



Framework for conducting reviews of tuberculosis programmes



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Framework for conducting reviews of tuberculosis programmes

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Photocredit: WHO/Soleil Labelle

Contents

Abbreviations	2
Foreword	3
1. Introduction	4
1.1 Definition	6
1.2 Purpose	6
1.3 Objectives	6
1.4 Target audiences	7
1.5 Process of reviewing a national TB programme	7
2. Phase 1: planning and preparing for the review	8
2.1 Appoint review coordinators	9
2.2 Establish a task force for the review	10
2.3 Define the review's objectives	10
2.4 Set the dates for the review	11
2.5 Select the members of the review teams, and define their roles and responsibilities	11
2.6 Select sites for the field visits	13
2.7 Plan the logistics	14
2.8 Prepare a budget and arrange funding for the review	15
2.9 Prepare the assessment checklists and background documents	16
2.10 Identify a lead writer to prepare the report	17
3. Phase 2: conducting the review	18
3.1 Briefing the review teams, and having team members meet with national authorities	18
3.2 Making field visits	20
3.3 Presenting the reports of the field visits to the entire review team	24
3.4 Debriefing teams' members about the findings and recommendations of the review	25
4. Phase 3: finalizing the report of the review, and the next steps	26
4.1 Finalizing the report of the TB programme review	26
4.2 Disseminating the final report of the TB programme review	29
4.3 Supporting the implementation of recommendations made in the final report	30
Annexes	31
Annex 1. Checklist for preparing and conducting a review of a national tuberculosis programme	32
Annex 2. General information and documents to be collected before the review of the national tuberculosis programme and to be made available to the reviewers	33
Annex 3. Terms of reference for the TB epidemiological and impact analysis component of a national programme review	36
Annex 4. Checklists for assessing selected areas of tuberculosis activities during a review of a national programme	42
Annex 5. Selected references	44

Abbreviations

AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral treatment
BMU	Basic Medical Unit
CPT	co-trimoxazole preventive therapy
DOT	directly observed treatment
DST	drug-susceptibility testing
FDC	fixed-dose combination
FEFO	first expiry, first out
GDP	gross domestic product
HEPA	high-efficiency particulate air
HIV	human immunodeficiency virus
IPT	isoniazid preventive therapy
MDR-TB	multidrug-resistant tuberculosis
NGO	nongovernmental organization
PAL	practical approach to lung health
TB	Tuberculosis
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Foreword

The review of a formal national tuberculosis (TB) programme (or the efforts that countries make to control the disease regardless of the existence of a formal “programme”) is an important exercise to evaluate the implementation and impact of TB prevention, care and control. It should be jointly undertaken by the government together with the relevant national and international partners that are involved in TB efforts.

A TB programme review assesses the performance of the strategy implemented to fight TB and identifies the strengths and weaknesses of interventions that have been put in place. An appropriate review must, then, describe specific recommendations on the strategic orientations that need to be adopted and developed to overcome the gaps identified in the way that TB prevention, care and control are being implemented. These recommendations provide the foundation for improving the strategy adopted to control TB and for revising or developing a national strategic plan. Moreover, the review of a TB programme provides an important opportunity to advocate for TB prevention, care and control among policy makers, to strengthen the engagement of national health authorities and key stakeholders, and to enhance the mobilization of resources from both domestic and international sources.

The first WHO guidelines on how to review a TB programme were published in 1998, and were designed to support the assessment of, and improvements to, the implementation of the DOTS strategy. Since then, there have been major evolutions in the WHO strategy for prevention, care and control of TB. Important new interventions have been defined, developed and implemented: for example, collaborative TB/HIV activities and the programmatic management of drug-resistant TB. Therefore, this new guidance takes into consideration all strategic approaches that are part of the current WHO strategy for TB control. In 2013, WHO began developing a post-2015 global tuberculosis strategy. Thus, this guidance will be further updated once the new strategy is fully translated into operational language.

The main purpose of this document is therefore to provide guidance on how to organize a review of a national TB programme. It identifies the keys steps needed to plan and prepare the review and specifies how to carry out field visits. It also describes the process of using the findings of the field visits, formulating recommendations and developing a review report. The document also includes, in annexes and in web-based format, checklists that can be adapted and used to assess key areas of TB prevention, care and control such as TB surveillance system, the management of the TB programme, and the process of TB case finding.

We strongly encourage national TB programmes, as well as agencies and organizations involved in TB control, to use the guidance included in this document to organize and implement the national programme reviews they are planning. The outcomes of the reviews should significantly contribute to improving the TB control situation in countries, revising or developing high-quality national strategic plans, and mobilizing the required resources.



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1. Introduction

Since 2000, significant progress has been made in reaching the World Health Organization's (WHO) global targets for tuberculosis (TB) prevention, care and control. In most countries, TB activities are organized within a national TB programme, which is usually housed within the Ministry of Health. To ensure and improve the performance of national TB programmes, regular external monitoring and evaluation are required. In 1998, WHO issued guidance on carrying out reviews of TB programmes in the context of DOTS implementation.^{1,2} Since 2000, however, there have been important changes in the global context of TB prevention, care and control.

- The strategy for controlling TB has evolved from the DOTS strategy, resulting in the development of the *Stop TB strategy* in 2006. In keeping with the Millennium Development Goal 6 and targets set by the Stop TB Partnership, this strategy aims at ensuring that TB incidence is falling by 2015 and that prevalence and mortality rates are halved by 2015 compared with a baseline of 1990. The *Stop TB strategy* has six major components:
 - » pursue high-quality DOTS expansion and enhancement;
 - » address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations;
 - » contribute to health system strengthening based on primary healthcare;
 - » engage all care providers;
 - » empower people with TB, and communities through partnership;
 - » enable and promote research.
- WHO and an increasing number of technical partners have been supporting national TB programmes to implement national policies that are aligned with international recommendations and to implement innovative approaches.
- Funding for TB prevention, care and control has increased dramatically during the past 10 years, and many donors are engaged both at the global level and at the country level in supporting TB prevention, care and control. National nongovernmental organizations (NGOs) have also made financial contributions towards TB control efforts.
- National TB programmes have been implementing DOTS and the Stop TB strategy for more than 15 years, and increasingly efforts are being made to measure the epidemiological impact of efforts to control and prevent TB. Ministries of finance, members of parliament and donor agencies are asking critical questions, such as “What is the value for the money that has been invested?” They are looking more closely at trends in the burden of TB and the extent to which positive changes can be explained by programmatic efforts and associated financing.

1 Guidelines for conducting a review of a national tuberculosis programme. Geneva, World Health Organization, 1998 (WHO/TB/98.240). (Also available from http://whqlibdoc.who.int/hq/1998/WHO_TB_98.240.pdf.)

2 DOTS is the basic package of interventions for TB control that underpins the Stop TB strategy. For more information, see The Stop TB strategy: building on and enhancing DOTS to meet the TB-related Millennium Development Goals. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.368). (Also available from http://whqlibdoc.who.int/hq/2006/WHO_HTM_STB_2006.368_eng.pdf.)

Reviewing the work of a national TB programme provides an important opportunity to assess the implementation of interventions to fight TB that have been defined in national policies, the quality of TB care and control services, and the progress that has been made towards reaching the programme's targets. A review usually takes place every 3 years to 5 years, depending on the programme's needs, and should involve independent and external peers who are experts in TB and are not affiliated with the programme being reviewed. The review should assess the appropriateness of the strategies and interventions being used and also consider the prevailing epidemiological situation and the context in which the programme operates. The findings of a review should result in recommendations for actions that should be undertaken by a national TB programme to remedy any deficiencies and/or enhance any strategies that seem to be working well (Box 1). These recommendations constitute important inputs for (i) reorienting the national TB programme, (ii) updating the existing national strategic plan or developing a new national strategic plan, and (iii) helping the national programme to mobilize financial and technical resources at the national level, the international level, or both. Lastly, the results of a review may provide answers to queries raised by the government and its partners, including donors, regarding the impact of the TB control efforts that have been undertaken.

This new framework for reviewing the work of national TB programmes considers the changes that have occurred in the global context of TB prevention, care and control, and it is designed to help national programmes review their own efforts within this new context.

Box 1. Benefits of a review

- Improve the effectiveness of the national TB programme and share with the international community the positive experiences of the review
- Strengthen national political commitments to TB-control efforts
- Strengthen the engagement of key stakeholders
- Improve and strengthen strategic planning for TB control, and mobilize resources
- Address governments' and donors' queries about the impact of their financial contributions

1.1 Definition

Reviews of national TB programmes are external evaluations that are conducted periodically and that aim at improving the managerial and technical performance of the programme in order to reduce morbidity and mortality from TB. Reviews involve national and international experts and stakeholders.

1.2 Purpose

The overall purpose of reviewing the activities of a national TB programme is to evaluate progress in the response to TB in the context of the goals, objectives and targets that have been specified in the national strategic plan to control TB. The review should assess programme outputs, outcomes and impact, including the quality of TB care in terms of its relevance to the epidemiology of the disease, equity as it relates to access to care and control services as well as to the quality of care received by all patients, the effectiveness of the care, and responsiveness – that is, how promptly care and control services are provided to populations that need them. The review may also significantly contribute to identifying best practices, challenges to implementation, and potential solutions to any problems that have been identified. A review should identify the strengths and weaknesses of TB prevention, care and control services as well as the opportunities for improving the services and the challenges to the programme that must be overcome. The review should provide recommendations for improving TB prevention, care and control activities.

1.3 Objectives

The objectives of a review are to:

- assess the epidemiology of TB in the country and the current capacity of national surveillance systems to directly measure the level of and trends in TB disease burden;
- assess the structure, organization and management frameworks for TB policy and the development of the programme within the health-care system and within the national agenda for development;
- assess the financial situation and human resources in light of the programme's performance and demands;
- assess whether progress has been made towards achieving national, regional and global targets;
- assess the performance of the programme in delivering strategic interventions, assess how well services are delivered, and assess any inequities in access to and quality of care;
- evaluate the arrangements and mechanisms for ensuring the engagement and participation of other stakeholders, such as representatives from other sectors (e.g., justice, labour, social protection), NGOs, other civil society organizations and affected communities;

- identify obstacles to meeting the objectives of the national TB programme;
- define the steps to be taken to improve the programme's performance or redefine the programme's strategic direction and focus; this may include suggesting revisions to policies and strategic plans.

1.4 Target audiences

This document provides guidance for all stakeholders that might be involved in the review process. These stakeholders usually include:

- staff of the national TB programme and the relevant departments of ministries of health;
- staff of other ministries, such as the ministry of planning, finance, justice or social welfare/social protection, and staff of governmental organizations;
- institutions that provide health training;
- civil society organizations, including patient organizations;
- technical agencies;
- technical consultants;
- donors;
- implementing partners;
- professional health associations;
- local government agencies.

1.5 Process of reviewing a national TB programme

The review of a TB programme usually comprises three phases.

- **Phase 1:** planning and preparing for the review.
- **Phase 2:** conducting the review in the field.
- **Phase 3:** writing and finalizing the report of the review, and recommending the steps that need to be taken to improve the national TB programme.

Checklists should be prepared to monitor the process of the review. These should include all of the activities that need to be undertaken during each phase of the review; they should specify the timeline for each phase (Annex 1).

2. Phase 1: planning and preparing for the review

Reviews of national TB programmes should be planned well in advance, and the frequency of such reviews should be clearly specified in the national strategic plan for TB control. The dates of the reviews should be specified in the operational component of the strategic plan, and the budget needed to carry out the review should be highlighted in the budgetary component of the plan. The dates of the reviews and the budget for them must be communicated early to partners involved in TB prevention, care and control.

During the first phase of the review, some preparatory missions may be undertaken to provide critical information for the review. For example, an excellent understanding of the level of and trends in TB disease burden, and how these have been (and can be) influenced by the implementation of prevention and treatment interventions is of considerable importance to national health programmes, as well as international donor agencies. Epidemiological and impact analysis should be included systematically in national programme reviews, and it may be useful to conduct at least part of the analyses in advance so that findings can be presented to team members at the start of the review. The terms of reference presented in Annex 3 cover the objectives, associated tasks and expected deliverables for TB epidemiological and impact analyses conducted as part of national TB programme reviews.

Planning is the first phase of a review and is critical to its success. This phase should be fully owned by the national programme and its partners. Planning usually takes 3–4 months and, if done well, will ensure that subsequent phases run smoothly. At the initiation of the planning process, the manager of the national programme should:

- have a full understanding of the purpose and methods of a review;
- make the decision to undertake the review;
- inform the ministry of health or other relevant authorities of the need to review the TB programme;
- ensure that any relevant governmental or other authorities will support the review.

Once the ministry of health or other relevant authority has agreed to a review, the following 10 actions should be taken:

1. review coordinators should be appointed;
2. a task force must be established;
3. objectives must be defined;
4. dates for the review must be agreed;
5. members of the review teams must be selected, and their roles and responsibilities defined;
6. representative sites must be selected for field visits;

7. logistics must be planned;
8. a budget must be prepared and funding must be mobilized;
9. checklists and background documents must be prepared; and
10. a lead report writer must be identified.

2.1 Appoint review coordinators

A review is usually conducted by a national TB programme with support from WHO or other agencies. Two coordinators are needed: one national review coordinator who is appointed by the ministry of health or other relevant authority and who is usually the manager of the national TB programme; and one international review coordinator who is from WHO or another technical agency. The international review coordinator should have extensive experience in implementing TB control strategies internationally and reviewing national TB programmes. The two coordinators need to be in regular contact with each other. The role of the national review coordinator is to oversee the local organization of the review, including the preparation of background materials and building national interest in the review. The national coordinator can accomplish some of these tasks by identifying and assigning them to a secretariat. The role of the international review coordinator is to provide technical advice on the content and process of the review, and to organize the participation of international team members (Table 1).

Table 1. Main duties of the national and international coordinators during the review of tuberculosis programmes

Tasks	National review coordinator ^a	International review coordinator ^b
Identify reviewers	National and international	International
Define responsibilities (section 2.5)	National reviewers	International reviewers
Plan logistics (section 2.7)	Arrange logistics for the review	NA
Develop the budget and identify funding sources	Prepare the overall budget for the review; identify local or external funding sources for the review	Help identify external sources of funding to complement locally mobilized funding
Prepare key documents for the review	Prepare background information for the review; prepare the protocol and the assessment checklists; if possible, field-test the tools that will be used to collect data	Prepare or help prepare the protocol for the review, and if necessary help prepare the checklists
Prepare the report about the review	Help develop, revise and finalize the report of the review	Coordinate the development and finalization of the report of the review
Submit the final report	Submit the report to the ministry of health or other relevant authority	Submit the report to the review teams and WHO for approval before it is submitted to the ministry of health

NA not applicable.

^a The national review coordinator is appointed by the ministry of health and is often the manager of the national TB programme.

^b The international review coordinator is usually from WHO or another technical agency.

2.2 Establish a task force for the review

The national TB programme and its partners should establish a task force to oversee the review and to take overall responsibility for it. The task force will define the terms of reference, evaluate the objectives and the expected outcomes, provide guidance to the teams conducting the review, and ensure that the recommendations outlined in the final report are followed up. The composition of the task force depends on the scope and objectives of the review. It could include:

- the two review coordinators;
- senior staff or representatives from the ministry of health or other relevant authorities;
- representatives from international agencies that are engaged in TB prevention, care and control and health system strengthening;
- funding partners and potential donors;
- representatives from academia;
- representatives from HIV/AIDS prevention, care and control programmes;
- relevant NGOs and civil society organizations;
- private health-care providers;
- representatives from other sectors that have been involved in work on TB nationally (e.g., justice, labour, social protection),
- members of relevant professional health associations.

Members of the task force should be knowledgeable about the technical aspects of TB prevention, care and control, programme organization and the national health-care system. When selecting members, it is necessary to consider their positions and their capacity to influence decisions. Sometimes, members of the task force are asked to participate in the review.

2.3 Define the review's objectives

The two review coordinators in collaboration with the members of the task force will establish the objectives of the review. The objectives depend on (i) the findings of any prior situational analyses, if available, (ii) the capacities of the national programme and any related developments in health system strengthening initiatives, (iii) the decisions made about which components of the national strategy to control TB will be evaluated, and (iv) the recommendations of the previous review, if one occurred. The objectives must be clearly defined because the review will be organized around them (for example, in terms of who is chosen for the review teams, which sites are to be visited, which staff and partners will be met). A tentative agenda for the review and an accompanying timeline will be established based on the review's objectives.

2.4 Set the dates for the review

The two review coordinators, in collaboration with the members of the task force, should select the dates for the review. The review will take at least 1 week, depending on the size of the country, the logistics of travel, the number of teams involved, and the components of the national strategy that will be evaluated. As an example, a 11–12 day review could include the following:

- arrival of the reviewers on Day 1 (usually during a weekend);
- brief visit by the reviewers with the relevant national health authorities, and a briefing of the teams at the start of the mission on Day 2;
- field visits on Days 3–6;
- preparation of information for a final debriefing on Day 7–8;
- debriefing at the central level on Day 8;
- preparation of drafts of the various sections to be included in the report on Days 9–10;
- departure of the reviewers on Days 11–12.

The review might require additional days depending on its scope and objectives, the number of representative sites to be visited and related travel involved, and the nature of the debriefing (for example, if it is to be a high-level meeting attended by officials from the ministry of health, potential and actual donors, or partner organizations, including civil society and patient associations).

Local festivals, national holidays, religious feasts, elections and the time of year may influence the timing, duration and impact of the review; these issues should be considered when scheduling the review.

2.5 Select the members of the review teams, and define their roles and responsibilities

A critical activity during Phase 1 is to select both national and international team members and team leaders to take part in the review. The roles and responsibilities of each team and each team member must be defined by the coordinators, and circulated to the members as early as possible during the planning phase.

Team members should have a variety of competencies, including critical thinking and problem-solving skills, communication skills that enable them to discuss the status and performance of the programme with staff at different levels of the health-care system, and the ability to write clearly. Team members should be selected for their expertise in the critical areas of TB prevention, care and control that have been defined by the review's objectives, such as epidemiology and impact assessment, programme management, case-finding, laboratory services, TB care provision, case-

management, co-infection with TB and HIV, MDR-TB, infection control, management of procurement activities and the supply chain, related health system issues such as financing or human resources, and monitoring and evaluation.

Team leaders should have in-depth experience with TB programmes and good communication and presentation skills.

The number of teams and the composition of each team depend on the size of the country, the number of sites to be visited, and which components of the programme are being evaluated. Usually, several teams take part in the review; the typical number is three to five teams, but sometimes more are needed. Each team should have a leader and include three to five national and international experts. If a team includes a large number of reviewers, some of them may be underutilized (or may feel that they are being underutilized). In addition, if teams are large, then personnel at health facilities may feel overwhelmed and have difficulty addressing the team's queries.

National reviewers should be recruited from the national TB programme, departments at the ministry of health, other national health programmes or departments (for example, primary health-care services, hospital departments or HIV/AIDS prevention, care and control programmes), other ministries, universities, NGOs, community-based organizations, research institutions, and members of the country-coordinating mechanism for projects financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, if relevant. Independent national experts may also be included, as well as managers of subnational health teams, TB focal points or coordinators, and experts in issues related to equity, gender, human rights and social protection who can provide assistance to reviewers during their site visits.

International experts should be recruited with the support of WHO and other partners. International reviewers bring different experiences and perspectives to the review, while national reviewers provide local expertise, insight and understanding of the local context.

In certain circumstances, it might be prudent to include a representative from a donor organization, a key implementing partner or a civil society organization. In countries with a high burden of HIV, it is mandatory to include representatives from national HIV/AIDS prevention, care and control programmes.

2.6 Select sites for the field visits

The programme review should include:

- visits to facilities at the central level;
- field visits to health facilities where TB is diagnosed and treated at the national, intermediate and peripheral levels;
- visits to communities where TB prevention, care and control services are provided;
- meetings with staff at institutions and partner organizations involved in TB activities.

The purpose of these visits is to observe how well the health infrastructure functions, the organization of TB prevention, care and control activities, the delivery of TB services, the management of the case-detection process, and to gather information in order to assess the quality and validity of the data on TB provided by the national programme.

Ideally, sites should be selected randomly to reduce bias in the results. In practice, regions and districts may be selected based on their representativeness of different realities in the country (with due attention to including areas across the spectrum of socioeconomic development, from the more disadvantaged to the more affluent), representativeness of the performance characteristics of the programme. The team should try to obtain a balance between urban and rural locations, and between districts that are performing well and those that are performing poorly. Specific efforts should be made to visit areas where there are large populations of persons at high risk of developing TB, such as urban slums.

The teams are expected to visit agencies or departments at the central level, and sites at the intermediate and peripheral levels. They are also expected to meet a certain number of TB patients who are receiving treatment, and to visit organizations, partners and communities involved in TB prevention, care and control. Efforts should be made to ensure that visits to communities are conducted in a way that avoids stigma for the patients and their families.

After having identified the sites to be visited in collaboration with the relevant authorities, a draft agenda for the field visits should be prepared, and appointments should be made with the relevant staff at each site, as well as with community workers or members of NGOs. The agenda and all appointments should be confirmed before the teams arrive at the sites. Each team should be assigned to specific sites for the field visits.

2.7 Plan the logistics

The logistics of the review (such as sending invitation letters, notifications of upcoming field visits, arranging transportation to the sites, and arranging accommodation, meeting space, secretarial support and per diems) should be coordinated by the review secretariat appointed by the national programme (Box 2). The international review coordinator should ensure that appropriate arrangements have been made to accommodate international experts taking part in the review.

Box 2. Logistics to be coordinated at the international level and the local level

INTERNATIONAL LEVEL

- Provide information to all relevant levels of WHO or to collaborating institutions, or both
- Invite international team members
- Arrange remuneration or per diems for international team members
- Make travel arrangements for international team members
- Arrange visas or appropriate government clearance for international team members (that is, ensure that all relevant information is provided to the appropriate authorities and that the external consultants are informed of any visa or other requirements in sufficient time)

LOCAL LEVEL

- Obtain government agreement for the review if necessary
- Invite national team members
- Arrange remuneration or per diem payments for national team members and support staff
- Make travel arrangements for national team members
- Make hotel reservations
- Hire interpreters, if needed
- Arrange meeting rooms for briefing, debriefing and preparing the final report
- Arrange for secretarial and administrative support as appropriate (for example, access to computers, printers, telephones, fax facilities, e-mail)
- Make arrangements for travel to sites within the country and notify the facilities that will be visited
- Arrange time for briefing and wrap-up meetings
- Notify the news media about the review

2.8 Prepare a budget and arrange funding for the review

The review coordinators, in collaboration with members of the task force, should prepare a budget for the review. Expenses for the various components of the review should be outlined, and funding sources should be identified.

The budget items to be considered include:

- remuneration or per diems for international and national team members;
- travel costs for international reviewers and, if needed, for national reviewers;
- local transportation costs during the review, including reimbursements of local travel costs for TB patients, civil society or community representatives who are involved in the site visit component of the review;
- hotel accommodation for team members;
- secretarial support;
- meeting rooms;
- communications costs (for example, the use of faxes, telephone and email);
- photocopying and printing;
- fees for interpreters, if necessary;
- refreshments for the briefing and debriefing meetings;
- press briefing and advocacy materials;
- translation of the final report, if needed;
- printing of the final report;
- dissemination of the final report.

The review coordinators in collaboration with the members of the task force, should mobilize funds (i) through the appropriate financial mechanisms available at the ministry of health or other relevant governmental organizations, (ii) from donors or partners, and (iii) through channels of bilateral and multilateral cooperation.

2.9 Prepare the assessment checklists and background documents

The checklists used to collect data will focus on the areas of TB prevention, care and control specified in the national policy and targeted by the review's objectives.

The use of standardized assessment checklists will ensure that the information collected by different teams during the review is comparable, which will make it easier to write the final report. Checklists that can be adapted and used in reviews are proposed in Annex 4; these checklists must be adapted to each country. General information on the country's health situation (for example, the life expectancy, the maternal mortality rate, the infant mortality rate, the burden of communicable diseases, the burden of noncommunicable diseases), health policies and the health-care system (Annex 2), as well as on the epidemiology of TB within the country and the status of TB control efforts (Annex 3) should be compiled before the review and made available to each team member.

Each team member should receive information on the following areas:

- the socioeconomic and demographic situation in the country;
- national health policies and plans;
- relevant reports on the national health system issued at the national and international levels;
- TB prevention, care and control policies, and guidelines that have been issued;
- annual and quarterly reports on TB;
- the national TB strategic plan, including the annual operational plans;
- reports from meetings organized by the national TB programme, as well as reports from any national conferences related to TB;
- the findings of previous reviews of the national TB programme and reports from any previous external assessments;
- proposals and their related annexes for requests for funding through bilateral or multilateral cooperation mechanisms (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank, the Canadian International Development Agency or the United States Agency for International Development) and any subsequent reports on implementation and monitoring;
- the most up-to-date data on financial protection for TB and TB-HIV patients;
- the involvement in TB activities of care providers operating outside the network of the national control programme;
- national and international partners involved in TB prevention, care and control efforts, included NGOs and civil society organizations;

- the latest assessment of TB epidemiology in the country, including results from recent surveys, and the current capacity of national surveillance systems to directly measure the level of and trends in TB disease burden;
- inter-sectoral collaboration (e.g. involving justice, labour or social protection authorities) relevant to TB.

After team members have been identified, the review coordinators should send them information on the burden of TB and TB efforts in the country; this should be sent before the review.

2.10 Identify a lead writer to prepare the report

The international review coordinator usually assumes the role of the lead report writer. However, sometimes the international coordinator is overwhelmed by other tasks during and after the review, and therefore cannot take on this role. In such circumstances, an alternative lead report writer should be identified, usually from among the international experts involved in the review. The report writer will work closely with the international review coordinator to compile and finalize the report.

3. Phase 2: conducting the review

Four main tasks are involved in reviewing the national TB programme:

- briefing the review teams, and having team members meet with the relevant national authorities;
- making field visits;
- presenting the reports of the field visits to the entire review team;
- de-briefing team members about the findings and recommendations of the review.

3.1 Briefing the review teams, and having team members meet with national authorities

Briefing the review teams is a critical step in conducting the review, and a briefing session must be organized for all team members. The aim of the briefing is to ensure a common understanding of and consensus among teams' members about the review's objectives, processes and methods.

During the briefing session, national and international reviewers will meet to prepare for field work. The task force provides key background information on population health, the burden of TB and the control situation; explains the purpose of the review; and fully describes how the review will take place. At this stage, reviewers may volunteer or be appointed to take on specific tasks, according to their expertise and their expected roles and responsibilities. The briefing session should provide the following information.

- Background information on the national socioeconomic and demographic situation.
- General information on health within the country – that is, information on:
 - » the national health situation;
 - » the national health policies;
 - » the structure of the health system;
 - » the nature and structure of the national health service's links with communities, NGOs and civil society organizations.
- TB and the control of TB:
 - » TB epidemiology and the current capacity of national surveillance systems to directly measure the level of and trends in TB disease burden;
 - » structure of the TB programme within the ministry of health;
 - » policies and strategies relevant to TB prevention, care and control activities;
 - » recommendations made after the previous review (if one occurred);
 - » current performance of the TB programme and progress made during the past years.

- Organization of the review:
 - » the rationale for and objectives of the review;
 - » assignments for field visits, the agenda for field visits and the logistics of the visits;
 - » tasks to be undertaken upon return from field visits;
 - » plans for disseminating the findings of the review.

A briefing protocol (see hereafter Box 3) may be useful to ensure that all of topics are covered and that teams' members are aware of what is expected from them.

It is important to provide an overview of the review's methods and the assessment checklists to ensure that information will be collected in a standardized manner by all team members: each item on a particular checklist must be explained, and the information to be collected for each item must be clarified. The reporting format should also be explained in order to facilitate the compiling of data and the presentation of the findings and observations made in the field; using a structured format will also facilitate the development of the various sections of the final report.

The briefing should allow for communication among teams' members and team-building. Teams' members should be given time to read the background documents if they were not distributed in advance.

Lastly, reviewers will be assigned to their teams for the field visits. The team leader should be introduced to the team. One member of the team (usually the team leader) should keep a list of facilities visited and persons met. The same member of the team, or another member, should keep a record of the key elements discussed by team members each day during the field visit.

In addition, a focal point for each component of the national programme being reviewed should be assigned from among the reviewers with the most relevant expertise.

Box 3. Suggested agenda for briefing reviewers (briefing protocol)

- Introduce teams' members.
- Present information about health and health care in the country.
- Present information about TB and TB activities in the country (include information on the burden of TB, the organization of TB activities including goals and objectives, the structure of the national TB programme, funding for the national TB programme, results of the most recent gap analysis, and whether recommendations made after the previous review were implemented).
- Present the results of the systematic assessment of TB surveillance, and the evaluation of the impact of TB efforts on the TB burden, as well as changes in the TB burden over time.
- Clarify the purpose and objectives of the review.
- Assign specific roles and responsibilities to teams and team members.
- Allocate the sites to be visited.
- Review the assessment checklists, providing detailed explanations of each item to ensure that data are collected in a standardized manner.
- Present and discuss the template that will be used to report findings from the field visits.
- Discuss the process of the review – that is, provide information on meetings and data to be collected – according to the programmatic areas to be assessed.
- Review the agenda and timing of the review.
- Discuss field visits and other logistical considerations.

It is necessary to organize meetings to discuss the objectives and methods of the review and to introduce the teams to key authorities (such as the minister of health, the head of planning and financial resources at the ministry of health, the heads of relevant departments within the ministry of finance, ministers from related institutions, and hospital directors) and, where applicable, to donors, and staff at NGOs and civil society organizations.

3.2 Making field visits

The field visit is one of the most important components of the review. Field visits give teams' members an opportunity to observe TB activities, and to validate data on the national programme's performance.

This section describes what reviewers should observe and do during the field visit. It outlines the service-delivery levels where the assessments should take place, the institutions that should be visited at the different service-delivery levels, and the specific aspects of TB prevention, care and control that should be evaluated.

The health workers practising in the health facilities that are visited should not feel that the review is an audit intended to punish poor performance. In order to ensure their full cooperation during the visits, the reviewers must emphasize that the review is being undertaken to identify (i) the areas in which TB prevention, care and control services are performing well, (ii) the supply-side bottlenecks that impair the services, (iii) explore demand-side issues of specific populations that may be barriers to services (e.g., high rates of poverty and illiteracy which impact treatment seeking and compliance behaviour, migrants lacking documentation, gender norms or ethnic/linguistic discrimination that may influence access to care); and (iv) possible solutions to overcoming any obstacles identified by the visit. The health workers should feel that the review will help them improve the services that they provide and ensure that TB is controlled.

Each team should check the consistency and credibility of data.

- **Consistency:** Teams should observe TB services, and collect quantitative data for agreed-upon time periods. They should check for consistency between the data they collect and the data reported to the routine reporting system.
- **Credibility:** Teams should confirm their observations and findings, and check the credibility of the data that are provided in registers and quarterly reports. Interviews with key personnel and on-the-spot checks may be used. (On-the-spot checks may include assessing, for example, how well the different categories of TB and treatment outcomes are understood and used.)

Teams should verify the information in the briefing materials, the background documents, and from presentations by TB programme staff; they should also verify the data collected and analysed by the national programme. Teams' members should record their findings, identify the strengths and weaknesses of the programme, analyse the reasons for these weaknesses, and propose solutions.

Additionally, teams' members should check the registers and reports, and observe interactions between patients and health workers. They should also assess the links between the national programme and other programmes and initiatives implemented by the ministry of health, as well as programmes implemented by other ministries and government agencies (for example, national initiatives to alleviate poverty).

Teams should record their findings using the standardized assessment checklists prepared for the review. One of the most common methods used in programme reviews is to ask questions based on the items in the checklists. Checklists are critical for ensuring that all relevant components of the national strategy to prevent and control TB and all programme activities are assessed in a standardized fashion.

3.2.1 Service-delivery levels to be visited

3.2.1.1 Central level

Visits should start with the central unit of the national TB programme. Other sites that should be visited include national referral hospitals, the national reference laboratory, the central pharmacy, the ministry of health's warehouse, relevant ministries (such as the ministries of finance, justice or social welfare), donors, implementing partners, key NGOs and civil society organizations, and health-education institutions, such as medical schools or nursing schools. One member of each team should be from the national TB programme in order to facilitate the logistics of the visits. The purpose of visiting staff at the central level is to assess the appropriateness and quality of:

- the country's national strategy to prevent and control TB and its integration in the national health plan;
- the national guidelines on TB prevention, care and control;
- the national TB strategic plan, including the budget and its operational component;
- the national health plan and/or strategy, covering top objectives in health, and important related health system strengthening issues such as financing, private sector regulation, and quality assurance mechanisms;
- the human-resources capacity, especially the programme's managerial and technical capacity to implement the national strategy to prevent and control TB;
- procedures for supervising staff, and for monitoring and evaluating implementation of the national programme;
- the social protection policy, and any benefits for TB patients (e.g., disability grants)
- the national plan for training staff, and the materials and methods used in training;
- coordinating mechanisms used with key stakeholders (such as the national reference laboratory, implementing partners, donors, civil society organizations, or the private sector);
- collaborations within the health sector (for example, with the programme addressing HIV and AIDS, and those addressing noncommunicable diseases) and with other government sectors involved in TB prevention, care and control;
- data collection, analysis and reporting;
- platforms for ongoing participation of civil society and communities on a regular basis in activities related to the national strategy to prevent and control TB,
- the agenda and activities for operational research.

3.2.1.2 Intermediate and peripheral levels

Field visits should include institutions at each level of health-care service, such as provincial or district health offices and hospitals, and peripheral health centres. Depending on the country and on official procedures, team members may first need to visit the health authorities of a particular province or district to explain the purpose of the review before starting the field assessment. Wherever possible, a one-page information note for each site visit should be prepared beforehand by the person in-charge of the health facility, in order to optimize the use of time during the visit and have more time for discussion with the local staff.

At the district level, a key place to visit is the basic management unit for TB activities where the TB treatment register and TB laboratory registers are kept. This unit serves as the centre for the diagnosis, treatment and reporting of TB patients. Teams should also visit other service providers, such as public and private hospitals, general outpatient clinics, paediatric wards, hospitals caring for patients with MDR-TB, pharmacies, and NGOs and civil society organizations providing community-based services through health workers or volunteers. It may be necessary to visit medical schools, penitentiary health services and workplace health facilities.

At the intermediate level, such as at the provincial or district level, it is important to assess the managerial capacities of the coordination unit in charge of the TB programme (for example, how capable the unit is in training and supervising staff, how well it manages the anti-TB medicines, coordinates with local stakeholders, and investigates the contacts of TB index cases).

During the field visit to the basic management unit, the following should be assessed:

- the number of trained staff and the availability of training opportunities;
- the process for identifying and managing patients suspected to have TB;
- the efforts made in implementing TB screening activities;
- the procedures used to diagnose TB and the quality of diagnosis;
- the procedures and approaches to addressing comorbidities (e.g., HIV/AIDS or diabetes) as well as risk factors such as smoking or malnutrition that may influence the effectiveness of care;
- the appropriateness of the TB treatment provided;
- the monitoring of and support provided to patients receiving treatment, and any related human rights concerns on access, discrimination or provision of care;
- the recording and reporting systems, the completeness of registration, the availability of quarterly reports, and whether there is consistency between the registers and reported data;
- how the implementation and provision of TB prevention, care and control services are supervised, and whether supervisory visits are recorded;
- the supplies of anti-TB medicines, including buffer stock, and laboratory consumables and equipment;
- whether informational, educational and communication materials are available to promote TB prevention, care and control within the community;
- whether mechanisms are in place to overcome access barriers related to stigma, discrimination, gender norms or other factors such as migrant status, as well as link TB patients to social protection mechanisms to ensure access to relevant benefits;
- the system established to refer patients suspected of having TB and patients diagnosed with TB from one basic management unit to another;
- collaboration between the national TB programme and the national HIV/AIDS programme and/or other national programmes addressing important comorbidities or risk factors;
- the level of involvement in identifying and managing patients with MDR-TB;
- the links with community-based organizations and volunteers.

When acceptable and feasible, discussions should be arranged with small groups of patients as well as with a small group of community workers and volunteers to elicit their perspectives on access to care and treatment. Interviews with individual patients should be also organized.

Following the visit to the district, the team should schedule appointments with the respective authorities (such as the provincial or district health director, the hospital director and relevant stakeholders) to provide feedback on their findings and to make recommendations for improvements, if necessary.

Individual team members should be given responsibility for making specific observations as well as for specific places to visit and people to meet. It is helpful if all team members stay in the same hotel so they can meet briefly at the end of each day to review and summarize their findings and observations, and plan the next days' activities. The designated recorder should note the key points of the discussion, and these should be included in the field report. Persons designated to draft the findings for specific components of the national strategy to prevent and control TB may also use their time in the evenings to begin drafting their contributions.

3.3 Presenting the reports of the field visits to the entire review team

Following the field visits, each team must prepare a presentation about their observations, using the standardized format, and propose preliminary recommendations. In some instances, the review coordinator may request that a written report be drafted by each team to be used to develop the final report. Regardless of whether the coordinator requests a written report, it is necessary to provide a list of places visited and persons met. Ideally, each team should prepare their report on a computer using the same word processing programme, and develop a slide presentation using a common template; the information to be presented may include background information, findings, strengths of the programme, weaknesses of or challenges to the programme, and conclusions and recommendations.

During a plenary meeting, each team presents its findings to all of the teams that took part in the review; experts who did not participate in the field visits may attend this meeting. The chairperson of the meeting should ensure that the discussions focus on the interpretation of findings and pay specific attention to the achievements and constraints of the programme rather than on issues unique to particular sites. The analysis of quantitative and qualitative data should go beyond a simple description of the programme. The content from the teams' presentations and the subsequent discussions will be used to develop the executive summary of the final report and the final debriefing presentation.

The teams should compare the information gathered and the interpretations of it before reaching consensus on the findings and recommendations. Time should be allotted for teams' members to discuss among themselves the appropriateness of the findings and recommendations from the different reports. Special attention must be paid to the possible reactions of the national TB programme regarding the findings and recommendations. The review team should ensure that the national TB programme takes ownership of the actions required to follow-up on the recommendations that have been made.

3.4 Presenting and debriefing the findings and recommendations to the national authorities

The international review coordinator usually makes the final debriefing presentation on behalf of the review teams. The presentation should include the key findings of the field visits and recommendations (see Box 4) on which all the reviewers have agreed.

The international review coordinator should introduce the reviewers, and present the executive summary and main recommendations. If the minister of health and other policy-makers are present at the debriefing, the focus should be on political issues and recommendations for which action can be taken by the ministry of health. During this type of debriefing, the discussion should avoid technical issues and recommendations that can be summarized in a fact sheet and handed out at the beginning of the session.

A more technical debriefing should be given to the staff of the national TB programme and to key implementing partners who will be more directly responsible for carrying out the technical recommendations that arise from the review. This type of debriefing should include adequate time for discussion, and should secure commitments to expedite the clearance of the final report. This more technical debriefing can take place prior to the meeting that will be attended by decision-makers and policy-makers.

It is the responsibility of the international review coordinator to ensure that an executive summary, which includes the key findings and recommendations of the review, is written. A copy of the executive summary should be given to the national TB programme prior to the departure of the reviewers, with the understanding that the full report will be prepared and submitted at a later date.

Box 4. Suggestions for developing the executive summary after the review of a national TB programme

- The executive summary should be precise, and capture all relevant findings and recommendations.
- The main messages derived from the review should be stated clearly and unequivocally.
- The main recommendations should be limited to the five or seven that will contribute most effectively to improving the TB programme.
- The draft findings and recommendations should be shared with and vetted by the national TB programme.

The debriefing may be followed by a media event, such as a press conference for national and international media. Journalists should be given the executive summary and a press kit. The aim is to highlight what is being done by the government and its partners, and to increase advocacy for, political commitment to, and public awareness of TB control in the country. This event should be organized by the ministry of health.

4. Phase 3: finalizing the report of the review, and the next steps

The three main activities to be carried out during this phase are:

- finalizing the report of the TB programme review;
- disseminating the final report;
- supporting the implementation of recommendations made in the final report.

The aim of this phase is to ensure that the report of the review is finalized and disseminated, and to ensure that the recommendations made in the report are followed up, including those proposing that policies and work-plans be updated and that activities be reorganized. This phase must be carefully planned, and the activities must be completed within agreed timeframes in order to maintain political commitment and increased awareness of the burden of TB and TB efforts, and to ensure that changes are implemented. The timeframe should be agreed by the national TB programme and the task force.

4.1 Finalizing the report of the TB programme review

The draft and final reports should be developed under the direction of the international review coordinator or another designated lead writer (Box 5); if the international review coordinator will not be the lead writer, then a writer should have been identified during Phase 1 (the planning and preparation phase). The lead writer manages the writing of the draft report of the review, and after that has been circulated for comments, finalizes the report with the international review coordinator. In general, this process should take no longer than 2 months.

The international review coordinator and team members, in coordination with the lead writer, agree which components should be included in the report (see a model in Box 6). The lead writer reviews the draft sections of the report (which may have been written by team members while they were in the country) and the executive summary, and in coordination with the international review coordinator assigns outstanding components of the report to specific reviewers; the lead writer also provides them with a deadline for returning their parts of the report. Once all the parts have been received, the lead writer combines them into a single report. In compiling the report, the lead writer must also consider any feedback provided by senior policy-makers, stakeholders, key implementing partners and civil society organizations during the in-country debriefing, and incorporate this if it is appropriate.

Box 5. Key steps in finalizing the report of the TB programme review

The lead writer in coordination with the international review coordinator should:

- compile the different sections of the report;
- check for consistency of language (help from a professional editor might be needed);
- check for consistency of findings;
- ensure that all of the recommendations made by the review teams have been vetted by the national TB programme and relate to problems identified during the review.

The draft report, including the executive summary, should be circulated for any final revisions to all members involved in the review. Once the final comments have been received and integrated into the report, the final report is submitted by the national TB programme to the members of the task force for endorsement. Once the task force has approved the report, the document is sent to WHO's country office and then forwarded to the ministry of health; in some instances, the report is forwarded directly to the ministry of health and a copy is sent to WHO's country office. The procedures for final approval may depend on the administrative organization of the country.

Box 6. Model for the contents of a report on a TB programme review

- Executive summary
 - » Main findings and recommendations
- Introduction
 - » Rationale behind undertaking the review of the national TB programme
 - » Expectations of the review
- Background information
 - » Demographic, geographical and socioeconomic features of the country
 - » Overview of the health issues facing the country
 - » TB within the National Health Plan or Strategy
 - » Description of the health- system
 - » History of TB activities
- TB epidemiology and impact analysis (see Annex 3 for detailed terms of reference). This includes analysis of geographical variation in disease burden and among subpopulations, and recommended actions to strengthen surveillance so that trends in disease burden can be directly measured using notification and vital registration data.
- Policies, structure and organization of services offered by the national programme
- Outcomes from and impact of the national programme's services, including any inequities in access, care or results
- Terms of reference for the review
- Methods used to assess the national TB programme
- Main findings, organized by thematic areas, including background, strengths, weaknesses and challenges, and recommendations for improvements. Thematic areas could include:
 - » programme management, human resources, financing and resource mobilization;
 - » identification and management of persons with symptoms compatible with TB, including any TB screening efforts;
 - » the laboratory network;
 - » case-finding;
 - » the case-management and treatment of TB patients;
 - » the procurement of anti-TB medicines, and management of the supply chain;
 - » supervision, and monitoring and evaluation;
 - » recording and reporting (that is, the information system);
 - » MDR-TB;
 - » coinfection with TB and HIV and other comorbidities such as diabetes;
 - » infection control;
 - » involvement of all care providers;
 - » use of the practical approach to lung health (also known as PAL);
 - » TB contact investigation;
 - » childhood TB;
 - » Approach to specific vulnerable groups (eg, prisoners, migrants, ethnic minorities etc.) ;
 - » engagement of patients, communities and civil society organizations;
 - » links with other programmes and initiatives including health system strengthening issues such as financing, regulation of private sector, etc;
 - » methods to eliminate stigma;
 - » linkages with other sectors (including justice, labour and social protection);
 - » operational research (including studies on specific subpopulations).
- District field-visit reports (these should be included as annexes)

The final report should include general and specific assessments, and a discussion of the qualitative and quantitative data collected during the review. The data should be organized and analysed in such a way that they provide the country and its partners with information on the magnitude of the TB problem, and the achievements of and constraints on the national TB programme with respect to the programme's expected impact on TB.

Findings and recommendations should be prioritized to emphasize those recommendations that will have the most impact on increasing the effectiveness of the national programme. The final report should suggest strategic interventions on which technical and political decisions can be based to improve TB control. The recommendations should include specific timelines and deliverables.

The final version of the report should be printed and forwarded to those who need to be informed about the review's findings and recommendations.

4.2 Disseminating the final report of the TB programme review

The impact of the review can be significantly increased by ensuring that the findings and recommendations of the report are widely disseminated. The ministry of health's information and communication office should be involved at an early stage of the planning process to identify ways to publicize the findings. Activities could include issuing a press briefing or a press release, and having relevant government officials make public statements supporting TB control at the conclusion of the review. The amount of effort spent on engaging the media depends on what gains are expected from media exposure (for example, increasing the visibility of TB control, raising political will and awareness, and furthering the efforts of the TB programme).

The final report should be discussed with and disseminated to all levels of the ministry of health and the national TB programme's network; also, it should be discussed with and disseminated to all key government stakeholders, as well as national and international partners. Other opportunities for disseminating the findings include writing articles to be published in journals, newsletters and on web sites. The results of the review might also be presented at conferences, and discussed during national and regional workshops on the findings of the review and the recommendations made in the report.

The manager of the national TB programme should take responsibility for disseminating the report of the review. The manager must ensure that the finalized and approved report is sent to all members of the task force and the review teams, senior policy-makers and relevant ministerial departments. Copies should also be sent to all institutions and individuals visited during the review, particularly TB control coordinators at the provincial or district level (the intermediate health level). In addition, the report should be circulated to all internal and external partners and donors.

4.3 Supporting the implementation of recommendations made in the final report

The manager of the national TB programme is responsible for coordinating and ensuring that the recommendations made in the report are implemented in a timely fashion. The recommendations should include specific timelines and deliverables. It may be useful if reviewers prepare a budget listing the main activities that need to be implemented according to the timelines in the report; this budget may be included in an annex and will help revise the budget component of the national strategic plan. Each activity should be specific, achievable and linked to output or process indicators. Estimates of the additional resources required to implement the activities (that is, the funding gap), and possible sources of funding, must be highlighted. The recommendations may be used to define the next steps to be taken to improve the programme's performance or to redefine the strategic direction and focus of the programme, which may include revising policies (Box 7).

The intent of a TB programme review is to identify gaps in the national strategy to prevent and control TB as well as in the implementation process; the review should also provide strategies for closing these gaps. The outcomes of the review constitute foundations for developing a new national strategic plan or improving the existing plan, and should provide sound objectives and appropriate strategic interventions that are consistent with these objectives and with the gaps identified in the review. The availability of a sound national strategic plan with an adequate budget, a monitoring and evaluation component, and a clear description of its operationalization is not only a key asset for the management of national TB programmes but also a fundamental element necessary for mobilizing resources, especially funding, from the government, national NGOs and external donors, and through bilateral and multilateral cooperation.

Box 7. Potential uses of recommendations made during a TB programme review

Recommendations from reports on programme reviews can be used to:

- revise technical policies and operational procedures;
- revise the national strategic plan for TB control and associated components in the national health strategy and plans of other sectors;
- revise the recording and reporting system;
- develop strategies to engage or strengthen the involvement of key stakeholders;
- develop or revise training materials;
- develop funding proposals.

Annexes

Annex 1. Checklist for preparing and conducting a review of a national tuberculosis programme

Annex 2. General information and documents to be collected before the review of the national tuberculosis programme and to be made available to the reviewers

Annex 3. Terms of reference for the TB epidemiological and impact analysis component of a national programme review

Annex 4. Checklists for assessing selected areas of tuberculosis activities during a review of a national programme

Annex 5. Selected references

Annex 1. Checklist for preparing and conducting a review of a national tuberculosis programme

The checklist outlines the steps required to undertake a review of a national TB programme.

Phase	Steps	Date	Comments
1: Planning and preparing for the review	1: Appoint review coordinators		
	2: Establish a task force for the review		
	3: Define the review's objectives		
	4: Set the dates for the review		
	5: Select the members of the review teams and define their roles and responsibilities		
	6: Select sites for the field visits		
	7: Plan the logistics		
	8: Prepare a budget and arrange funding for the review		
	9: Prepare the assessment checklists and background documents		
	10: Identify a lead to write the report		
2: Conducting the review in the field	1: Brief the review teams and meet with the relevant national health authorities		
	2: Field visits		
	3: Present the findings from the field visits to the entire review team		
	4: Present a debriefing on the findings and recommendations		
3: Writing and finalizing the review report and making recommendations	1: Finalize the report of the TB-programme review		
	2: Disseminate the report of the TB-programme review		
	3: Support the implementation of the recommendations		

Annex 2. General information and documents to be collected before the review of the national tuberculosis programme and to be made available to the reviewers

Information should be provided to the reviewers about (i) the overall demographic, economic and political situation in the country; (ii) the general health status of the population, and national health policies; (iii) the burden of TB; and (iv) TB prevention, care and control activities. This information should be sent to the reviewers prior the review. The information will help them when making their observations during the review and help them understand the context in which TB care is delivered in the country.

Type of information	Purpose	Topics on which specific data are needed
Population	To help reviewers estimate the burden and describe the distribution of TB; to help them calculate the incidence of TB	<ul style="list-style-type: none"> Population size Distribution of the population by age group and sex Population groups stratified according to characteristics relevant to the country (for example, by socioeconomic status or ethnic group) Distribution between urban and rural areas Annual rate of population growth
Economics, government and development agenda	To help reviewers determine political commitments to economic and social development, health in general and TB control in particular	<ul style="list-style-type: none"> Gross national product Gross national product per capita Sources of government revenue Distribution of poverty within the population Government health expenditure Administrative structure (for example, national or federal level, regions or states, provinces and districts) Development agenda
Overall health of the population	To help reviewers understand the epidemiological situation	<ul style="list-style-type: none"> Overall mortality, and distribution of the proportionate mortality rate Overall life expectancy, and life expectancy stratified by sex Infant mortality Maternal mortality Burden of communicable diseases (for example, TB, HIV, and vector-borne, waterborne and foodborne diseases) Burden of noncommunicable diseases (for example, diabetes, cardiovascular diseases, cancer) Status of the epidemiological transition Status of malnutrition in the population Population groups that are overweight or obese Tobacco use and alcohol consumption Other relevant information

Type of information	Purpose	Topics on which specific data are needed
Health system and services	To give reviewers information on how the health system is structured	<ul style="list-style-type: none"> • Description of the various components of the health system (for example, public sector, private sector, community) • National health policies and priorities • National health planning and allocation of resources • Organization and delivery of health-care services • Capacities of the health system to provide health services (for example, the type and number of health facilities, the national health programmes available, the human resources available within the health system) • Health-care financing and levels of financial protection (by income quintile if possible) • Health-sector reforms
TB	To provide information about the epidemiology of TB in terms of burden and mortality, as well as of their distributions	<ul style="list-style-type: none"> • Number of cases • Prevalence • Incidence • Mortality from TB • Distribution of the above indicators by geographical area (such as by region, or in urban areas versus rural areas, population density level) and population group (for example, by sex; age; HIV status or other disease, such as diabetes; by occupation, such as mining; other social vulnerability (eg prisoners, ethnic minorities, migrants etc), and by other high-risk condition, such as alcoholism, tobacco use or malnutrition), as well as the trends in these indicators over time
National TB programme	To fully describe the organization of the national programme and the implementation of TB prevention, care and control services	<ul style="list-style-type: none"> • National policy to control TB • Guidelines and standard operating procedures developed to implement the national policy • Structure of the national TB programme (for example, information about activities at the central level, intermediate level, primary health-care level, community level) • National strategic plan (including the core plan, budget, monitoring and evaluation plan, the operational plan, and specifications of the technical assistance needed) • Information on the national TB laboratory network and the procedures used to diagnose TB • Sources of funding (including governmental, bilateral and multilateral cooperation mechanisms, internal and external donors) • Details of the information system used in the national programme's network (including information on the registers, forms and list of indicators used routinely) • Training modules • Information on the management of anti-TB medicines • Roles of the various partners involved in control activities • Types of collaboration and methods of coordination with partners, including civil society organizations

Type of information	Purpose	Topics on which specific data are needed
Results of TB efforts	To provide information on the implementation of TB activities and their outcomes	<ul style="list-style-type: none"> • Notification of TB and its distributions, as well as its trend over time • Outcomes of TB prevention, care and control activities • Burden of retreatment of TB cases • Status of MDR-TB • Level of development and implementation of the interventions specified in the national programme's policies • Gaps identified in policy and activities • Budget allocated and resources mobilized • Funding proposals developed and submitted
Others	To provide additional relevant information	<ul style="list-style-type: none"> • Information produced by the national programme on TB and TB prevention, care and control efforts (for example, annual reports) • Advocacy material produced by the national programme or its partners to mobilize resources at national or international levels • Information on TB activities provided by external monitoring missions (for example, reports by WHO or other international partners) • Information on implementation of specific activities or projects (for example, reports by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Stop TB Partnership's Global Drug Facility, the Green Light Committee) • Description of TB prevention, care and control efforts provided in a previous review of the programme • Any relevant analyses of TB prevention, care and control in the country (for example, published articles or internal reports)

Annex 3. Terms of reference for the TB epidemiological and impact analysis component of a national programme review

The epidemiological and impact analysis may be undertaken, if appropriate, prior to the review. In this case, the lead person conducting the analysis should take part in all debriefing sessions. If the analysis is undertaken during the national programme review, it should also take into consideration any additional findings/information generated by the evaluation of TB programme components assessed during the review.

OBJECTIVES

1. Describe and assess 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).
2. Assess the level of, and trends in, TB disease burden (incidence, prevalence, mortality) using available surveillance, survey, programmatic and other data.
3. Assess whether recent trends in TB disease burden indicators are plausibly related to changes in TB-specific interventions taking into account external factors including economic or demographic trends.
4. Define the investments needed to directly measure trends in TB disease burden in future.

TASKS BY OBJECTIVE

Objective 1: Assessment of 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

- a) Provide a written description and explanation of the main features of the current national TB surveillance and vital registration systems. These should include the data being captured (e.g. notified cases, treatment outcomes, causes of death); definition of the agencies/individuals responsible for data collection, analysis and reporting and how they interact; mechanisms/processes used to capture and transmit data between different administrative levels and agencies (e.g. standardized forms; paper-based and/or electronic systems) and to assure data quality; timing and timeliness of reporting including lag times that hamper capacity to detect, investigate and contain events such as local epidemics (including events related to the emergence of drug resistance); the type of data available at the national level (e.g. aggregated reports, case-based

data); approach to analysis and reporting of data; staffing levels; how systems for capturing TB data are related to/linked with other health information systems (e.g. health insurance, hospital reporting systems, district health information systems). *To help characterize the TB surveillance system, Part A of the WHO TB surveillance checklist (18 questions) should be completed.*³

- b)** Assess the current capacity of national TB notification and vital registration systems to provide a direct measure of TB disease burden using the WHO TB surveillance checklist (Part B). *The ultimate goal is to measure TB incidence and mortality directly from notification and vital registration data, respectively; Part B of the checklist consists of a set of 13 standards and associated benchmarks that allow assessment of the extent to which existing surveillance systems (notification and vital registration) meet these standards.* (NB the first standard in the checklist relates to case definitions. In this context, there should be an assessment of whether the 2013 WHO revised case definitions and reporting framework have been adopted and implemented, and at what scale, and any actions needed to introduce or fully implement them).
- c)** Summarize the main strengths of the current surveillance system and the weaknesses/gaps that need to be addressed, based on the findings from a) and b).

(Suggested data sources⁴ : Interviews with relevant staff; national and sub-national case-based or aggregated TB notification data, national or sample vital registration data, results from facility audits (e.g. Service Availability and Readiness Assessment, SARA) or reviews of the quality of recorded data, results from drug resistance surveillance including drug resistance surveys, research literature). A comprehensive list of data sources is provided in the user guide that accompanies the checklist)

Objective 2: Assessment of the level of, and trends in, TB disease burden

This assessment includes 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 sub-nationally and among sub-populations); analysis of TB notification data; and interpretation of available data.

- a)** Analysis of the level of, and trends in, TB mortality.
 - i.** Analysis of trends in TB mortality among HIV-negative individuals. This is best done using data from a national or sample civil registration system of vital statistics with cause of death data that meet the standards defined in the WHO TB surveillance checklist. Each year, WHO publishes estimates of TB mortality among HIV-negative people from 1990 onwards for all countries in the annual global TB report (the global TB report also identifies the countries for which mortality among HIV-negative individuals has been estimated from vital registration data and mortality surveys, and the countries for which estimates rely on other methods).
 - ii.** Analysis of trends in the distribution of contributory causes of AIDS deaths (with particular emphasis on TB), if data are available. From 2012, estimates of TB mortality among HIV-positive people are being produced using the TB component of Spectrum, and published on an annual basis by WHO and UNAIDS.

³ http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/en/

⁴ It is likely that some of the suggested data are not yet available. The identification of these data gaps is important and they should be identified in a specific section of the final report, along with clearly defined next steps for addressing these gaps.

(Suggested data sources: WHO TB database, AIDInfo database, records from national or sample civil registration of vital statistics with cause of death data from NTP/MoH databases, results from mortality surveys, research literature)

- b)** Analysis of the level of, and trends in, TB prevalence. If data are available from a baseline and at least one repeat survey, then there is strong evidence about trends in disease burden. If results from two surveys conducted about 10 years apart are not available, estimates of trends are available from WHO but uncertainty intervals are wide. The results from a recent survey 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.

(Suggested data sources: results from surveys of the prevalence of TB disease, WHO TB database, research literature)

- c)** Analysis and interpretation of the level of, and trends in, TB case notifications (e.g. for the last 5-10 years).
- i.** Plot time series of case notifications and analyse results, including to assess trends and to identify if there is any evidence of reporting problems (e.g. missing data or sudden changes in time-series of reported new episodes of TB at national and first subnational level e.g. state or province). Analysis of results should take into consideration any changes in reporting policies and practices, and case definitions.
 - ii.** Analysis of the geographic distribution of case notification rates among subnational areas and how this has changed over time, and exploration of reasons for observed trends and geographical heterogeneity. These include, but are not limited to, the availability of TB diagnostic services, case finding activities, changes in the ratio of TB cases to the number of people investigated for “presumptive” TB (note that data on the number of people investigated for TB are often not quality-assured and duplicate entries from multiple visits by the same person may exist), health systems characteristics, determinants of/risk factors for TB (e.g. overall levels of income and poverty, HIV prevalence).
 - iii.** Analysis of trends in the proportions of notified cases: (a) by type of TB disease - bacteriologically confirmed and extra-pulmonary TB; (b) by age group, including the proportion of cases among children (0-4, 5-14); (c) by category (retreatment out of the sum of new and retreatment cases).
 - iv.** Trends in age- and sex-specific case notification rates, the average age of newly notified cases, and the extent to which these can be explained by demographic or other factors.
 - v.** Analysis of the level of (and ideally trends in) under-reporting from national inventory studies if these are available before the assessment.
 - vi.** Any data available on TB in high risk groups such as people living with HIV, the elderly, people with diabetes, people with compromised immune systems, prisoners, miners, etc.; numbers, denominators; and if available proportions and trends.
 - vii.** Other miscellaneous analyses that may be relevant in specific settings (to be determined by the epidemiologist(s) undertaking the assessment).

(Suggested data sources: National and sub-national case-based or aggregated TB notifications, laboratory data, results from inventory studies to measure TB under-reporting (and under certain circumstances estimate incidence), laboratory data, research literature, national databases with information about overall health system characteristics and determinants/risk factors related to TB)

Objective 3: Are recent trends in TB disease burden plausibly related to changes in TB-specific interventions accounting for other external factors?

Funding for and implementation of high-quality TB-specific interventions should result in detection of people with TB and curative treatment; in turn, this should have a direct impact on TB mortality (cutting case fatality rates compared with no treatment or substandard treatment). Shortening the duration of disease through detection and treatment of cases will also reduce the prevalence of TB disease, and therefore, transmission. There will be an impact on TB incidence if transmission can be reduced sufficiently and/or if preventive treatment of people with latent TB infection is effectively implemented on a large scale. At the same time, a range of factors besides TB-specific interventions influence levels of TB disease burden, by affecting population susceptibility to both TB infection and the risk of developing TB disease once infected. These include overall levels of wealth and the distribution of wealth (measured e.g. as GNI per capita, the proportion of people living in poverty), the overall coverage and quality of health services and the prevalence of HIV and other risk factors for TB. Having considered trends in disease burden in Objective 2, it is important to assess whether these trends can partly be related to changes in TB-specific interventions (and associated funding).

- a)** Define and compile data that are relevant to assessment of the extent to which changes in TB disease burden in recent years (e.g. for the last 5–10 years) can be explained by TB-specific interventions/programmatic efforts. This should include, at a minimum:
- i.** Government and international donor funding for TB care and control;
 - ii.** Number of health facilities providing TB diagnostic services per 100,000 population;
 - iii.** Number of health facilities providing TB treatment services per 100,000 population;
 - iv.** Number of people investigated for presumptive TB (if available data are reliable) and the ratio of presumptive TB to notified TB cases;
 - v.** Performance of community/active case finding (number of cases screened and detected by each mechanism);
 - vi.** Performance and coverage of public-private mix activities in the country. Coverage should be expressed where possible both as % of the country (geographic) and type, the % of providers covered (e.g., 30% of estimated pharmacies and 50% of estimated private pulmonologists);
 - vii.** Any quantitative data on diagnostic delays (due to patient, private sector, or public sector delays);
 - viii.** Number of people successfully treated for TB out of all notified;
 - ix.** MDR-TB treatment coverage (comparing numbers detected and treated with the estimated number of cases among notified TB patients and describing the size of waiting lists), and treatment outcomes among MDR-TB patients. This is especially relevant in countries in which MDR-TB cases account for a relatively large share of the total number of TB cases;
 - x.** HIV testing, ART and CPT coverage of TB patients, treatment outcomes among PLHIV. This is especially relevant in countries with a high TB/HIV burden.

(Suggested data sources: WHO TB database, NTP database and reports, Service Availability and Readiness Assessments (SARAs), results from inventory studies that show the level of TB under-reporting, research literature, grey literature, national TB prevalence surveys, WHO HIV/AIDS data and statistics, AIDSinfo database, MOH and NGO databases, <http://www.foreignassistance.gov> for USAID funding data)

- b)** Define and compile data that are relevant to assessment of 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 funding and associated interventions. This should include, at a minimum:
- i.** Prevalence of HIV among the general population, and ART coverage. (Suggested data sources: WHO HIV/AIDS data and statistics, AIDSinfo database);
 - ii.** Prevalence of diabetes, tobacco use and under-nutrition. (Suggested data sources: WHO HIV/AIDS data and statistics, AIDSinfo database, WHO Global Health Observatory)
 - iii.** GNI per capita and the % of the population under the poverty line, and the impact of economic crises. (Suggested data sources: World Bank Indicators);
 - iv.** Coverage of financial protection for health care costs (by government health budget or health insurance etc.) and social protection programmes (overall, and for DS-TB and MDR-TB specifically where available) and the percentage of health-care expenditures accounted for by out-of-pocket payments (Suggested data sources: Research literature, national health accounts, social protection/welfare programme information on coverage of target groups, as relevant and available from WHO at www.who.int/nha; research literature)
 - v.** Demographic changes; percentage of population who are less than 15, and those more than 65, years (Suggested data sources: UNPD database)
 - vi.** Under-5 mortality rate (as an indicator of the overall performance of the health-care system).

(Suggested data sources: WHO Global Health Observatory)

Objective 4: Assessment of investments needed to directly measure trends in disease burden in the future

- a)** From the implementation of the WHO TB surveillance checklist: for standards defined in the checklist that are not yet met due to data gaps or data quality problems, identification of the investments required to improve surveillance (including estimated budget).

(Suggested data sources: same as in 1.b, NTP reports)

- b)** Assessment of whether a baseline or repeat survey (e.g. prevalence survey, inventory study, cause of death survey) is needed and if so what timing would be appropriate. An appropriate amount of time should be ensured between repeat surveys (for example, a repeat TB prevalence survey should normally be done about 10 years after the previous one). Guidance on countries where prevalence surveys are recommended is available from the Global Task Force on TB Impact Measurement.

DELIVERABLES

A comprehensive report as well as presentation material prepared for all debriefing sessions addressing all tasks under the three objectives of the epidemiological and impact analysis outlined in this document with a conclusion section on:

- a) The robustness of estimates of TB incidence, prevalence and mortality and their sources of uncertainty.
- b) Whether it is plausible that TB control interventions have contributed to changing the course of the TB epidemic, accounting for other external factors.
- c) Whether there are specific geographical areas or subpopulations (vulnerable/those with poor access) or sectors (e.g. mining, prisons/detention, etc.) in which the burden of disease is especially high and that warrant increased attention including greater investment of financial resources and/or reallocation of resources to focus on more effective, higher impact interventions.
- d) Investments needed to improve evidence about trends in disease burden in future.

PROFILE REQUIRED

- A senior epidemiologist or statistician with extensive quantitative skills and a proven track record of producing results and communicating them well (including in scientific publications in peer reviewed journals);
- Excellent understanding of TB epidemiology, TB policies and interventions, and health systems;
- Extensive experience in working with national TB health programmes and offering technical assistance.

TIME REQUIRED

This depends in part on the extent to which the person(s) conducting the analysis are already familiar with the country where the assessment is being done and the associated data, their previous experience of conducting such analyses, but also the availability and expertise of national monitoring and evaluation counterparts who will participate in this exercise. For someone familiar with the country and the data and with previous experience of such work, it is estimated that 2 weeks of in-country work are required. An additional 2 weeks of preparatory work might be necessary depending on the country context.

Guidance on and related examples of schedules for previous missions that covered the Terms of Reference described are available from WHO on request.

Annex 4. Checklists for assessing selected areas of tuberculosis activities during a review of a national programme

This annex lists the online checklists that can be adapted and used to assess specific areas covered by the review. Each checklist focuses on assessing one specific area of tuberculosis (TB) prevention, care and control using qualitative and quantitative approaches, and covers aspects to be evaluated at all levels of the health system. These checklists may also be used to assess all TB activities according to their administrative level; for instance, a specific checklist may be designed for the central unit of the national TB programme, for the coordination unit of the programme at the intermediate health level (for example, at the provincial or district level), for the basic management unit, for a peripheral health facility or for use in community settings.

The proposed checklists are available for download and adaptation at www.who.int/tb/publications/jmm_2014/en/index.html. They focus on areas of TB prevention, care and control that are often considered during programme reviews, such as:

- the management of the national TB programme;
- the national strategic plan for TB prevention, care and control;
- TB case-finding including –
 - » identification and management of patients suspected to have TB;
 - » TB contact investigation;
 - » TB case-finding in high-risk groups;
- quality-assured diagnoses made by TB laboratories;
- the quality of TB diagnoses;
- the management of TB cases;
- The programmatic management of drug-resistant TB;
- TB/HIV collaborative activities;
- patients' adherence to TB treatment;
- the management of anti-TB medicines and supplies;
- recording and reporting;
- activities to address childhood TB;
- infection control;

- public–public and public–private mix approaches;
- the implementation of the practical approach to lung health (PAL);
- the engagement of civil society, nongovernmental and community organizations;
- human resources development;
- how TB activities are integrated within the health system.

It is not necessary to assess all of the areas listed above during a review of a national TB programme, and others might need to be considered depending on the national strategy and the objectives of the review.

These proposed checklists can be also used as background material to establish and adapt new checklists to be used by administrative levels (i.e.: central unit, district level, BMU and peripheral health facility level).

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