFA;
- patient pathway analysis reports;
- integrated molecular surveillance (IMS) data on volume of TB drugs sold;
- WHO HIV/AIDS data and statistics;
- national HIV programme data;
- AIDSinfo database;
- WHO Global Health Observatory;
- World Bank;
- patient cost survey reports;
- national health accounts;
- social protection or welfare programme information on coverage of target groups;
- United Nations Development Programme (UNDP) database;
- SDG indicator database; and
- published and grey literature.

Objective 3. Define a comprehensive set of recommendations to strengthen the surveillance system to directly measure trends in TB disease burden, strengthen M&E processes and address programmatic gaps, including, where feasible, an indication of what type of technical assistance or additional funding would be required.

Task 3.A. Define a comprehensive set of actionable recommendations based on the findings and gaps identified from the epidemiological review and assessment of the surveillance system. These recommendations should be based on findings from all dimensions assessed in Objective 1 to strengthen the surveillance system to better measure TB burden and monitor the impact of programmatic action, analytical capacity and data use. They should also be based on findings from Objective 2 to inform programmatic action, identify needs for additional analyses or investigation (e.g. national programme review), and guide the prioritization of research activities to fill any important data gaps.

Task 3.B. Define any needs for additional technical assistance and estimated funding, where feasible, to implement the set of recommendations.
**Task 3.C.** Assess whether a periodic survey should be carried out to improve estimates of TB burden in the country; this could be a baseline or repeat prevalence survey, an inventory study, a drug resistance survey or a cause of death survey. Recommendations for such surveys should be carefully considered and be in line with the country’s eligibility and feasibility for implementation.

**Objective 4.** Provide feedback to the NTP, the WHO regional and country offices, WHO headquarters, relevant funding agencies and technical partners on key findings, recommendations and prioritization, following approval by the NTP.

**Task 4.A.** Synthesize findings and recommendations (Objectives 1–3) into a debriefing presentation for the appropriate audiences, to be delivered at the end of the mission.

**Task 4.B.** Synthesize findings and recommendations (Objectives 1–3) into a detailed report for submission to the NTP and local stakeholders, as well as international partners (including WHO headquarters) to monitor progress, and use findings to guide global priorities and support burden estimation.

**Objective 5.** Build local capacity for epidemiological reviews and assessments of surveillance systems by involving members of the NTP to actively participate in Objectives 1–4.

**Task 5.A.** Engage the NTP and local partners directly in the review process (Objectives 1–4). Where appropriate, this can be achieved by sharing analytical tasks, collaborating on the interpretation of findings, and collaborating on interviews and register checks, particularly at the health facilities and laboratories visited during the mission.

**Task 5.B.** Provide guidance and training to the NTP and local partners throughout the review, to build local capacity and integrate relevant components of the review into routine practice.

**A1.4 Deliverables**

**Deliverable 1.** One or more slide decks of the debriefing presentations delivered at the end of the mission.

**Deliverable 2.** A detailed report that addresses all tasks under Objectives 1–4.

**Deliverable 3.** Completed Parts A and B of the standards and benchmarks checklist (1). This may be included within the main report (Deliverable 2), ideally completed in sufficient detail to form a core component of the report.

**A1.5 Time and personnel requirements**

A full epidemiological review and assessment of the surveillance system takes a total of 4 weeks. This includes a week on desk-based preparations (e.g. engaging with local partners to set up the agenda, and prepare documents and data), 2 weeks of in-country work (carrying out Objectives 1–5), and a week to finalize the report (finalizing Task 4.B).

Two external consultant epidemiologists should be mobilized for the review and should be supported by local personnel, including, at the very minimum, M&E staff from the NTP. It is of great benefit to involve national professional officers from the WHO country office and local M&E staff from implementing and technical partners, because these stakeholders will often be responsible for continuing to work with the NTP to follow up on recommendations.

If additional objectives are added or if the ToR for other complementary activities are appended to this ToR, then additional external or local technical support should be considered, depending on the expected additional level of effort required for a high-quality review.
References


## Appendix 2.
Framework for synthesizing recommendations

### A2.1 Recommendations synthesis checklist

**Table A2.1** Checklist for synthesizing recommendations that were made during an epidemiological review with a standards and benchmarks assessment

<table>
<thead>
<tr>
<th>High-level recommendations related to the standards and benchmarks checklist (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Increase HR capacity for surveillance and M&amp;E</td>
</tr>
<tr>
<td>☐ Develop or review SOPs or tools for data quality and validity</td>
</tr>
<tr>
<td>☐ Train staff on recording and reporting to improve data quality</td>
</tr>
<tr>
<td>☐ Strengthen routine supervision for data quality checks or implement data validation workshops (or similar)</td>
</tr>
<tr>
<td>☐ Carry out a nationally representative data quality assessment; for example, including a TB module in SARA or HHFA</td>
</tr>
<tr>
<td>☐ Transition towards or strengthen digital case-based, real-time surveillance</td>
</tr>
<tr>
<td>☐ Measure the level of underreporting of diagnosed TB cases through an inventory study or implement routine record linkage exercises</td>
</tr>
<tr>
<td>☐ Make TB notification a legal requirement</td>
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<tr>
<td>☐ Improve reporting from the public and private sectors</td>
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<tr>
<td>☐ Ensure that all people diagnosed with TB are reported and included in the total national count of notified cases (e.g. initial lost to follow-up, death before starting treatment, DR-TB)</td>
</tr>
<tr>
<td>☐ Improve the capacity for diagnosis (e.g. by including TB in the UHC package, improving the health facility network)</td>
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<tr>
<td>☐ Improve the availability and quality of TB mortality data</td>
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<tr>
<td>☐ Improve the diagnosis and reporting of childhood TB</td>
</tr>
<tr>
<td>☐ Implement a drug resistance survey to estimate the burden of RR-TB</td>
</tr>
<tr>
<td>☐ Improve the integration and collaboration of TB/HIV services, and recording and reporting</td>
</tr>
<tr>
<td>☐ Align treatment outcome definitions with global guidance, or strengthen the quality of treatment outcome data</td>
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<tr>
<td>☐ Align PMTPT indicators with global guidance, or strengthen the quality of PMTPT data</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>High-level recommendations related to strengthening digital case-based, real-time surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Review the existing paper-based recording and reporting tools</td>
</tr>
<tr>
<td>☐ Transition to or strengthen aggregate digital system</td>
</tr>
<tr>
<td>☐ Transition to or strengthen digital case-based system for DR-TB only</td>
</tr>
<tr>
<td>☐ Transition to or strengthen digital case-based system for all TB cases</td>
</tr>
<tr>
<td>☐ Review the existing digital system</td>
</tr>
</tbody>
</table>
Recommendations associated with epidemiological reviews

☐ Strengthen data analysis and use for decision-making
☐ Strengthen operational and implementation research
☐ Conduct a TB prevalence survey
☐ Conduct a patient pathway analysis
☐ Conduct a patient cost survey
☐ Review existing data (e.g. fill data gaps and validate existing data)
☐ Safeguard historical TB surveillance data with tbhistoric.org (2)
☐ Implement, strengthen or scale up a unique identification system

A2.2 Definitions of recommendations in the synthesis checklist

Table A2.2 Framework for synthesizing recommendations for strengthening surveillance, based on the standards and benchmarks checklist (1)

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve data quality</td>
<td>Increase HR capacity for surveillance and M&amp;E</td>
<td>Hire additional staff to address gaps in personnel or to support surveillance and M&amp;E activities at any level.</td>
</tr>
<tr>
<td></td>
<td>Develop or review SOPs or tools for data quality and validity</td>
<td>Develop SOPs or tools (e.g. checklist for paper-based system or application for electronic system) to improve data quality and validity. If documents or tools already exist, then review and revise these as needed.</td>
</tr>
<tr>
<td></td>
<td>Train staff on recording and reporting to improve data quality</td>
<td>To improve data quality, train staff (at any level) on recording and reporting, as new guidelines or definitions are implemented, and by providing refresher training on existing guidelines; also, train new staff when they are hired and train existing staff that have not undergone training.</td>
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<tr>
<td></td>
<td>Strengthen routine supervision for data quality checks or implement data validation workshops (or similar)</td>
<td>Implement (where not existent) or improve (where existent but weak) data quality check processes or conduct data validation workshops (or similar).</td>
</tr>
<tr>
<td></td>
<td>Carry out a nationally representative data quality assessment; for example, including a TB module in SARA or HHFA</td>
<td>Assess TB data quality at health facility level by including a TB module in SARA, integrating TB data quality into HHFA, or through another type of nationally representative assessment of TB data validity and completeness for any steps along the pathway of prevention and care.</td>
</tr>
<tr>
<td>Transition from paper-based aggregate to digital case-based, real-time recording and reporting</td>
<td>Transition towards or strengthen digital case-based, real-time surveillance</td>
<td>Start the transition from aggregated paper-based recording and reporting to aggregated digital recording and reporting or a digital case-based surveillance platform. Strengthen the existing case-based surveillance platform or support implementation or scale-up.</td>
</tr>
<tr>
<td>Category</td>
<td>Recommendation</td>
<td>Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>Reduce underreporting</td>
<td>Measure the level of underreporting of diagnosed TB cases through an inventory study or implement routine record linkage exercises</td>
<td>Carry out an inventory study (or similar study to measure the level of underreporting in the country), or implement routine record linkage exercises where feasible to monitor and minimize underreporting.</td>
</tr>
<tr>
<td>Make TB notification a legal requirement</td>
<td>Advocate for mandatory notification of TB or make notification of TB cases a legal requirement.</td>
<td>Fill gaps in reporting from both the public and private sectors, including missing reports from health facilities and laboratories; engage private service providers through public–private initiatives or public service providers through public–public initiatives.</td>
</tr>
<tr>
<td>Improve reporting from the public and private sectors</td>
<td>Fill gaps in reporting from both the public and private sectors, including missing reports from health facilities and laboratories; engage private service providers through public–private initiatives or public service providers through public–public initiatives.</td>
<td>Fill gaps in reporting from both the public and private sectors, including missing reports from health facilities and laboratories; engage private service providers through public–private initiatives or public service providers through public–public initiatives.</td>
</tr>
<tr>
<td>Ensure that all people diagnosed with TB are reported and included in the total national count of notified cases (e.g. initial lost to follow-up, death before starting treatment, DR-TB)</td>
<td>Include any patients missing from the total case count who were identified in the review (e.g. people who did not initiate treatment or who died before initiating treatment, not including DR-TB in total notification counts, as reported to WHO).</td>
<td>Include any patients missing from the total case count who were identified in the review (e.g. people who did not initiate treatment or who died before initiating treatment, not including DR-TB in total notification counts, as reported to WHO).</td>
</tr>
<tr>
<td>Reduce underdiagnosis</td>
<td>Improve the capacity for diagnosis (e.g. by including TB in the UHC package, improving the health facility network)</td>
<td>Implement initiatives for increasing access to diagnosis and care, with the goal of diagnosing more cases, moving towards UHC (e.g. through wider geographical coverage of TB services, training of doctors for proper diagnosis, ensuring diagnostics are available and expanding the laboratory network).</td>
</tr>
<tr>
<td>Vital registration</td>
<td>Improve the availability and quality of TB mortality data</td>
<td>Implement sample registration systems or mortality surveys, and advocate for the implementation or improvement of a vital registration system in the country that is of high coverage and quality, including improved use of mortality data.</td>
</tr>
<tr>
<td>Childhood TB</td>
<td>Improve the diagnosis and reporting of childhood TB</td>
<td>Improve the diagnosis and reporting of childhood TB to address both underreporting and overdiagnosis.</td>
</tr>
<tr>
<td>DR-TB</td>
<td>Implement a drug resistance survey to estimate the burden of RR-TB</td>
<td>Carry out a national survey of anti-TB drug resistance.</td>
</tr>
<tr>
<td>TB/HIV</td>
<td>Improve the integration and collaboration of TB/HIV services, and recording and reporting</td>
<td>Improve TB/HIV services (e.g. improve screening of HIV among TB patients or vice versa) and improve data capturing for accurate TB/HIV surveillance and M&amp;E.</td>
</tr>
<tr>
<td>Treatment outcomes</td>
<td>Align treatment outcome definitions with global guidance, or strengthen the quality of treatment outcome data</td>
<td>Review treatment outcome definitions to align with global guidance or data quality assessment, to ensure that the data are complete and consistent.</td>
</tr>
<tr>
<td>Screening and prevention</td>
<td>Align PMTPT indicators with global guidance, or strengthen the quality of PMTPT data</td>
<td>Review the M&amp;E indicators for PMTPT to align with global guidance or ensure that the minimum data are collected to calculate the indicators, or undertake a data quality assessment to ensure that the data are complete and consistent.</td>
</tr>
</tbody>
</table>

### Table A2.3  Framework for synthesizing supplementary recommendations specifically related to the transition to digital case-based, real-time surveillance

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition from aggregated paper-based reporting to digital case-based surveillance</td>
<td>Review and strengthen existing paper-based recording and reporting tools</td>
<td>Update and implement paper-based tools to address gaps identified during the review (e.g. adding columns to capture key data) or to make the data-capture process more efficient (e.g. reducing the number of forms).</td>
</tr>
<tr>
<td>Transition to an aggregate digital system</td>
<td>Recommendations made for moving from a paper-based aggregate system to a digital aggregate system, to support scale-up, or to strengthen existing system.</td>
<td></td>
</tr>
<tr>
<td>Transition to a digital case-based system for DR-TB only</td>
<td>Recommendations made for transitioning towards a digital case-based platform, starting with DR-TB cases or provide support for scale-up.</td>
<td></td>
</tr>
<tr>
<td>Transition to a digital case-based system for all TB cases</td>
<td>Recommendations made for transitioning towards a fully digital case-based system for all TB cases, to support scale-up, or to strengthen existing system.</td>
<td></td>
</tr>
<tr>
<td>Review and strengthen the existing digital system</td>
<td>Review and improve the existing platform to fill any gaps identified during the review, improve functionality or improve the efficiency of the system.</td>
<td></td>
</tr>
</tbody>
</table>

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

### Table A2.4  Framework for synthesizing additional recommendations associated with national TB epidemiological reviews

<table>
<thead>
<tr>
<th>Category</th>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidemiological Review</td>
<td>Strengthen data analysis and use for decision-making</td>
<td>Improve analytical skills and the use of TB data to guide decision-making, usually through the implementation of a face-to-face data analysis and use workshop or through e-learning approaches.</td>
</tr>
<tr>
<td></td>
<td>Strengthen operational and implementation research</td>
<td>Specific topics for operational research and implementation research priorities based on findings from the epidemiological review were provided, or recommendations were made to strengthen research (e.g. through collaboration with academic institutions or by setting up a mechanism directly within the NTP for carrying out operational and implementation research).</td>
</tr>
<tr>
<td></td>
<td>Conduct a TB prevalence survey</td>
<td>Carry out a national TB prevalence survey.</td>
</tr>
<tr>
<td></td>
<td>Conduct a patient pathway analysis</td>
<td>Carry out a patient pathway analysis.</td>
</tr>
<tr>
<td></td>
<td>Conduct a patient cost survey</td>
<td>Carry out a national survey of costs faced by TB patients and their households.</td>
</tr>
<tr>
<td></td>
<td>Review existing data (e.g. fill data gaps and validate existing data)</td>
<td>Review data that currently exist within the surveillance system (including historical data) to address any specific data quality issues that were identified during the epidemiological review.</td>
</tr>
<tr>
<td>Category</td>
<td>Recommendation</td>
<td>Description</td>
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<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>Safeguard historical TB surveillance data with tbhistoric.org (2)</td>
<td>Use the tbhistoric.org DHIS2 platform for safeguarding of TB data.</td>
</tr>
<tr>
<td></td>
<td>Implement, strengthen or scale up a unique identification system</td>
<td>Identify, implement, strengthen or scale up the use of a high-quality unique ID system.</td>
</tr>
</tbody>
</table>

DHIS2: District Health Information Software 2; ID: identification; NTP: national TB control programme; TB: tuberculosis.

References
