MDR/XDR-TB Assessment and Monitoring Tool

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NOTE: This document is available electronically for free download in both Microsoft Word and PDF formats at the following address: http://www.path.org/publications/details.php?i=1678

Table of Contents

Abbreviations and Acronyms

ACSM	advocacy, communication, and social mobilization
C+	culture-positive
CB-DOTS	community-based DOTS
CCM	Country Coordinating Mechanism
DOT	directly observed treatment
DOTS	the internationally recommended strategy for TB control
DR	drug-resistant
DRS	drug resistance survey
DST	drug susceptibility testing
EQA	external quality assurance
FDCs	fixed-dose combination drugs
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GLC	Green Light Committee
HCW	health care worker
HR	human resources
HSS	health systems strengthening
IUATLD	International Union Against TB and Lung Disease
MDR-TB	multidrug-resistant tuberculosis
M&E	monitoring and evaluation
MOH	ministry of health
NGO	non-governmental organization
NRL	national reference laboratory
NTP	national tuberculosis program
OR	operations research
PAL	Practical Approach to Lung Health
PEPFAR	President’s Emergency Plan for AIDS Relief
PPM	public-private mix
QA	quality assurance
R&R	recording and reporting
RMP	rifampicin
SOPs	standard operating procedures
SS-	sputum smear-negative
SS+	sputum smear-positive
TB	tuberculosis
TB/HIV	tuberculosis/HIV co-infection
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

MDR/XDR-TB Assessment and Monitoring Tool

Introduction

This analytical tool addresses two important questions related to multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) control at the national or sub-national level:

1) Are there high-priority gaps in the DOTS program that must be corrected to prevent the development of cases of MDR-TB and XDR-TB?
2) What high-priority areas should be addressed to improve diagnosis and treatment of MDR-TB and XDR-TB?

This tool can be used by national tuberculosis program (NTP) staff, consultants, donors, and others for several purposes:

- Preparing national or sub-national plans for MDR/XDR-TB prevention and control.
- Providing baseline information and monitoring progress.
- Providing data and analysis to prepare for Green Light Committee (GLC) and Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) applications.
- Providing information to guide requests for external technical assistance.
- Providing information to guide donor investment in MDR/XDR-TB interventions.

The tool has been designed taking into account existing guidance on the management of MDR-TB and XDR-TB, including *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis* (http://whqlibdoc.who.int/publications/2006/9241546956_eng.pdf), and its *Emergency Update 2008* (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf), GLC application instructions (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.369_eng.pdf), and GFATM guidance (http://www.who.int/tb/dots/planningframeworks/en/index.html).

The tool collects key data that are the most immediate indicators of a country's risk for MDR-TB or XDR-TB, such as treatment outcomes for TB patients (particularly when drug resistance surveillance data are not available or are limited in scope). Analysis of these key data elements can point to gaps in programming that should be explored further. The tool then uses the six elements of the Stop TB Strategy to collect data on potential contributing factors to these gaps, so that these factors can be identified, prioritized and used to develop an action plan to improve performance.

In each section corresponding to a component or sub-component of the Stop TB Strategy, there is a set of questions with assigned scores. These questions are considered essential in evaluating that component with respect to MDR/XDR-TB. Each section receives an overall score that can be used to assess the national or sub-national performance in that area (e.g., adequate, minor improvements needed, or inadequate with major improvements needed) *but no overall cumulative score will be calculated*. The scores are meant to provide a relative, not absolute, evaluation of performance and to help prioritize areas for improvement. Users of the tool will be required to draw on their experience and knowledge of the country setting to interpret scores and assess the relative importance of each component when planning for MDR/XDR-TB activities. In addition, each section of the tool allows collection of supporting information through unscored questions that can provide important details about the underlying causes of some of the challenges identified, so that recommendations can be tailored to the unique situation in each country.

This tool is not intended to provide a full TB program evaluation, but to focus inquiry specifically on issues related to MDR-TB and XDR-TB. However, it can complement and also draw information from national TB program evaluations and other assessments.

General instructions

The application of this tool in a country or region of a country should be undertaken with the full collaboration of the NTP and with clearance from the Ministry of Health (MOH) or other appropriate official bodies. The tool is designed for three to five days' fieldwork for a national-level assessment, assuming that some data are available through WHO publications, NTP annual reports, and other standard sources of information.

Prior to the initiation of fieldwork, obtain as much data as possible from the most recent *WHO Global Tuberculosis Control Report (Global TB* report*)* and *Anti-tuberculosis Drug Resistance in the World: Report No. 4.* If you are an international consultant working in a high-burden country, review the most recent high burden country (HBC) profiles in the *Global TB Report* for a summary of accomplishments and challenges over the last few years. If the data obtained from the annual WHO report differ from the figures provided by the NTP, investigate possible reasons for the discrepancy and agree on the data source(s) to be used in the assessment.

Consultants and NTP managers bring a wealth of experience to inform the use of this tool; the data collection experience and interpretation of results depend heavily on the user's prior experience in-country or in other countries. This wealth of experience is both an advantage and a disadvantage: users with many years experience in the country or region will be able to work more efficiently than less experienced users; however, their interpretation of the data may be biased by the expectations informed by prior experience in the field. Therefore, it is extremely important to verify and validate data collected with this tool, and wherever possible, consult more than one data source in order to note discrepancies for key data points. Additionally, the report and recommendations should be reviewed by a variety of stakeholders to ensure that key points are not missed and recommendations are grounded in programmatic reality.

Logistics

There is no one "correct" way to organize the activities to be undertaken when using this tool. Practical considerations such as the budget and availability of human resources will guide the use of this tool in a given setting. Sub-national data collection may be limited by transport and whether or not district offices can spare an individual to provide input for data collection. The following questions are meant to provide a starting point for planning an international mission or in-country data collection effort.

- **Planning**
  If applied sub-nationally, how many regions/districts will you include? What is your strategy or criteria for selecting regions/districts? How many people will you need to send to the field? Will you need to have a training event to prepare data collectors (for instance, instead of sending people out to the field, can you bring existing staff to a central location for training and then have them collect the data as part of an enhanced supervision?)
- **Budget**
  Who is funding the effort? How much money is available? What costs are associated with use of this tool? Will you need to hire an international consultant? Will you need to hire local consultants?
- **Communication**
  Whom do you need to contact in advance of your trip, both international trips and site visits? Who will make appointments and get clearance from the corresponding authorities (for

instance, head of the National Reference Laboratory [NRL] if you need to visit the NRL, district medical officer if you visit a district office?)

- **Report**
  Who will be responsible for analyzing the data and writing up the results? Who should be included in the review process? Who will prepare and present findings to key stakeholders at the conclusion of the assessment? Who should receive a copy of the report? Who will be the point person for follow-up on specific action items prioritized in the report? (See Appendix 2 for sample outline for the final report.)

Completing the Tool

The *MDR/XDR-TB Assessment and Monitoring Tool* consists of two main parts divided into sections:

Part 1: National MDR/XDR-TB Situation Analysis consists of three sections (*Country Snapshot*, *TB Case Detection and Treatment Outcome Data*, and *Drug Resistance Data*) and includes a series of tables on the overall TB situation, cohort analysis for recent treatment cohorts, and a summary of data on drug resistance (for example, from a drug resistance survey). Part 1 is structured around the two priority questions guiding the activity:

1. Are there high-priority gaps in the DOTS program that must be corrected to prevent the development of cases of MDR-TB and XDR-TB?
2. What are the high-priority areas the country (or sub-region) should improve to be more effective in diagnosing and treating MDR-TB and XDR-TB cases?

These questions are addressed with an analysis of key case detection and treatment outcome indicators, for example, failure, default and death rates, to assess whether or not the program data indicate potential risks for drug resistance.

Data collection tables in Part 1 are followed by a series of scored questions. Detailed instructions for completing the tables appear in each section. The scored questions are structured as follows:

Question	Answer	Score	Identified gaps/comments

Part 2: Gap Analysis by Stop TB Strategy Component consists of a series of tables requesting detailed information on NTP activities, organized by components of the Stop TB Strategy.

Tables in Part 2 include scored and unscored questions to inform overall findings and recommendations for the NTP. These tables are structured as follows:

Question	Answer	Score	Identified gap	Action/ Recommendation	Data source/Comments

The tool user should respond as completely as possible to each item under each section of the tool, including a description of gaps for each component and where applicable, for individual items. Practical actions/recommendations should be formulated for each gap identified, and as noted above, data sources should be recorded for each item, along with comments that will provide useful insights when completing the report and making final recommendations.

At the end of each section or sub-section in both Parts 1 and 2, space is provided to summarize the apparent strengths and issues of concern for that component or sub-component. These brief summaries can be used to 1) check the evaluators' overall impressions with program managers and identify areas that may need further clarification; 2) pull out information to prepare the end-of-mission presentation; and 3) prepare the final report.

Users should be able to complete the tool at the national level in three to five days time, if the mission is well-organized and key data sources are available prior to the fieldwork. Depending on the setting, users may focus on specific sections. For example, if there are no private providers involved in diagnosis and/or treatment of TB, Component 4 in Part 2 (Engage all care providers) may not be relevant. Quality assurance and verification of data to the extent feasible will improve the relevance of the findings and the usefulness of the recommendations. Ideally, the tool should be completed by each member of a team and results compared; the team can discuss any discrepancies in data or scoring and arrive at consensus for each question and section.

Data sources

Keep a running list of all resources used in preparation for the data collection activity and document each data source used for each question. The *Country Snapshot, TB Case Detection and Treatment Outcome Data*, and *Drug Resistance Data* sections require the user to complete a series of tables, analyze the data, and answer questions related to each section. In Part 2, data for each Stop TB component are gathered through a structured questionnaire that will require both quantitative and qualitative assessments. Suggested data sources appear in the instructions for each section; where these sources are not available in the local setting, the consultant or program manager should provide his/her observations and/or consult with an on-site provider. However, given the limitations of second-hand reports, they should be clearly documented in the data source section for the corresponding question. Users should review representative facility and laboratory registers to verify all reported data; ideally, at the central, intermediate, and lower levels of the health care system. Additionally, where local providers are used as a key source of information, the consultant should seek opinion/insight from all cadres; the experience of nurses, auxiliary health professionals, and laboratory technicians, for example, should be meaningfully considered when assessing actual practices and program implementation at the facility level.

Tips

Recording

The tool allows you to write down answers directly on the pages of a hard copy, or to input the information electronically using the Word version of the tool. In either case, it is recommended that each member of the team records answers as you go along, so that all information can be compiled at the end of the day and any discrepancies in data can be noted and resolved before the end of the mission.

Key informant interviews

Interviews with TB program staff are an important source of information. Organize the interviews in such a way that all questions for which you would like a specific informant's input are anticipated ahead of time to make the most efficient use of each person's valuable time. For example, if there are national-level staff who cover multiple areas related to the Stop TB Strategy components, ensure that all sections that need to be included in the interview are marked ahead of time.

Scoring

Throughout Part 2, most questions have the option of a partial score; users should avoid adding a partial ("in-between") score unless local circumstances truly lend themselves to a partial score. For example, where NTPs have drafted but not finalized key guidelines, a partial score may be appropriate. In such cases, the reason for the partial score should be documented in the *Data source/Comments* section for that question AND the consultant should document the time frame for actions that would result in a full score and recommend follow-up on these items with the NTP as part of the final report.

Assessment of NTP policies, guidelines, and practices

Throughout the tool, there are a number of questions related to national policies, guidelines, and practices with respect to DOTS program implementation and management of MDR/XDR-TB. During site visits, actual practice should be assessed to ensure that NTP guidelines are followed. For example, if NTP guidelines stipulate that all doses are recorded on an individual treatment card, verify that providers are recording doses correctly.

Some questions ask whether or not national guidelines are based on internationally recommended strategies or WHO recommendations. In addition, some questions may ask the user to differentiate between development and implementation of policies. For example, many of the scored questions are structured such that a full score should be considered only if an internationally recommended policy is in place and there is evidence that it is implemented, while a partial score is appropriate if the policy is in place but not yet widely implemented. In some settings, policy development and/or endorsement will be a formidable task requiring much more effort than the translation or dissemination of the policy, whereas in other settings endorsement of international guidelines may not be as cumbersome, but dissemination and promotion of the policy may require resources beyond the country's current capacity. The user's first-hand knowledge of NTP practices will be very important in making these distinctions, which should be noted in the *Data source/Comments* column that appears for each question. Any additional descriptive information you can provide in the comments section will be helpful in interpreting the results of the assessment and preparing the final report. For example, if national guidelines are not in line with internationally recommended standards, this is an overarching issue that needs to be addressed beyond whether or not the national guidelines are implemented.

Definitions

MDR-TB

A case of TB with bacteriologically confirmed resistance to at least isoniazid and rifampicin.

XDR-TB

A case of TB with bacteriologically confirmed resistance to at least isoniazid and rifampicin (among the first-line anti-TB drugs) plus resistance to any fluoroquinolone and at least one second-line injectable anti-TB drug (amikacin, capreomycin, or kanamycin).

Case detection and treatment outcomes

Standard case detection and treatment outcome definitions for MDR-TB can be found in Appendix 1. However, NTPs may have adapted these definitions, for example, by defining treatment cohorts according to their own guidelines related to MDR/XDR-TB diagnosis and treatment. Similarly, NTPs may have adapted the standard definition for a chronic TB case. Where local adaptations differ from those found in the Appendix, document the NTP definition to facilitate data interpretation. Lastly, given the ongoing development of guidelines such as MDR/XDR-TB treatment protocols and second-line drug susceptibility testing, users should consult the WHO website and working groups related to MDR/XDR-TB and update the definitions in Appendix 1 accordingly.

PART 1: National MDR/XDR-TB Situation Analysis

Question 1:

Are there high-priority gaps in the DOTS program that should be corrected to prevent the development of cases of MDR-TB?

Country Snapshot

Instructions: This information should be abstracted from the most recent *WHO Global TB Report* and used as a reference point as you proceed through the assessment. Additionally, the tool can be used to gather sub-national data. In this case, one copy should be reserved for the national data, and additional copies can be made to record individual sub-national–level results for input to the national summary. There may be discrepancies among the data from different regions, in which case it will be necessary for the user to interpret the data. The final version of the data should always be prepared in collaboration with national authorities. Lastly, if data are available by age group, gender, treatment modality (facility-based vs. community-based) or other key variables, any key details or unusual findings related to these variables can be recorded and discussed in this section.

(Use the latest year for which data are available. Often data may come from different years, in which case the year should be indicated for the individual cells.)

	Value		Data Year/Source
Total population			
DOTS coverage (%)†			
Estimated case detection rate			
TB case notification (new SS+ cases)*	Number	Rate	
TB case notification (all reported cases)*	Number	Rate	
Estimated TB prevalence (all cases)*°			
Absolute number and case notification rate, confirmed MDR-TB cases* (never previously treated > 1 month)	Number	Rate	
Absolute number and case notification rate, confirmed MDR-TB cases (previously treated > 1 month)	Number	Rate	
Estimated HIV prevalence (% of population ages 15 to 49 years old)			
Estimated prevalence of HIV infection among all new TB cases (%)			

† DOTS coverage is measured by dividing the population of districts/oblasts/regions that have adopted the DOTS strategy by the total population of the country (*Global Tuberculosis Control 2008: Surveillance, Planning, and Financing*). This is a gross estimate of the availability/coverage of key services that constitute DOTS; specific gaps in the coverage of DOTS services should be noted in the comments section.

*Estimated incidence, prevalence, and actual case notification to be reported as both absolute numbers and rate per 100,000 population.

° Indicate if the estimate used for prevalence is from WHO or NTP.

___ Data not available

Comments:

TB Treatment Outcome Data

Instructions:
Fill in the following data in order to complete the scoring table below and to provide information for the final report or plan. In many cases, not all data will be available. Use the best available data (e.g., for sub-regions or specific institutions if national-level data are not available) and use the comments section to provide specific details. If for some reason cohort data are not available in annual increments, please revise and specify which increment you are using (quarter, month, etc.). Lastly, document the definition for **chronic TB** used by the local program in Section 2 (treatment outcomes among all retreatment cases).

1. For the last three annual treatment cohorts (insert years), the treatment outcomes among all **new smear positive cases** were as follows:

Outcome	Year 1 ( )		Year 2 ( )		Year 3 ( )	
	#	%	#	%	#	%
Treatment success						
Cured						
Completed treatment						
Failed						
Defaulted						
Died						
Transferred out						
Not evaluated						
Total New SS+ Cases						

___ Data not available

Comments:

2. For the last three annual cohorts (insert years), the treatment outcomes among all **retreatment cases**[1] were as follows:

Outcome	Year 1 ( )		Year 2 ( )		Year 3 ( )	
	#	%	#	%	#	%
Treatment success						
Cured						
Completed treatment						
Failed						
Defaulted						
Died						
Transferred out						
Not evaluated						
Total Retreatment Cases						
Number of chronic cases*						

***** Document NTP definition for chronic cases—which cases are designated "chronic" in a retreatment cohort?

___ Data not available

Comments:

[1] For countries where only SS+ cases are classified as retreatment, use data on SS+/C+ or SS+.

Scoring of Data

Instructions: Choose the answer that best fits the local scenario and check the corresponding score; document any critical gaps associated with the indicator. Add the scores for the indicators that appear in the table to produce an overall section score.

Question	Answer	Score *(check)*	Identified gaps/comments
What percent of the country's population is estimated by the NTP to be covered by DOTS services?	100%	( ) 8	
	>80%	( ) 4	
	<80%	( ) 2	
	Unknown	( ) 0	
What is the estimated case detection rate?	>70%	( ) 8	
	50-70%	( ) 4	
	<50%	( ) 0	
For the latest available annual cohort, what proportion of all new SS+ cases defaulted?	<5%	( ) 8	
	5-10%	( ) 4	
	>10%	( ) 0	
For the latest available annual cohort, what proportion of all new SS+ cases failed?	≤1%	( ) 10	
	1-2%	( ) 7	
	2-4%	( ) 4	
	>4%	( ) 0	

Question	Answer	Score *(check)*	Identified gaps/comments
For the latest available annual cohort, what proportion of all retreatment cases defaulted?	<5%	( ) 8	
	5-10%	( ) 4	
	>10%	( ) 0	
For the latest available annual cohort, what proportion of all retreatment cases failed?	≤1%	( ) 8	
	1-5%	( ) 4	
	>5%	( ) 0	

* If available, it is recommended to analyze the outcomes of relapses, failures, and defaulters separately; analysis by regimen category (II or IV) is also recommended.

Section score:	Possible interpretation:	33-50	No major gaps; individual indicators needed to improve
		16-32	Some critical gaps needing action
		<16	Major gaps

Brief Data Interpretation Summary

Instructions: Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps. This will help guide the more detailed assessments that will follow in Part 2.

Areas of Strength:

Issues of Concern:

Question 2:

What high-priority areas should be addressed to improve diagnosis and treatment of MDR/XDR-TB?

Instructions: Throughout this section, all data refer to bacteriologically confirmed MDR-TB cases (smear and culture), given that some patients can be smear-negative. Consult the 2008 version of *Anti-Tuberculosis Drug Resistance in the World: Report No. 4*, available at: http://www.who.int/tb/features_archive/drsreport_launch_26feb08/en/index.html for additional information to supplement what is available in-country. Standard MDR-TB cohort analysis should be performed on all MDR-TB cases that are registered during a given quarter; however, there may be some countries where patients who do not initiate treatment are not included in the treatment outcome data (e.g., MDR-TB cases who die or default before starting treatment). Document local practices with regard to cohort analysis and determine the extent to which outcome data may not include deaths or primary default prior to initiating treatment. Lastly, the user should document NTP capacity to diagnose MDR-TB and chronic cases or failures as key background information for interpreting the results of this section of the tool.

Drug Resistance Data

1. **If a drug-resistance survey has been performed, list the results:** ***(If multiple surveys have been done, copy the table and add results from the two most recent surveys.)***

Instructions: Fill in the following data in order to complete the scoring table below and to provide information for the final report or plan. Use the best available data—national data may not be available, in which case regional surveys or other published studies may yield some useful information. If data are not available, reliable, or representative, consider recommending additional studies (e.g., DRS). If available, include detailed DRS results with specific resistance patterns. See Part 2, Component 2 for more detail; some of the data needed to complete scored and unscored questions should be available in this section if drug-resistance data are not available.

Year of DRS: _____	Total tested	Any drug resistance		MDR-TB		XDR-TB*	
	#	#	%	#	%	#	%
New cases							
Retreatment cases							

*Calculated as % of MDR cases

___ Data not available

Additional questions:

1. When was the first DRS performed in the country? If multiple surveys have been performed, is drug resistance increasing or decreasing?

2. How many DRS have been performed? At what level was the DRS performed (national, regional, specific city, etc.)?

3. Briefly describe the protocol used for each DRS. Is there any information about the quality of the survey procedures? If so, please summarize any documented concerns.

4. Briefly summarize the sampling procedures for the most recent DRS. Are there any concerns about the sampling procedures that compromise the results of the survey? If possible, estimate the proportion of new TB cases that were notified during the study period that were included in the DRS.

5. Are there any planned activities based on the DRS results? If yes, please describe in the space below:

Comments:

2. MDR-TB treatment coverage

Instructions: This indicator is difficult to measure. Adequate and appropriate treatment is defined as treatment that meets current international guidance. The answer here will depend on whether or not the country uses individualized, empirical, or standardized treatment according to internationally recognized guidelines. For example, if the NTP is using an individualized treatment strategy, there should be adequate capacity for first-line DST, and treatment decisions should be made in collaboration with MDR-TB experts. If standardized regimens are in use, they should be formulated according to WHO guidelines for standardized treatment of MDR-TB. In some countries, cases may be diagnosed but drugs may not be available to treat all patients, or patients may be receiving regimens that are not recommended. Use the comments section below to elaborate on the situation in the country.

Coverage	Year 1 ( )	Year 2 ( )	Year 3 ( )
Number and proportion of all confirmed MDR-TB cases diagnosed that were started on adequate and appropriate treatment			
Number of all confirmed MDR-TB cases being treated under GLC projects			

___ Data not available

Additional questions:

1. Has the country submitted an application(s) to the GLC?

2. Are there approved GLC projects being implemented? What is the current status of these efforts?

Comments:

3. HIV prevalence among the last three annual cohorts of MDR-TB cases*

HIV prevalence	Year 1 ( )	Year 2 ( )	Year 3 ( )
Proportion of all confirmed MDR-TB cases tested for HIV			
Proportion of all confirmed MDR-TB cases tested for HIV with HIV-positive test result			

*Specify local cohort definition for the purpose of HIV testing among MDR-TB cases (e.g., diagnostic cohort, treatment cohort—see Appendix 1).

___ Data not available

Comments:

4. For the last three annual treatment cohorts (insert years), the treatment outcomes for all bacteriologically confirmed MDR-TB patients were as follows:

Instructions: Annual treatment cohort refers to the group of confirmed MDR-TB patients who began treatment in the same calendar year and for which final outcomes are available; interim outcomes should not be reported here. These data will be difficult to locate but where available, they should be used to complete the chart. Interim outcomes for cohorts that have started but not completed treatment should not be included here.

	Year 1 ( )		Year 2 ( )		Year 3 ( )	
Outcome	**#**	**%**	**#**	**%**	**#**	**%**
Treatment success						
Cured						
Completed treatment						
Failed						
Defaulted						
Died						
Transferred out						
Not evaluated						
Still on treatment						
Total MDR-TB Cases						

___ Data not available

Comments:

5. HIV prevalence among the last three annual diagnostic cohorts of XDR-TB cases

HIV prevalence	Year 1 ( )	Year 2 ( )	Year 3 ( )
Proportion of all confirmed XDR-TB cases tested for HIV			
Proportion of all confirmed XDR-TB cases tested for HIV with HIV-positive test result			

*Specify local cohort definition for the purpose of HIV testing among MDR-TB cases (e.g., diagnostic cohort, treatment cohort).

___ Data not available

Comments:

6. For the most recent annual treatment cohorts for which outcome data are available (insert year), the treatment outcomes* for bacteriologically confirmed XDR-TB patients were as follows:

	Year ( )		Year ( )		Year ( )	
Outcome	#	%	#	%	#	%
Treatment success						
Cured						
Completed treatment						
Failed						
Defaulted						
Died						
Transferred out						
Not evaluated						
Continuing treatment < 24 months						
Continuing treatment >24 months						
Total XDR-TB Cases						

*Specify national adaptation of treatment outcomes where different from those that appear in the table.

___ Data not available

Comments:

Scoring of Drug-Resistance Data

Instructions: Choose the answer that best fits the local scenario and circle the corresponding score; document any critical known gaps associated with the indicator. Add the scores for the indicators that appear in the table to produce an overall section score. MDR-TB incidence calculations should include only those with bacteriological confirmation. Relapses without bacteriological confirmation should NOT be included in the numerator. Additional questions related to availability of culture and other laboratory issues are found in Part 2, under Component 1B.

Question	Answer	Score *(check)*	Identified gaps/comments
What proportion of the total population has access to MDR-TB treatment consistent with current international standards?	>80%	( ) 10	
	40–80%	( ) 5	
	<40%	( ) 0	
What percent of the country's new pulmonary SS+ cases from the most recent cohort were MDR-TB, based on existing surveillance/survey data?	<2%	( ) 10	
	2-5%	( ) 5	
	>5% or not known	( ) 0	
What percent of the country's retreatment cases from the most recent cohort were MDR-TB?	<7%	( ) 10	
	7-15%	( ) 5	
	>15% or not known	( ) 0	
For the latest available MDR-TB cohort, what proportion of all MDR-TB cases achieved treatment success?	≥60%	( ) 8	
	40-59%	( ) 4	
	<40%	( ) 0	

Section score:	Possible interpretation:	25-38	No major gaps; individual indicators needed to improve
		12-24	Some critical gaps needing action
		<12	Major gaps

Brief Data Interpretation Summary

Instructions: Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps. This will help guide the more detailed assessments that will follow in Part 2. The results of this section should be considered in the context of the availability and quality of DST services as assessed in Part 2; the final report should integrate the results of these two sections in the discussion and consider both sections in the overall recommendations.

Areas of Strength:

Issues of Concern:

PART 2: Gap Analysis by Stop TB Strategy component

Component 1: Pursue high-quality DOTS expansion and enhancement

A) Political commitment with increased and sustained financing

Scored questions

Instructions: This section includes questions to assess the level of political commitment to TB at the national and where applicable, sub-national level. Political commitment to TB control is difficult to measure quantitatively; however, there are key elements of political commitment that should be in place in order to maintain high-level policy, financial, and institutional support for TB programming. The following scored and unscored questions are aimed at assessing the extent to which political, financial, and institutional support is available and interpretation of the results should focus on the balance of political commitment in these three areas and gaps within each area. For further detail on measurement of political commitment and possible interpretation, see pages 78-102 of the *Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs*, available at http://www.stoptb.org/wg/advocacy_communication/assets/documents/Compendium%20of%20Indicators%20for%20Monitoring%20and%20Evaluating%20NTP.pdf.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
1. Has TB been declared an emergency in the country or is it a stated priority of the MOH?	**1a. Yes** (The country has declared TB an emergency and/or has stated that TB is a priority for the MOH.)	( ) 8			
	1b. No (The country has not taken this action.)	( ) 0			

2. Is there a specific budget for TB control at the national level?	**2a. Yes** (There are no funding gaps; all elements of the strategy are funded.)	( ) 10			
	2b. Yes, minor gaps identified (No immediate danger for the functionality of the program, but possible future problems [e.g., key areas exclusively or in large part are funded by external sources].)	( ) 5			
	2c. No, major funding gaps identified (Immediate danger for the functionality of the program [e.g., all drugs funded by GFATM with risk of funding delay and consequent stockout].)	( ) 0			
3. Within the national TB budget, what has been the funding trend for TB control for the last five years?	**3a. Increasing** (Trend is increasing or is sufficient to fund all elements of the Stop TB Strategy, or has been maintained at the level of the previous years.)	( ) 8			
	3b. Stable (No changes from previous year in a situation when the budget has minor or major funding gaps as defined in the previous question.)	( ) 4			
	3c. Decreasing (Trend is decreasing in a situation when the budget has minor or major funding gaps as defined in the previous question.)	( ) 0			

4. Is there a well-defined NTP with authority to make decisions?	**4a. Yes** (No gaps identified; NTP is within the MOH with capacity to make decisions.)	( ) 8			
	4b. Yes, NTP defined but with weak capacity to make decisions (Sub-optimal program leadership/management, lack of capacity to make decisions.)	( ) 4			
	4c. No (There is no defined NTP at the MOH level; serious leadership/management problems.)	( ) 0			
5. Is there an adequately staffed Central Unit within the NTP?	**5a. Yes** (NTP Central Unit is adequately staffed with qualified personnel to ensure that all program activities are effectively managed given the TB burden and the specific problems the country is facing.)	( ) 8			
	5b. Yes, partial (Some positions unfilled, capacity is weak, and/or not there is enough staff time to perform sub-national supervision.)	( ) 4			
	5c. No (NTP Central Unit is considered understaffed by the MOH, external reviews, and the consultant's opinion.)	( ) 0			

Section score:	Possible interpretation:	24-42	No major gaps; individual actions needed to improve
		16-23	Some critical gaps needing action
		≤15	Major gaps at political commitment level

Unscored questions to inform recommendations
1. What proportion of the NTP budget is funded? Is there specific funding for MDR/XDR-TB activities? Are there gaps?
2. What proportion of the total TB control budget is provided by government, including loans?
3. Is there a national TB policy? Is it consistent with the Stop TB Strategy?
4. Is there a national ACSM strategy? Does it include specific activities regarding MDR/XDR-TB?
5. What sources of external funding does the country receive for TB control (e.g., GFATM, World Bank, bilateral)?
6. Is the total amount listed in the NTP budget actually available for the program (have the funds been transferred to the program)?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to political commitment.

Areas of Strength:

Issues of Concern:

(Component 1: Pursue high-quality DOTS expansion and enhancement continued)

B) Case detection through quality-assured bacteriology

Scored questions

Instructions: This section includes questions to assess the overall capacity of the laboratory network to provide minimum services necessary to support DOTS and diagnosis of MDR/XDR-TB. At a minimum, users should visit the NRL and at least one sub-national laboratory at each level of the periphery (e.g., regional, district, and facility) in order to assess how well the overall network is functioning. Specific issues such as availability of specimen transport and timely return of test results should be described at each level. Given the ongoing introduction of new diagnostic tools throughout the world, the user should assess the degree to which new tools for rapid culture and DST have been implemented and if not, whether there are plans to introduce such methods. In many settings, lack of laboratory capacity will be a major issue. In other settings, there may be too many labs performing culture with inadequate QA and infection control. While there may be "adequate coverage and distribution" in terms of numbers and geographic location, the quality of services may be quite weak. In this context, briefly summarize the situation in the comments section.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
1. Is the laboratory network well organized and functional at all levels?	**1a. Yes** (Tasks assigned to central, intermediate, and peripheral-level labs by national guidelines are performed correctly and are consistent with international WHO, IUATLD, and *International Standards for TB Care* (ISTC) recommendations.)	( ) 10			
	1b. Yes, minor gaps (i.e., not sufficiently important to compromise the functioning of the laboratory network. Each specimen has a reasonable probability of bacteriological evaluation according to international recommendations as noted above.)	( ) 5			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
	1c. No, major gaps exist (Major gaps identified; laboratory network does not function according to international recommendations. As a consequence, a given proportion of specimens are subjected to to sub-standard laboratory evaluation.)	( ) 0			
2. Is DST routinely performed for first-line drugs at the NRL (or regional reference laboratory, if appropriate) according to national guidelines?	**2a. Yes** (NRL performs DST for first-line drugs according to national guidelines.)	( ) 8			
	2b. Yes, irregularly (DST for first-line drugs is performed irregularly or in a sub-optimal way due to lack of funds, technical, and/or other problems.)	( ) 4			
	2c. No (DST for first-line drugs is not performed. If national guidelines do not exist, the score is 0.)	( ) 0			
3. Is DST performed for second-line drugs as a routine at NRL (or regional reference laboratory, if appropriate) according to national guidelines? *Note: Check which second-line drugs are recommended by WHO (guidelines are finalized) against those being tested and actually used.*	**3a. Yes** (NRL routinely performs DST for second-line drugs according to national guidelines.)	( ) 6			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
	3b. Yes, irregularly (DST for second-line drugs performed irregularly or in a sub-optimal way due to lack of funds, technical and/or other problems [including when the laboratory only performs testing for some of the second-line drugs or tests others than those recommended].)	( ) 3			
	3c. No (DST for second-line drugs not performed. If national guidelines do not exist, the score is 0.)	( ) 0			
4. Is the NRL quality-controlled by a supranational reference laboratory (SRL)?	**4a. Yes** (An SRL performs EQA and results are available [see below].)	( ) 10			
	4b. Yes, but first results are not yet available (EQA is in process and results are not yet available.)	( ) 5			
	4c. No (No SRL has been selected for EQA or no EQA has been performed.)	( ) 0			
5. What was the agreement with the SRL on DST for first-line drugs last year?	**5a. >80%** (An SRL performs EQA and agreement is greater than 80% for the key parameters [reproducibility, positive predictive value of resistant and susceptible test, etc.] on all drugs.)	( ) 8			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
	5b. < 80% (SRL performs EQA and agreement is less than 80% for at least one of the key parameters [reproducibility, positive predictive value of resistant and susceptible test, etc.] for at least one drug.)	( ) 4			
	5c. EQA not done (If EQA is in process or not done the score is 0. All information on the agreement between the SRL and the NRL should be collected.)	( ) 0			
6. What is the coverage of DST services (taking into consideration the number and location of the culture laboratories and national guidelines)? *Note: Coverage includes geographic distribution of DST facilities and existence of a referral system to allow for timely transport of specimens requiring culture and/or DST to the NRL or other facilities, etc.*	**6a. At or near 100%** (The real population coverage is almost 100%.)	( ) 8			
	6b. Estimated at >80% (The real population coverage is greater than 80%, taking into account factors such as incomplete expansion, distance from the NRL, absence of a sufficient number of DST laboratories, difficulties involving the private sector, insufficient referral mechanism, etc.)	( ) 4			
	6c. Estimated at <80% (Same but less than 80%.)	( ) 0			

Section score:	Possible interpretation:	30-50	No major gaps; individual actions needed to improve
		16-29	Some critical gaps needing action
		≤15	Major gaps at quality assured bacteriology level

Unscored questions to inform recommendations
1. What is the proportion of retreatment, pulmonary SS-, and extrapulmonary TB cases among incident cases? If available, what is the proportion of chronics among prevalent cases? Are these proportions consistent with what one expects, given local epidemiology?
2. What is the turnaround time for culture and DST results? What methods and equipment are currently being used (e.g., solid, liquid media, etc.)? Are there plans to introduce new diagnostic technologies? Which ones?
3. How many DSTs are performed per quarter at the NRL? At other labs? What proportion of isolates show resistance to the tested drugs?
4. Which second-line drugs are tested within the DST performed at the NRL?
5. Are SOPs for DST available at the NRL?
6. Are national guidelines for infection control available and correctly implemented at the NRL?

7. Is there adequate coverage to perform culture nationwide (taking into consideration number and location of the culture laboratories)?
8. Are laboratories other than the NRL performing DST for first- or second-line drugs? How are they hierarchically linked to the NRL? Do they participate in a regular EQA system?
9. How many staff have been trained to perform culture and DST and what is their geographic distribution?
10. Are private-sector laboratories involved in TB diagnosis? How and to what extent?
11. Proportion of SS+ cases confirmed by culture from the last annual diagnostic cohort with data available. Is the information available?
12. Proportion of SS+ cases from the last cohort with data available with DST performed. Is the information available?

13. Is laboratory and infection control equipment maintained according to a written plan? Are there barriers to adequate equipment maintenance?
14. Are there policies on obtaining DST for TB cases? For which cases is DST recommended? (For example, does the country prioritize Category 2 failures, contacts to MDR cases, Category 1 failures at five months or those who are smear positive at two months, etc., per Chapter 5 of the 2006 WHO *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis*.)

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to TB diagnosis through quality-assured bacteriology.

Areas of Strength:

Issues of Concern:

(Component 1: Pursue high-quality DOTS expansion and enhancement continued)

C) Standard treatment, with supervision and patient support

Scored questions

Instructions: This section includes questions related to the management of TB cases in terms of which medications are in use and how patients are monitored from initiation of treatment until a final treatment outcome is assigned, including implementation of DOT and use of facility- vs. community-based models of care. Users should record standard regimens for Category I, II, and III patients in the Data source/Comments section of Question 1 and verify information gathered at the national level with a review of patient records at the site level, for example, by looking to see whether or not drugs prescribed and dosages are appropriate for a subset of patients. In addition to assessing the national guidelines for treatment supervision, observe and ask about how DOT is implemented in practice during a site visit. For scored questions, do not use the patient interview/report as a source of data; this information should be available in patient records and/or the treatment register. Lastly, request information for the unscored questions from a variety of providers representative of all cadres that supervise and support patients, including doctors, nurses, nursing assistants, social workers, community-level treatment supporters, and any other type of health worker that works in this area.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
1. Are treatment regimens used (e.g., Category I, II, III) consistent with international recommendations? (*Record specific regimens in the Data source/Comments column. User should assess regimens as they appear in national policy/guidelines, and where possible, examine a sample of patient records or observe which drugs are available in facilities to verify whether or not correct regimens are in use*.)	**1a. Yes** (Standard treatment regimens are consistent with international recommendations in terms of drug selection, dose, duration, RMP given under DOT, etc.)	( ) 10			
	1b. Yes, minor inconsistencies (Minor inconsistencies are observed [i.e., drug and dose selection mistakes are sporadic or RMP-containing regimens are given without DOT].)	( ) 5			
	1c. No, major inconsistencies (Major inconsistencies are observed [e.g., the problem is generalized/ systematic and might pose risk of further development of drug resistance].)	( ) 0			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
2. Are fixed-dose combination (FDC) first-line drugs used for treatment?	**2a. Yes** (FDCs are available and used according to national guidelines in all units.)	( ) 8			
	2b. Yes, but in a limited number of facilities (FDCs are mentioned in the national guidelines but they are available in some units only [e.g., in the capital city or region, or in large hospitals only].)	( ) 4			
	2c. No (FDCs are not mentioned in the national guidelines and are used only in some units; they are not available on a routine basis.)	( ) 0			
3. Is adherence assessed systematically through DOT and recording and reporting of observation? (*Clarify policy regarding DOT and recording and reporting at the national level; where possible, review of individual patient cards is necessary to answer this question.)*	**3a. Yes** (National guidelines indicate that chart review is used to verify that at least 80% of doses are observed for the duration of treatment.)	( ) 8			
	3b. Yes, partial (Routine verification of DOT not done or only done for intensive phase.)	( ) 4			
	3c. **No** (Adherence not assessed at all or not systematically, even during the intensive phase.)	( ) 0			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/Comments
4. Is there a system to retrieve patients who have not collected their medication or presented to the health facility when required, based on home visits or other initiatives? (Describe by whom, when, and how.)	**4a. Yes** (Default tracing is done systematically through staff, community care, or other strategies and described in the national guidelines.)	( ) 8			
	4b. Yes, but not systematically applied (Default tracing is done through staff, community care, or other strategies, but not systematically. In some areas it works better than others.)	( ) 4			
	4c. No (The program does not have this capacity. If national guidelines do not exist, the score is 0.)	( ) 0			

Section score:	Possible interpretation:	16-34	No major gaps; individual actions needed to improve
		11-15	Some critical gaps needing action
		≤10	Major gaps at treatment delivery process level

Unscored questions to inform recommendations
1. At what level and in what facilities are TB cases diagnosed, treated, and reported (e.g., primary–health-facility level, specialized facilities, provincial level only, etc.)?

2. How is treatment monitoring organized?
3. Who provides DOT? Is it based in facilities, or are there home visits by health workers and/or community-based DOT activities? How many times per week is DOT done (during intensive and continuation phase of treatment)? Are incentives or enablers used to support patients in completing treatment? Is any other support provided?
4. Is it possible to estimate the proportion of SS+ cases that are managed under DOT for the entire duration of treatment?
5. Are there specific policies and protocols for the treatment of failures, relapses, and retreatment cases? Are they in line with international recommendations?
6. Is it possible to estimate which proportion of patients are given FDC versus separate drugs? If so, what is the proportion of patients that are given FDC versus separate drugs? Are there policies for use of FDCs? Which patients are provided FDCs?
7. What specific challenges related to MDR/XDR-TB does the NTP face in terms of vulnerable populations (e.g., mobile populations, illegal immigrants, socially marginalized groups) and what actions have been taken to address these challenges?

8. Are there situational or environmental conditions that may pose barriers to diagnosis and treatment completion, such as conflicts, natural disasters, or geographic barriers? Have other barriers to treatment adherence been assessed in the local context (e.g., homelessness, substance abuse) and if so, what are the key issues?
9. What human resources are active in providing TB control services (quantity, cadre, geographic distribution)?
10. Is there a process for prompt identification and follow-up of patients who miss appointments? Specifically, is there an appointment/attendance register, a person who is tasked with contacting patients who miss appointments, and is transport available to support this activity?
11. What is the process for training and supervising treatment supporters? Are there formal home visits to the patient to introduce him/her to the treatment supporter? Is there any training/orientation for treatment supporters and patients?
12. Is there a formal patient transfer system in place with paper and telephone communication to facilitate reporting?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to TB treatment.

Areas of Strength:

Issues of Concern :

(Component 1: Pursue high-quality DOTS expansion and enhancement continued)

D) An effective drug supply and management system

Scored questions

Instructions: This section includes questions related to procurement, distribution, and prescription of drugs by the NTP and related authorities. Assessment of the drug supply and management system should include a key informant interview with the senior drug supply manager at the national level, and where possible, a visit to the medical stores department. Additionally, drug supply and procurement concerns should be documented at each level of the health system, and the first- and second-line drugs in use should be verified at the most peripheral level of the DOTS program.

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/Comments
1. In the past 12 months, were there any stockouts of first-line drugs?	**1a. No** (No stockouts identified in the last 12 months.)	( ) 10			
	1b. Yes, minor problems (No major stockouts identified in the last 12 months; minor stockouts limited to individual peripheral units and were of short duration [≤1 week]. The system was able to organise emergency supply; no patients were denied treatment due to stockout.)	( ) 5			

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/Comments
	1c. Yes, major problems (Major stockout[s] identified with resulting treatment interruptions. Stockout was at central level and/or affected one or more peripheral areas and emergency supply was not immediately available. A given number of patients were denied treatment or were referred to the private sector.)	( ) 0			
2. Are adequate supplies of second-line drugs (for approved treatment regimens) available to treat all MDR-TB cases?	**2a. Yes** (No stockouts identified in the last 12 months.)	( ) 10			
	2b. Yes, minor problems (No major stockouts identified in the last 12 months; minor stockouts limited to individual peripheral units and were of short duration. The system was able to organize emergency supply; no patients were denied drugs due to a stockout.)	( ) 5			
	2c. No, major problems (No second-line drug program exists; or if program exists, major stockout[s] identified. Stockout was at central level and/or affected one or more peripheral areas and emergency supply was not immediately available. A given number of patients were denied drugs or were referred to the private sector due to a stockout in the public sector.)	( ) 0			

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/Comments
3. Is there a national policy that promotes procurement of quality-assured medicines in accordance with international standards?	**3a. Yes** (Internationally recommended drug-quality specifications are in procurement documents; procurement from quality-assured international sources is allowed [e.g., GDF, GLC].)	( ) 10			
	3b. No (By law, country must procure only the cheapest medicines; direct procurement from quality-assured international sources is not allowed.)	( ) 0			
4. Are first-line drugs available on a regular basis outside the NTP system (e.g., through private pharmacies)?	**4a. No** (Country policy restricts use of first-line drugs to the NTP.)	( ) 8			
	4b. Yes, by prescription only (Country policy allows free use of first-line drugs outside the NTP system, by prescription only.)	( ) 4			
	4c. Yes, no prescription required (No country policy to regulate distribution of first-line drugs in pharmacies, or existing policy is not enforced.)	( ) 0			
5. Is there evidence that private pharmacies sell fluoroquinolones to TB patients?	**5a. No** (Country policy prohibits the sale of fluoroquinolones to TB patients by private pharmacies.)	( ) 6			

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/Comments
	5b. Yes by prescription only (TB patients can obtain fluoroquinolones by prescription only.)	( ) 3			
	5c. Yes, no prescription required (No country policy to prohibit the distribution of fluoroquinolones in pharmacies, or existing policy is not enforced.)	( ) 0			

Section score:	Possible interpretation:	23-44	No major gaps; individual actions needed to improve
		11-22	Some critical gaps needing action
		≤10	Major gaps at drug management level

Unscored questions to inform recommendations
1. Is there a consistent and detailed national budget for drugs and laboratory supplies?
2. Is there a special unit/trained staff ensuring efficient drug and laboratory supplies procurement at the MOH or NTP level?
3. How is procurement conducted?

4. What first- and second-line drugs are procured for TB treatment? What quantities of each? What second-line drugs have been used in the past, if different? Is linezolid in use in this country?
5. Are second-line drugs procured through the GLC and/or the GDF?
6. Which drugs, if any, are manufactured in-country? (First- and second-line.) Are they quality controlled?
7. What is the drug quality-assurance process? Have low-quality, expired, or otherwise damaged drugs been documented in more than one location in the country, either inside or outside the NTP system?
8. Where and how are drugs stored at central, provincial, and peripheral levels? (Suggest doing a visit to the central medical stores.)
9. How is drug distribution done—responsibility, frequency, etc. (for first- and second-line drugs)?

10. Is there a system for monitoring supplier performance?
11. What medicines that can be used in second-line treatment are registered and available in the country?
12. Is pipeline data readily available at the NTP?
13. Is there systematic monitoring of MDR/XDR-TB patients for adverse effects? Are medicines required for the treatment of TB drugs' adverse events available? How are they selected and procured? What is the budget for these medications?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to TB drug supply management.

Areas of Strength:

Issues of Concern:

(Component 1: Pursue high-quality DOTS expansion and enhancement)

E) Monitoring & evaluation system, and impact measurement

Scored questions

Instructions: This section includes questions related to the monitoring and evaluation capacity of the NTP and the availability of data on MDR/XDR-TB and TB/HIV. Assessment of M&E systems should include a key informant interview with the senior data manager at the national level and observation of registers at all levels of the reporting and recording system. Where electronic recording and reporting systems are used to generate routine case detection and treatment outcomes, the user should request a demonstration of the system at each level visited during the assessment. Issues of data quality, analysis, and feedback should be documented at each level of the recording and reporting system.

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/ Comments
1. Is systematic supervision and monitoring performed from national to provincial and from provincial to local levels according to a national M&E plan? Is it used to improve performance?	**1a. Yes** (Yes, supervision and monitoring activities are conducted according to the national M&E plan, documented, and used to improve performance.)	( ) 8			
	1b. Yes, minor problems (Supervision and monitoring activities are conducted according to the national M&E plan in some geographical areas or time periods, for different reasons [e.g., lack of funding, insufficient HR, poor planning, etc.]. There is little evidence that results are used to improve performance.)	( ) 4			
	1c. No, major problems (Supervision and monitoring activities are irregular. Implementation of the M&E plan is at risk. If there is no plan, score is 0.)	( ) 0			

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/ Comments
2. Are routine data on MDR/XDR-TB and TB/HIV available through the NTP surveillance system?	**2a. Yes** (Yes, these data are routinely reported through the NTP surveillance system.)	( ) 8			
	2b. Yes, partial (For example, routine data available for TB/HIV indicators; MDR/XDR TB data not routinely available.)	( ) 4			
	2c. No (No, these indicators are not routinely reported through the NTP surveillance system.)	( ) 0			

Section score:	Possible interpretation:	13-16	No major gaps; individual actions needed to improve
		8-12	Some critical gaps needing action
		≤7	Major gaps at M&E level

Unscored questions to inform recommendations
1. Is there a central unit (in or outside the NTP) assigned the responsibility for collecting and reporting TB data from the peripheral to the central level? What is the frequency of reporting to the national level?
2. What routine practices are in place to ensure data quality? Are district-, regional-, and national-level data managers trained on data quality; are data routinely checked at each level; and is missing data prioritized for follow-up?
3. Are data analyzed at the national level and used to improve program performance? Is there evidence of data analysis and use at the sub-national level?

4. Is an electronic R&R system in place? Is it based on individual data or aggregated data? Are basic WHO forms used nationwide or in some territories only? Are there any key variables missing or collected but not analyzed?
5. If monitoring is not done systematically, why not? (Lack of funding? Lack of HR? Poor planning?)
6. Has the NTP conducted a prevalence survey in the past five years or is there a prevalence survey planned in the next two years?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to TB control program monitoring and evaluation.

Areas of Strength:

Issues of Concern:

Overall Score for Component 1:

Maximum component score for DOTS implementation (A+B+C+D+E): 186			
Overall Component 1 score:	**Possible interpretation:**	102-186	No major gaps; individual actions needed to improve
		58-101	Some critical gaps needing action
		≤57	Major gaps at Stop TB Strategy/DOTS implementation level

Additional Comments:

Component 2: Address TB/HIV, MDR-TB, and other challenges

Scored questions

Instructions: This section includes many questions aimed at gaining a broad understanding of the extent to which the country or sub-national unit has the capacity to address TB/HIV, MDR-TB, and other challenges described in the Stop TB Strategy. Users should expand on specific challenges related to TB/HIV and MDR-TB, such as high prevalence of both among marginalized groups (for example, injecting drug users) and program design issues that prevent adequate response to both (for example, lack of integration of TB and HIV services at any level of the health system). Users should also check the WHO website for the most up-to-date version of guidelines on the management of MDR/XDR-TB and TB/HIV co-infection, as these documents are frequently revised.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
1. Are there national treatment guidelines or protocols for MDR/XDR-TB in use? Are these guidelines consistent with current WHO recommendations?	**1a. Yes** (National treatment guidelines or protocols for MDR/XDR-TB are in use and consistent with current international recommendations.)	( ) 8			
	1b. Yes, with deviations (National guidelines are available but are not implemented; guidelines exist but are not consistent with international recommendations.)	( ) 4			
	1c. No (No guidelines are available/used.)	( ) 0			
2. Is there a policy to refer MDR/XDR-TB cases to clinical facilities identified by the MOH based on set criteria (e.g., expertise, location, infrastructure) as having the capacity to manage these	**2a. Yes** (Final policy is in place and implemented.)	( ) 8			
	2b. Yes, but policy is not yet implemented. (Final policy is in place but not yet widely implemented.)	( ) 4			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
cases? Note: Clinical reference centers and specialized institutions are those facilities specifically equipped and staffed to treat MDR/XDR-TB cases according to internationally recommended standards.	**2c. No** (No policy exists.)	( ) 0			
3. Are clinical decisions on MDR/XDR-TB cases taken by individual clinicians only or in consultation with a group of experts?	**3a. Group consultation** (Decision taken by expert panel [generally in agreement with treating clinician] involving different perspectives [clinical, surgical, public health], [e.g., consilium—as it is called in Russian-speaking countries or similar bodies.)	( ) 8			
	3b. Individual decision (Decision taken by the individual clinician.)	( ) 0			
4. Is there capacity within facilities to provide isolation for MDR/XDR-TB patients while on inpatient treatment?	**4a. Yes** (Adequate isolation is available for all cases.)	( ) 8			
	4b. Yes, minor problems (There is some capacity for isolation but not all cases can be accommodated. Minor risk of spreading TB infection is identified. It can be corrected by expanding capacity.)	( ) 4			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
	4c. No, major problems exist (No capacity to isolate MDR/XDR TB patients. Major risk of spreading TB infection is identified. It cannot be corrected with the available capacity and resources.)	( ) 0			
5. Is adequate infection control protection (administrative, environmental, personal) available for health-care workers in facilities that treat MDR/XDR-TB? *Note: Refer to the latest WHO guidelines for information on infection control to determine adequacy of measures.*	**5a. Yes** (Administrative, environmental, and personal infection control protection measures are available and used in facilities that treat MDR/XDR-TB patients.)	( ) 8			
	5b. Yes, partial (Some infection control measures are implemented or in process, but gaps remain.)	( ) 4			
	5c. No (Some or all measures are not available. There is a real risk of nosocomial transmission of TB.)	( ) 0			
6. Are drugs for management of adverse effects of second-line drugs available and are providers trained on how to use them? (The question is self-explanatory. Consultant must visit specialized institution/s treating MDR/XDR-TB patients with second-line drugs in order to answer this question.)	**6a. Yes**	( ) 6			
	6b. Yes, partial (Drugs are available, but providers are not yet trained or vice versa.)	( ) 3			
	6c. No	( ) 0			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
7. Are MDR/XDR-TB patients managed outside the NTP?	**7a. No** (Treatment of MDR/XDR-TB is not available in the private/semi-private sector; if available, services are linked to the NTP. Note: Linked means that the private sector notifies and manages cases according to national guidelines.)	( ) 6			
	7b. Yes (MDR/XDR-TB patients are treated in the private/semi-private sector and services are not linked to the NTP. Note: Linked means that the private sector notifies and manages cases according to national guidelines.)	( ) 0			

Section score:	Possible interpretation:		
		28-52	No major gaps; individual actions need improvement
		17-27	Some critical gaps needing action
		≤16	Major gaps in addressing TB/HIV and/or MDR/XDR-TB

Unscored questions to inform recommendations

1. Where does MDR-TB treatment occur? In hospital, outpatient departments? Are patients hospitalized for intensive phase and/or continuation phase of treatment? Are patients treated outside the hospital? Day hospital, outpatient clinic, outreach HCW? Other options? How are the different options combined? Are there any fees for MDR/XDR-TB services?

2. Is treatment of MDR-TB cases standardized, individualized, or empiric? Any combination of the three? Which of the three treatment strategies are utilized by the institutions involved in MDR-TB treatment throughout the country? For the most recent MDR-TB treatment cohort, what proportion were treated with a second-line regimen? Are surgical interventions used, and if so, what are the criteria?
3. Is treatment duration for MDR-TB cases adequate (e.g., at least 18 months or longer)?
4. What treatment adherence support is provided to MDR/XDR-TB patients? Are incentives provided to MDR/XDR-TB patients? Are enablers available to support MDR/XDR-TB patients?
5. Are patients who fail to retrieve MDR/XDR-TB treatment or attend required follow up visits identified and successfully traced before defaulting from treatment? What systems are in place to identify them and bring them back into treatment?
6. Is follow-up after treatment performed? At what intervals?

7. Taking into account the country snapshot data, how reliable are the data according to previous evaluations/missions, taking into consideration the criteria recommended by WHO and IUATLD (representativeness, sample size, distinction between new and retreatment cases)? What criteria are used to distinguish between new and retreatment cases?
8. How many practitioners are trained to manage MDR/XDR-TB? TB/HIV co-infection?
9. What is the HIV testing policy for TB cases?
10. What proportion of HIV-positive confirmed MDR-TB cases are on antiretroviral therapy?
11. What are the most recent outcome data for TB/HIV co-infected cases (see *WHO Interim Policy on Collaborative TB/HIV Activities* as a guide)?
12. If ACSM related to MDR-TB is being promoted, what are the key messages being provided and to what audiences? How are messages being disseminated? Have there been any unintended negative consequences (e.g., increased stigma) as a result of these messages?

13. What infection control measures are in place? Are TB suspects separated from others in outpatient clinics? Are in- or outpatients separated by category (smear negative of any category, Category 1, 2, 4, etc.)? Is it possible to avoid overcrowding? Is personal respiratory protection available for staff and visitors?
14. Is it possible/permitted to order culture for those at risk of MDR-TB prior to starting treatment rather than waiting for treatment to fail at two months, thus reducing delay? If possible, who can order the culture? Are nurses authorized to order culture? Is there a system to report these culture results back to the provider in a timely fashion and to change the treatment regimen?
15. Does the NTP record deaths among confirmed MDR/XDR-TB cases who die before they start treatment, and if so, how do they record and report these data?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to MDR-TB and TB/HIV treatment.

Areas of Strength:

Issues of Concern:

Component 3: Contribute to health system strengthening (HSS)

Scored questions

Instructions: The questions in this section address issues related to overall health-system capacity to support the NTP and the extent to which the NTP is engaged in activities to improve the overall health system and benefit programs outside of the NTP. For example, HSS activities implemented through the NTP may focus on building capacity for procurement and management of drugs, which has the potential to benefit the overall drug-management system in countries where the anti-TB drugs are procured and distributed centrally and not specifically through the NTP.

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/ Comments
1. Is there a national plan to provide adequate human resources for diagnosis and management of MDR/XDR-TB?	**1a. Yes** (National plan exists and is implemented; there is a specific component on the resources to be used to manage MDR/XDR-TB.)	( ) 8			
	1b. Yes, partial (National plan exists or is under development but not yet implemented.)	( ) 4			
	1c. No (There is no plan or the issue of MDR/XDR-TB is not addressed in the current plan.)	( ) 0			
2. Is there a national plan for laboratory strengthening to provide adequate culture and DST capacity throughout the country?	**2a. Yes** (National plan exists and is implemented; there is a specific component on culture and DST.)	( ) 8			
	2b. Yes, partial (National plan exists or is under development but is not yet implemented.)	( ) 4			
	2c. No (There is no plan or only one component is implemented, [e.g., culture but not DST].)	( ) 0			

Question	Answer	Score *(check)*	Identified gap	Action/ Recommendation	Data source/ Comments
3. Is there an operational system for referral and follow up of discharged MDR-TB patients from specialized TB treatment facilities to local primary-care facilities for continuation of treatment on an outpatient basis?	**3a. Yes** (There is a clear system to refer all cases discharged from specialized institutions to local primary-care facilities for continuation of treatment on an outpatient basis.)	( ) 10			
	3b. Yes, partial (System is under development or not yet fully implemented.)	( ) 5			
	3b. No (There is no clear referral system; follow-up care for outpatients is based on the initiative of individual physicians.)	( ) 0			
4. Is there an operational system for referrals of TB patients between the civil and penitentiary health sectors?	**4a. Yes** (There is a clear system of referral from the prison system to civil health-care facilities for continuation of treatment; the system functions for all TB cases, including MDR/XDR-TB cases.)	( ) 8			
	4b. No (There is no clear referral system; follow-up care for outpatients is based on the initiative of individual prison staff.)	( ) 0			

Section score:	Possible interpretation:	16-34	*No major gaps; individual actions needed to improve*
		10-15	*Some critical gaps needing action*
		≤9	*Major gaps at health system strengthening level*

Unscored questions to inform recommendations
1. Are GFATM or other sources of funding available for HSS activities?
2. Is the PAL initiative implemented in the country?
3. What partners are involved in TB control and MDR/XDR-TB control (e.g., NGOs, private sector, international organizations, etc.) and are they represented on the CCM or other coordinating bodies?
4. What type of regulation of drugs in general and antibiotics in particular exist in the country, and how is such regulation enforced (registration, import, sales, prescription rights, etc.)?
5. Is there any national strategy, beyond regulation, to improve rational use of drugs, with special attention to reduce antibiotic resistance in general?

6. Is the MDR/XDR-TB threat used for advocacy in support of strengthening the general health system's capacity to prevent and deal with antibiotic resistance in general?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to health systems strengthening.

Areas of Strength:

Issues of Concern:

Component 4: Engage all care providers

Scored questions

Instructions: The questions in this section refer to the linkages between private providers and the NTP. Private sector health care providers are defined broadly and depend largely on the context. For example, in some settings, private providers are independent clinicians providing services completely outside public sector management and insurance schemes. In other settings, faith-based organizations are considered private providers but often have management authority over public facilities, especially in the case of mission hospitals that have transitioned from faith-based ownership to the public sector. Many countries have initiated partnerships with local associations of private providers in order to integrate NTP standards of care and reporting systems. The user should identify the most common ways in which private providers are engaged in TB diagnosis and treatment when responding to the items in this section.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
1. Are private/non-NTP providers who treat TB linked with the NTP in any formal way?	**1a. Yes** (Linked means that private providers notify and manage cases according to national guidelines. The answer is yes when special programs [PPM] have been implemented to involve the private sector.)	( ) 8			
	1b. Yes, partial (Some elements of the national guidelines are implemented by the private sector but the providers are not fully engaged with the NTP.)	( ) 4			
	1c. No (The answer is no if the link is considered as something spontaneously achieved by the private providers.)	( ) 0			
2. Does the NTP provide drugs, supervision, and training to private providers who diagnose and treat TB cases?	**2a. Yes** (The NTP provides drugs, supervision, and training to private providers who diagnose and treat TB cases.)	( ) 8			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
	2b. Yes, partial (The NTP provides oversight for some activities, for example, drug procurement, but is not involved with other key elements.)	( ) 4			
	2c. No (The NTP is not involved with drug procurement, supervision, and/or training for private providers who diagnose and treat TB cases.)	( ) 0			
3. Do private/non-NTP providers diagnose and treat MDR-TB cases in the absence of a strong link to the NTP? (For example, manage a large number of cases outside the NTP system or not using NTP protocols.)	**3a. Yes** (A large proportion of MDR-TB patients is managed by private sector providers [e.g., >10%].)	( ) 0			
	3b. No (Private-sector providers play a minor role or are not at all involved in managing MDR-TB cases.)	( ) 8			
4. Has the country adopted the *International Standards for TB Care* and disseminated this document to all providers?	**4a. Yes** (ISTC document has been endorsed by the NTP/MOH or other equivalent national authority; document has been promoted and disseminated in the national language.)	( ) 4			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
	4b. No (ISTC document has not been endorsed by the NTP/MOH or other national authority or has not been promoted or disseminated in the local language.)	( ) 0			

Section score:	Possible interpretation:		
		21-28	No major gaps; individual actions needed to improve
		13-20	Minor gaps with some (implementation) action needed
		≤12	Major gaps at PPM level

Unscored questions to inform recommendations
1. Is the private sector important in providing health care in the country? Please summarize the role that the private sector plays in the provision of health care.
2. Are there results from PPM projects available? Are the PPM projects achieving programmatic outcomes that are comparable to the NTP? Are there any key indicators that show weaknesses on the part of PPM projects?
3. Is there any information on outcomes of patients treated in the private sector? How do they compare with outcomes reported by the public sector providers?

4. Are patients managed in the private sector offered individualized regimens or drugs whose quality is uncertain? Are there systems in place to detect problems with drug quality in the private sector, and if so, what actions have been taken to address any problems found?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to engaging all care providers.

Areas of Strength:

Issues of Concern:

Component 5: Empower people with TB and communities

Scored questions

Instructions: The following questions are aimed at assessing the extent and quality of community contribution to TB care in the country. Community contribution to TB care is broadly defined but usually involves the integration of community health workers in treatment supervision and support and sometimes a more extensive role, such as outreach and education, intensified case detection, and follow up to identify defaulters and bring them back into treatment. Users should look for clear evidence of community involvement in TB care and request as diverse a group as possible to respond to these questions, including representatives of affected communities.

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
1. Have affected communities been actively consulted in the preparation of any national guidelines on MDR/XDR-TB?	**1a. Yes** (The answer is yes when representatives of affected communities had been part of committees developing national guidelines on MDR/XDR-TB.)	( ) 6			
	1b. No (The answer is no when there is no evidence that affected communities participated in the development of national guidelines on MDR/XDR-TB.)	( ) 0			
2. Do affected communities have representation on the CCM or other national bodies that set policy for TB control?	**2a. Yes** (The answer is yes when representatives of affected communities are included in the CCM and policy committees that develop national guidelines.)	( ) 6			
	2b. No (The answer is no when there is no evidence that affected communities participate in the CCM and policy committees that develop national guidelines.)	( ) 0			

Question	Answer	Score (*check*)	Identified gap	Action/ Recommendation	Data source/ Comments
3. Do community-based DOTS projects receive government funding? For example, does the government fund elements of CB-DOTS such as training, supervision, transport subsidies, and/or incentives for community health workers?	**3a. Yes** (A budget line item for community-based DOTS is included in the national budget for TB.)	( ) 6			
	3b. No (There is no line item for community-based DOTS in the national budget for TB.)	( ) 0			
4. Are community-based DOTS projects being implemented with documented treatment success of at least 85%?	**4a. Yes** (The answer is yes when the projects are based on sound principles and achieve a satisfactory success rate.)	( ) 8			
	4b. Yes, partial (Program is not operational everywhere, or only on a pilot basis.)	( ) 4			
	4c. No (Community-based DOTS projects do not achieve at least 85% treatment success rate or are not implemented according to sound principles.)	( ) 0			

Section score:	Possible interpretation:		
		16-26	No major gaps; individual actions needed to improve
		7-15	Some critical gaps needing action
		≤6	Major gaps at community level

Unscored questions to inform recommendations
1. Is the TB Patient Charter translated into the local language(s) and widely used?
2. Is there a plan for community care? Does it include treatment of MDR-TB? Does the plan include community health workers (paid); volunteer stipends; or the payment of management fees to NGOs to manage the recruitment, selection, and training of DOT volunteers either with government or donor funds?
3. What is the annual budget for CB-DOTS?
4. Are community-based DOTS projects supervised by the NTP and treatment supporters assessed in any way by the local facility? What training do they receive?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to empowering people with TB and communities.

Areas of Strength:

Issues of Concern:

Component 6: Enable and promote research

Scored questions

Instructions: Clinical and operations research conducted under the auspices of the NTP is increasingly emphasized as a key source of information to enhance responses to MDR/XDR-TB and to improve DOTS programs. Research may be undertaken collaboratively between internal and external partners, and results shared widely to all stakeholders. The questions in this section focus on capacity to implement research activities, ensure ethical clearance, and utilize research results. The user should consider both financial and human resources capacity to support operational research. Increasingly, PEPFAR focus countries or NTPs with Global Fund grants may have adequate financial resources to support operational research but little local expertise in how to conduct OR. Other countries may have plenty of local capacity to conduct research but very little funding. It is important to differentiate between these two scenarios in the comments. Where possible, include a list or copies of recent publications based on local research efforts (particularly those involving MDR/XDR-TB) in the final report.

Question	Answer	Score *(check)*	Weakness/Gap	Action/ Recommendation	Data source/ Comments
1. Is there a national TB research agenda based on country-specific priorities that includes MDR/XDR-TB (e.g., operational research on TB treatment adherence, defaulter tracing, or other MDR/XDR-TB–related activities)?	**1a. Yes** (A national TB research agenda is included in the five-year plan and/or in the annual action plan and issues related to MDR/XDR-TB are included.)	( ) 6			
	1b. No (The answer is no if the research agenda is not included in the five-year plan and/or in the annual action plan.)	( ) 3			
2. Are there transparent procedures to define research priorities, authorize research activities, and hold researchers accountable for reporting results to the MOH? Is NTP clearance required to publish results?	**2a. Yes** (The MOH has documented procedures for setting research priorities and authorizing research activities; guidelines for authorized research include reporting and publication requirements.)	( ) 6			
	2b. Yes, partial (The MOH has documented procedures for some but not all of these research processes.)	( ) 3			

Question	Answer	Score *(check)*	Weakness/Gap	Action/ Recommendation	Data source/ Comments
	2c. No (The MOH has no procedures at all for these research processes.)	( ) 0			
3. Is there a research review committee in place at the national level? Does this committee include an ethicist?	**3a. Yes** (There is a committee and it includes an ethicist; the committee meets according to a regular schedule and outcomes are documented.)	( ) 6			
	3b. Yes, partial (There is a committee but it is either poorly organized or does not include an ethicist.)	( ) 3			
	3c. No (There is no such committee or there is no evidence at all of their active involvement in reviewing research.)	( ) 0			
4. Is there adequate in-country human resource capacity and funding to conduct operational research?	**4a. Yes** (Adequate funding and human resources capacity are available to support operational research.)	( ) 6			
	4b. Yes, partial (Either funding or human resource capacity is inadequate. Indicate which is the most challenging in the summary of gaps.)	( ) 3			

Question	Answer	Score *(check)*	Weakness/Gap	Action/ Recommendation	Data source/ Comments
	4c. No (The answer is no when international support is essential to allow design, implementation, and analysis of results of operational research projects and the majority of research funding comes from international donors.)	( ) 0			
5. Is there evidence that recent research has resulted in change to policies or guidelines? For example, have research findings been used to change or update policies/practices?	**5a. Yes** (The NTP has revised guidelines or scaled up change to program strategy based on research findings.)	( ) 6			
	5b. No (The NTP has not changed any guidelines or otherwise utilized findings from research efforts.)	( ) 0			

Section score:	Possible interpretation:	21-30	*No major gaps; individual actions needed to improve*
		11-20	*Some critical gaps needing action*
		≤10	*Major gaps at research level*

Unscored questions to inform recommendations
1. What research has recently been undertaken and who is funding and/or supporting the research? Which donors/external partners are involved, if any?
2. Are research results generated by international organizations or donors shared with the NTP and used to improve programs?

3. What research on MDR-TB, if any, has been planned or recently completed?
4. What are the key obstacles to implementing research? Funding or capacity or both? If capacity, is there support to send local collaborators for training opportunities?

Brief Data Interpretation Summary

Based on the data gathered above, write a brief summary of the program's apparent strengths and gaps with respect to enabling research.

Areas of Strength:

Issues of Concern:

Appendices

Appendix 1

MDR/XDR-TB Case detection and treatment outcome definitions

Case detection and registration

MDR-TB

There are three case registration categories for MDR-TB patients based on previous treatment categories. Date of sputum collection should be used to determine the MDR-TB diagnosis date and case registration group.

Category	Definition
New MDR-TB case	MDR-TB patient who has never received TB treatment, or who has received TB treatment for ≤ 1 month
MDR-TB case previously treated with only first-line drugs	MDR-TB patient who was treated for ≥ 1 month with only first-line anti-tuberculosis drugs (HRSEZ) and Thioacetazone (in some countries)
MDR-TB case previously treated with second-line drugs	MDR-TB patient who was treated for ≥ 1 month with at least one second-line anti-tuberculosis drug (with or without first-line drugs). Patient should be further defined by the outcome of the most recent previous treatment: failure, return after default, relapse, or transfer in.
Transfer in	MDR-TB case transferred from another MDR-TB register to continue treatment. Treatment outcome should be reported to the transferring unit so that they can report their outcomes in the cohort in which the person originally started MDR-TB treatment.

XDR-TB

There are two case registration categories for XDR-TB[2] patients based on previous treatment categories. At the time this MDR/XDR TB assessment tool was developed, there was no further guidance on XDR case detection and registration and MDR-TB case registration guidelines were adapted for XDR-TB based on expert opinion. Users should seek information on the most recent case detection and registration definitions and modify this section accordingly if updates are forthcoming soon after publication of this tool.

Category	Definition
New XDR-TB case	XDR-TB patient who has never received TB treatment, or who has received TB treatment for ≤ 1 month
Previously treated XDR-TB case	XDR-TB patient who was treated for ≥ 1 month with any first or second line anti-tuberculosis drugs
Transfer in	XDR-TB case transferred from another MDR-TB register to continue treatment. Treatment outcome should be reported to the transferring unit so that they can report their outcomes in the cohort in which the person originally started MDR-TB treatment.

Cohorts

[2] XDR-TB case definition: any individual with confirmed MDR-TB AND resistance to at least one flouroquinolone and one second-line injectable drug (amakacin, capreomycin, kanamycin)

Definitions for MDR-TB diagnostic and treatment cohorts are listed below. It is important to verify the cohort definition being used to analyze data at both national and local levels to facilitate data interpretation.

Category	Definition
Diagnostic cohort	A group of cases entered in the Category IV register (or diagnosed and recorded as MDR-TB cases) during a specific period.
Treatment cohort	A group of patients who start Category IV treatment (or treatment for MDR-TB or XDR-TB) during a defined time period.

Treatment outcomes

At the time of publication, there was no guidance on XDR outcomes beyond the MDR-TB treatment outcomes already in use. Therefore, MDR-TB and XDR-TB treatment outcomes should be defined the same way. Users should seek information on the most recent treatment outcome definitions and modify this section accordingly if updates are forthcoming soon after publication of this tool. Lastly, given the emphasis of the tool on *final* treatment outcomes for MDR/XDR-TB, definitions for interim outcomes are omitted.

Category	Definition
Cure	MDR TB patient who has completed treatment according to country protocol and has been consistently culture-negative (with at least five results) for the final 12 months of treatment. If only one positive culture is reported during that time, and there is no concomitant clinical evidence of deterioration, a patient may still be considered cured, provided that this positive culture is followed by a minimum of three consecutive negative cultures, taken at least 30 days apart.
Treatment completed	MDR TB patient who has completed treatment according to country protocol but does not meet the definition for cure or treatment failure due to lack of bacteriologic results (i.e., fewer than five cultures were performed in the final 12 months of therapy.
Death	MDR TB patient who dies for any reason during the course of MDR-TB treatment.
Treatment default	MDR-TB patient whose MDR-TB treatment was interrupted for 2 or more consecutive months for any reason.
Treatment failure	MDR TB patient with two or more positive cultures out of the five cultures recorded in the final 12 months of therapy OR with one positive culture out of the final three culture results/ Treatment will also be considered to have failed in a clinical decision has been made to terminate treatment early due to poor response or adverse events.
Transfer out	MDR-TB patient who has been transferred to another reporting and recording unit and for whom the treatment outcome is unknown.

Source: Laserson et al. 2005. "Speaking the same language: treatment outcome definitions for multidrug-resistant tuberculosis." *International Journal of Tuberculosis and Lung Disease.* 9 (6): 640-645.

Appendix 2

Suggested framework for final report

Front pieces

Title page
List of authors
Acknowledgments
List of acronyms used

Body of report

1. Executive summary with major recommendations
2. Background
3. Current TB control performance
    a. Country data as reported by NTP
    b. Sub-national data (specify regions)
4. Detailed performance by Stop TB Strategy component
    a. Component 1: Pursue high-quality DOTS expansion and enhancement
        i) Political commitment with increased and sustained financing
        ii) Case detection through quality-assured bacteriology
        iii) Standard treatment, with supervision and patient support
        iv) An effective drug supply and management system
        v) Monitoring & evaluation system, and impact measurement
    b. Component 2: Address TB/HIV, MDR-TB, and other challenges
    c. Component 3: Contribute to health system strengthening
    d. Component 4: Engage all providers
    e. Component 5: Empower people with TB and communities
    f. Component 6: Enable and promote research
5. Conclusions
    a. Priority activities to address MDR/XDR-TB
    b. Recommendations for additional technical assistance

Appendices

A. Assessment terms of reference
B. Assessment schedule/agenda
C. Persons met
D. (Others as appropriate)