

MDR-TB Planning Toolkit

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MDR-TB Planning Toolkit introduction and user's guide

Welcome to the MDR-TB Planning Toolkit. This set of tools is designed to help countries develop or strengthen a multidrug-resistant tuberculosis (MDR-TB) component within their national TB strategy. The toolkit contains key steps for the planning process, including developing objectives for a strong MDR-TB component, identifying and addressing current gaps in service coverage, and determining how to secure resources and monitor progress.

The MDR-TB Planning Toolkit is intended for countries, technical partners, international organizations, and donors who want to use WHO standards and policies to improve the diagnosis, treatment, and care of patients with drug-resistant TB. It creates an easy-to-follow process that draws together existing guidance from international organizations, including the World Health Organization (WHO) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

The tools can be used by countries drafting their first plan for the programmatic management of MDR-TB, as well as countries revisiting an existing plan or facing bottlenecks in scale-up. The toolkit can help countries implement an ambulatory model of MDR-TB care,¹ or it can form the basis of an application to the Global Fund or to other donors. It can be used for MDR-TB planning at the national or subnational level. Ultimately, its aim is to help countries achieve the goals of providing universal access to high-quality care for people with drug-resistant TB and halting the transmission of drug-resistant TB.

Scaling up the diagnosis and treatment of MDR-TB requires detailed planning. Countries need to spell out objectives and how they are to be achieved, the time frame for scale-up, who is responsible, and how much implementation will cost.² This toolkit is intended to help countries produce a detailed plan to define the most urgent steps to accomplish in the next few years. Such a plan can operationalize the MDR-TB sections of a national TB strategy, which often covers a longer period of time and contains more general goals.

This toolkit focuses on detecting and curing existing MDR-TB cases and stopping the spread of drug-resistant TB. It starts with the assumption that the national TB strategy is already addressing the prevention of acquired drug resistance by means of standard TB regimens with quality-assured medicines, patient support, and proper supervision. These are critical interventions for reducing the burden of MDR-TB. Similarly, strong systems for detecting TB are essential for detecting multidrug resistance. Although the detection and treatment of TB are outside the scope of this toolkit, each country will need to consider the relative priority of activities to address MDR-TB within the context of its TB strategy and epidemiology.

How to use the MDR-TB Planning Toolkit

This toolkit contains eight tools. Each one asks key questions that need to be answered to create or strengthen an effective MDR-TB response within the national TB strategy.³ Worksheets included in the tools will help planning teams address the questions. The worksheets can be filled out on the screen using Microsoft Word or printed. (A worksheet-only version of this document is available at <http://www.path.org/publications/details.php?i=1678>). Many worksheets can be pasted into a Microsoft Excel spreadsheet. Those in Tool 2 have Excel versions with built-in formulas posted on <http://www.path.org/publications/details.php?i=1678>.

Toolkit overview

Tool	Key questions	Worksheets
1	Why create or revise an MDR-TB plan? Who needs to participate in the planning process?	1A, 1B
2	What would success look like?	2 A; 2B or 2C
3	What are the gaps in addressing MDR-TB?	3
4	Which are the most important gaps to address first?	4
5	Why do the gaps exist? What should be done to address the causes?	5
6	Will the planned activities lead to desired results?	6A, 6B, 6C
7	What resources are needed to implement each activity? Where will they come from?	7
8	Does the MDR-TB component contain the key ingredients of a sound plan?	8

Because each country is at a different place in the planning process, pick and choose the tools that meet your particular needs. If you are at the beginning of the planning process, you may want to follow these tools step by step. (See “Creating a new MDR-TB plan” below). If you are further down the road, scaling up an already existing program, for example, some steps may not be necessary. You may find that certain tools need to be revisited a number of times over the course of planning and implementing services. Users are encouraged to select those tools that fit your country’s needs, tailor them, and use them in the order that fits the planning process you design.

This toolkit can also be used to review and strengthen an existing MDR-TB plan. (See “Revising an existing MDR-TB plan” below). At the end of the toolkit, you will find useful resources, including references to WHO recommendations.

Creating a new MDR-TB plan. The tools are designed to build upon each other:

- Worksheets 1A and 1B are for getting organized at the beginning of the planning process.
- Worksheet 1A and Worksheets 2 through 7 are designed to help you create specific parts of your MDR-TB plan. (See sample outline below.²) As you are working through these tools, you are generating your plan.
- Parts of Worksheets 2A, 5, 6, and 7 are designed to become pages of your plan. The information you fill in on Worksheets 1A, 3, and 4 will help you write several other parts of your plan.
- Worksheet 8 is for reviewing the plan at the end of the process.

Using the worksheets to create an MDR-TB plan

Worksheets to inform each section of your plan		Plan outline (sample)
	1A. Get ready	<i>Introduction</i> <ul style="list-style-type: none"> • Purpose, time frame • Relation to the national TB strategy and other plans • Political commitment to the planning process, stakeholder involvement, endorsements • Process used to develop the plan, secure commitments • Process for dissemination, implementation, and monitoring
		<i>MDR-TB situation</i>
	2A. Preliminary targets	<ul style="list-style-type: none"> • Your country's progress toward universal access
3. Analyze situation →	4. Prioritize gaps	<ul style="list-style-type: none"> • Highest-priority gaps, reasons they were selected
	6A. Results framework	<i>Intended results</i>
	6B. Objectives	<ul style="list-style-type: none"> • Outputs, outcomes, and impact
		<i>Sections* of your plan, each of which should contain:</i>
	6B. Objectives	<ul style="list-style-type: none"> • Objective
4. Prioritize gaps →	5. Design activities	<ul style="list-style-type: none"> • Problem statement (key gaps and their causes) • Activities to address the gaps and contribute toward the objective • Lead organization and due date for each activity
	6C. Interim targets	<i>Monitoring (aligned with the sections* of your plan)</i>
	7. Resources	<i>Budget (aligned with the sections* of your plan)</i>

**The sections of your plan should correspond to the sections of your national TB strategy. These will include such topics as MDR-TB case-finding, treatment, drug supply, and monitoring and supervision. In this toolkit, Worksheets 3 through 7 use the components of the Stop TB Strategy⁴ as they apply to MDR-TB. View these as “modules” to re-order or group to match the sections in your national TB strategy.*

Revising an existing MDR-TB plan. The need to scale up coverage, implement ambulatory MDR-TB treatment, adopt technology innovations, or respond to new epidemiologic data may prompt the need to revisit an existing plan. If you have an existing MDR-TB plan, you can use Tool 1 to prepare for the planning process, and then use Tool 8 to assess your existing plan. If aspects of your plan need strengthening, Tool 8 will suggest which other tools to work through.

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Tool 1: Prepare for the planning process

Before you begin your planning to create or revise an MDR-TB plan, some key issues to consider include:

- Are there already elements to address MDR-TB in the national TB plan?
- Why is a (revised) plan for MDR-TB necessary?
-
- What model of care will be used to treat MDR-TB patients?
- Is there a defined funding amount that the planning process needs to work within?
- Who needs to participate in the planning process, and is there support?
- What are the steps necessary to produce the plan, and who will pay for them?

Fitting within other plans. This toolkit is designed to integrate MDR-TB detection and treatment activities into the country's overall TB strategy. There should be clear links with the related national plans, such as those addressing HIV, human resource development, laboratory strengthening, and infection control. Furthermore, WHO recommends that national TB plans be consistent with global TB targets and objectives.³ Several WHO regions have MDR-TB response plans that provide guidance to country-level planning efforts.⁵⁻⁹

This toolkit is designed to assist you in setting ambitious yet feasible targets on the way toward providing universal access to MDR-TB diagnosis and treatment. Often, the planning process will reveal resource gaps that will require advocacy to fill. Tool 7 will help you address those gaps.

Planning team and process. Many countries convene a core planning team to design and steer the planning process. When this toolkit uses the term “you,” think “the planning team.” Usually the planning team is led by the national TB program (NTP) within a country's Ministry of Health (MOH), and the MOH “owns” the plan. However, this toolkit can also be used to develop or revise a subnational plan, in which case you will substitute “MOH” with the appropriate health authority at the regional or provincial level.

Planning teams should select and tailor the tools to the country situation. It may work best for individuals or small working groups to complete some or all of the worksheets and draft all or parts of the plan and then present to a larger group for review. Other countries may prefer to convene larger meetings earlier in the process. The planning team also needs to decide who will facilitate working groups and whether consultants from in or outside the country are needed.

It is essential to engage stakeholders (including civil society and communities) in the planning process. “Participatory approaches generate political commitment, build ownership and create champions, ensuring that the issues raised are considered from multiple perspectives,” according to WHO.¹⁰ If the process only includes technical experts, interventions may prove unacceptable or unable to address the needs of beneficiary communities or other important stakeholders.

Also think about all the different levels of the health system that will need to implement the MDR-TB plan. Decentralization requires effective coordination among hospitals, health facilities, and community implementers, so these providers will need to be represented in the planning effort.¹¹ For stakeholders to approach for your planning team, consider each of the groups and individuals in the box on the right.

This section includes two worksheets: **1A: Get Ready** and **1B: Task Timeline for Developing, Endorsing, Disseminating, and Monitoring the Plan**. Complete both before you begin the planning process.

Stakeholders to engage in the planning process:

- Ministry of Health departments critical to MDR-TB scale-up, such as pharmacy, laboratory, human resources, infection control, and HIV.
- Ministries of planning, finance, labor, justice, social protection, customs, and importation of drugs and tools.
- Providers at each level of the health system who will implement the plan.¹¹
- Civil society groups representing people impacted by TB and/or HIV, and community representatives.
- Institutes for training health professionals.
- Private providers and professional associations.
- Nongovernmental and faith-based organizations serving vulnerable populations, such as migrants and injection drug users.
- Technical agencies.
- Donors.

Worksheet 1A: Get Ready

The Get Ready worksheet will help you think through the purpose of your MDR-TB plan, how the plan will fit with other national plans, and who to involve in the planning process. In addition to helping you prepare for the planning process, your responses to these questions can form the basis for your plan's introduction. (See the sample plan outline on page 5.)

Plan purpose, time frame, relation to other plans

1. What is the purpose of the plan?
2. What is the time frame for the plan?
3. How will the timing fit with the country's planning and budget cycles at the central and subnational levels?

Start date (date that the first activities in the plan will be implemented) _____ End date _____

4. If there is already an MDR-TB component in the national TB plan, what is prompting the need to revise it? Examples include the need for more rapid scale-up, to decentralize treatment from hospital based to the community, to reprogram in response to changes in funding levels, or to implement technological innovations.
5. How will this MDR-TB plan fit within the national TB strategy?

Specify if the MDR-TB planning process can reprioritize gaps and add (or omit) objectives and activities from the national TB strategy.
6. How will the MDR-TB plan link with related national plans (such as HIV/AIDS, laboratory strengthening, airborne infection control, and human resource development)?
7. How will it align with the targets in, and help implement, your WHO region’s MDR-TB response plan?⁵⁻⁹
8. How will the plan respond to recommendations of recent technical assistance reports relevant to MDR-TB scale-up?
9. How will the plan update, unify, or strengthen work plans of partner organizations that address MDR-TB?
10. Is there a defined budget limit for the implementation of the overall plan or parts of the plan? If so, specify.

Political commitment to the planning process and stakeholder involvement

11. Who in the Ministry of Health will lead the planning process?
12. Do you have political support from the appropriate levels of the MOH for the planning effort? If not, how will this be secured?
13. Use the chart below to list stakeholders to include in the planning process. Insert the names of key individuals to contact and secure their commitment to participate in the planning process. Add lines to the worksheet as needed.

Stakeholders to include in planning process	Individuals to contact

14. Who will pay the costs of developing the plan? (See the Task Timeline in Worksheet 1B below.)
15. Who will manage the budget for the planning process?

Resource commitments to implement the plan

16. Once the plan is drafted, what steps will be taken to secure NTP and stakeholder commitments to carry out the particular activities suggested for them?
17. How will a financial gap analysis be conducted (i.e., determining the resources needed for each activity and comparing to available resources from NTP or partners)? (See Worksheet 7.)

Endorsement

18. What are the steps to secure endorsement by the Ministry of Health and other agencies?
19. Will other stakeholders (including civil society and communities) need to endorse the plan? If so, what steps need to be taken to secure their endorsement?

Release, implementation, and monitoring of the plan

20. How will the plan be released and disseminated?
21. How will the plan be implemented at the provincial or district levels?
22. How will the plan be implemented in sectors outside the Ministry of Health?
23. What organization will convene the first (and regularly scheduled) meetings to review implementation and monitor the plan? Who will participate?

Instructions for Worksheet 1B: Task Timeline for Developing, Endorsing, Disseminating, and Monitoring the Plan

The Task Timeline will help you organize your planning process by answering four key questions:

- What tasks are you envisioning for the planning process?
- What are your projected due dates for each task?
- Who will be responsible for accomplishing each task?
- What is the estimated cost of each task?

Use the table below to list the specific tasks needed to accomplish steps 14 through 23 from Worksheet 1A. This will help you think through the whole process, from developing the plan to endorsement, dissemination, and monitoring.

The Task Timeline should also include the following tasks:

- Compile background information needed for the planning process. (See Annex B.)
- Convene the planning team. List the schedule of meetings.
- Identify and orient stakeholders.
- Reserve rooms for meetings of the planning team and larger stakeholder groups.
- Identify and prepare facilitators. Develop an agenda for each meeting, prepare needed materials, and record decisions.
- Once drafted, distribute version 1 of the plan for comments.
- Incorporate comments, produce subsequent drafts, and finalize the plan.
- Translate the plan (if needed).
- Date of the first meeting of the group convened to monitor implementation.

Add lines to Worksheet 1B as necessary. Once you have completed the worksheet, you can develop a budget for the planning process.

Worksheet 1B: Task Timeline for Developing, Endorsing, Disseminating, and Monitoring the Plan

Planning task	Due date	Responsible party	Cost

Tool 2: Set preliminary targets

To start the planning process, the team needs to describe what results should be achieved by the final year of the plan. This tool will help you look at “the big picture” to answer the questions:

- How well is the country currently meeting WHO recommendations for diagnosing and treating MDR-TB patients?
- What do we intend the country to achieve by the final year of the plan? What would success look like?

In a 2009 World Health Assembly resolution, countries committed to achieving universal access to MDR-TB diagnosis and treatment, “thereby saving lives and protecting communities.”¹²

*The Global Plan to Stop TB 2011–2015*¹³ provides three key measures of country progress on the path toward universal access and sets the following targets for 2015:

- Greater than 50 percent of the estimated MDR-TB cases will be detected and notified.
- 100 percent of confirmed MDR-TB patients will start treatment.
- Greater than 75 percent of MDR-TB patients will be successfully treated.

These three measures provide a snapshot of a country’s performance in detecting and treating MDR-TB.

This tool contains three worksheets that will help you set preliminary targets for these measures. **Worksheet 2A: Preliminary Targets for MDR-TB Notification, Enrollment, and Treatment** is for all countries. Depending on your country’s MDR-TB case-finding strategy, complete either **Worksheet 2B: Preliminary Targets for MDR-TB Testing of Previously Treated Patients** or **2C: Preliminary Targets for MDR-TB Testing in New and Previously Treated TB Cases**. The targets you develop in these worksheets will be used in the next tools as you develop or refine your plan.

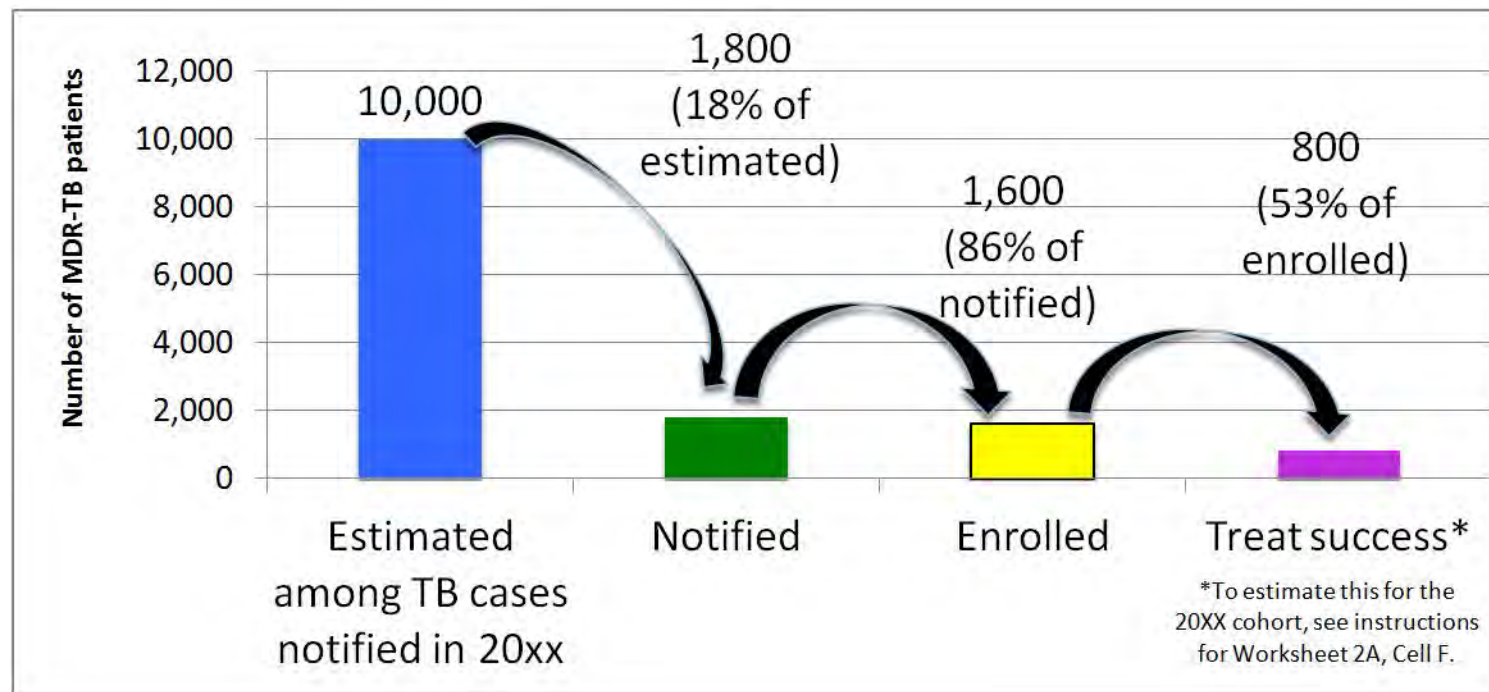
Overview of Worksheet 2A: Preliminary Targets for MDR-TB Notification, Enrollment, and Treatment

Figure 1 shows the performance of Country A, a hypothetical country with an estimated 10,000 MDR-TB cases among notified TB cases in the year 20xx. You can generate this bar graph for your country’s baseline performance along these three measures by going to <http://www.path.org/publications/details.php?i=1678>. The instructions to Worksheet 2A walk you through how to do so.

In most countries, MDR-TB patients are lost to follow-up at each step; the arrows on Figure 1 show the drop-offs in patients served.^a Setting targets means describing how much better your country will do (i.e., how many more patients your program will serve). The targets you will set in the worksheets in Tool 2 are preliminary targets. Tool 3, which follows, will help you analyze in more detail the country's current MDR-TB service coverage and gaps, assess the country's current capacity, and identify capacity that needs strengthening. Tool 4 will help you set priorities among the gaps, and Tool 5 will help you look at the causes of patient losses to follow-up at each step. Tool 6 will then ask you to revisit and finalize the provisional targets set here in Tool 2 and rephrase them as objectives for your plan.

^a Country A has the same level of performance in MDR-TB case notification, enrollment, and treatment as the world in 2011.¹⁴

Figure 1. MDR-TB notification, enrollment, and treatment, Country A, baseline (20xx).



	Estimated	Notified	Enrolled	Successfully treated
Number of MDR-TB patients	10,000	1,800	1,600	800
Percentage of previous column		18%	86%	53%
Percentage of estimated ^b		18%	16%	8%

^b While not discussed in this toolkit, this is another way to look at the MDR-TB diagnosis and treatment cascade.

Instructions for Worksheet 2A: Preliminary Targets for MDR-TB Notification, Enrollment, and Treatment

Fill in the cells of Worksheet 2A below (or on the Excel version at <http://www.path.org/publications/details.php?i=1678>) using these instructions for your country's baseline and target performance.

- 1. Baseline.** To determine your country's baseline performance in MDR-TB notification, enrollment, and successful treatment, use your country's profile on the WHO website¹⁵ or more recent national data.¹⁶

Estimated MDR-TB cases among TB notifications (first bar in Figure 1):

- **Cell A:** Sum of best estimates of MDR-TB cases in the country's new pulmonary and retreatment cases notified in the most recent year.¹⁵ Use your country's or WHO's¹⁵ estimate of the number of MDR-TB cases that could be found if all notified new pulmonary and retreatment cases were tested for MDR-TB.^c

Notified MDR-TB cases (second bar in Figure 1):

- **Cell B:** Number of MDR-TB cases confirmed and notified to the national TB program in the most recent year.
- **Cell C:** Express this number as a percentage of the estimated cases in cell A. (Excel will calculate this for you by dividing B by A and multiplying by 100.)

MDR-TB patients enrolled in MDR-TB treatment (third bar in Figure 1):

- **Cell D:** Number of confirmed MDR-TB patients who began MDR-TB treatment in the most recent year.^d
- **Cell E:** Express this number as a percentage of the notified cases in cell B. (Excel will calculate this for you by dividing D by B and multiplying by 100.)

^c The WHO estimate is based on a current year's TB notifications, so it does not capture MDR-TB patients who were notified in a prior year but are still waiting for treatment.

^d Some of these patients who began treatment may have had their MDR-TB detected the previous year.

MDR-TB patients successfully treated (fourth bar in Figure 1):

- **Cell F:** Since MDR-TB treatment is lengthy, the most recent outcomes are from a cohort that started treatment three years earlier. The treatment outcome of the most recent MDR-TB cohort reported to WHO from your country is available from the WHO website (see reference 27).^e For this worksheet, you could assume the current cohort will have the same success as the earlier cohort and insert this percentage into cell F.
- **Cell G:** Since you will not know the outcomes yet for the enrolled cases from cell D, for this worksheet you could apply the percentage successfully treated in the earlier cohort (cell F) to the number of MDR-TB patients enrolled (cell D) in the current year. Excel will calculate this for you by multiplying the percentage in cell F by the number in cell D and dividing by 100.

Once you fill in these cells, Excel will generate Figure 1 for your country. Be sure to record the baseline year in the title of your figure.

2. Targets. Review any national targets already set for MDR-TB notification, enrollment, and successful treatment. These should be consistent with your WHO region's MDR-TB response plan⁵⁻⁹ and the Global Plan 2011–2015.¹³ Compared to your country's baseline performance, how many more MDR-TB patients can be served by the final year of your plan? Targets should be ambitious but realistic (taking into account the anticipated pace of scale-up and feasibility of overcoming constraints).¹⁷ Targets should also be set through a participatory process involving all stakeholders who agree to use the same set of targets. (See Tool 1.)

- **Cell H:** First, set the target for the number of MDR-TB cases to be detected and notified in the final year of the plan; fill in cell H.
- **Cell I:** Express your target as a percentage of estimated MDR-TB cases (cell A). (Excel will do this by dividing H by A and multiplying by 100.) For simplification, this assumes the same number of MDR-TB cases will arise in the final year of the plan as in the baseline year.
- **Cell J:** Since all notified patients need to be enrolled in treatment, fill in cell J with the same number as cell H.
- **Cell K:** This should be 100 percent. (Excel will calculate this by dividing cell J by H and multiplying by 100.)
- **Cell L:** Set a target for the percentage of enrolled MDR-TB patients in the final year of the plan who will be successfully treated.^f
- **Cell M:** Apply the percentage given in cell L to the target for enrolled patients in cell J. (Excel will do this by multiplying the percentage in cell L by the number in cell J and dividing by 100.)

Once you fill in these cells, Excel will generate another figure for your country that compares targets to the baseline.

^e If your country does not yet have an MDR-TB cohort with treatment outcomes, you can look at the proportion with treatment success in countries with comparable programs.¹⁴

^f If your country does not yet have an MDR-TB cohort with treatment outcomes, you can set targets using interim results as a useful surrogate. Examples include the percentage with negative culture at six months^{18,19} described in Annex C, section 1C. You can also look at the proportion with treatment success in countries with comparable programs.¹⁴

Worksheet 2A: Preliminary Targets for MDR-TB Notification, Enrollment, and Treatment

The column headings correspond to the bars in Figure 1. Go to <http://www.path.org/publications/details.php?i=1678> to download this worksheet as an Excel file with built-in formulas for the calculations. Based on the data you input into the white cells, Excel will make the calculations in the light gray cells, and then generate bar graphs (as in figure 1) for your country's baseline and target performance.

	Estimated	Notified	Enrolled	Successfully treated
Baseline number of MDR-TB cases in 20xx	A	B	D	$G = (F \times D)/100$
Baseline as percentage of previous column		$C = B/A^*$	$E = D/B^*$	F
Target number of MDR-TB cases in 20xx		H	J	$M = (L \times J)/100$
Target as percentage of previous column		$I = H/A^*$	$K = J/H^*$	L

Since all confirmed MDR-TB cases need to be treated, targets H and J should be the same number of MDR-TB patients (so K will be 100 percent).

**Multiply by 100 to show as a percentage.*

Instructions for Worksheet 2B: Preliminary Targets for MDR-TB Testing of Previously Treated TB Patients

This worksheet is for countries focusing on previously treated TB patients for their MDR-TB case-finding strategy. If instead, your country is planning to set MDR-TB testing targets for both new TB patients and previously treated patients, then skip this worksheet and proceed to Worksheet 2C.

In order to diagnose MDR-TB, TB patients will need testing for multidrug resistance. In this toolkit, the term “MDR-TB testing” encompasses both drug susceptibility testing (DST) using conventional methods like culture and rapid molecular tests⁹ (such as line probe assays or Xpert[®] MTB/RIF). WHO recommends that countries perform MDR-TB testing on all TB patients who have been previously treated,²⁰ since levels of MDR-TB are on average six times higher in this patient group than in new TB patients.¹⁴

Fill in the cells of Worksheet 2B below using these instructions or use the downloadable Excel version from <http://www.path.org/publications/details.php?i=1678>, which will use built-in formulas to make the calculations in the gray cells based on the data you enter in the white cells.

1. **Baseline.** Use your country’s data (or see the most recent data your country reported to WHO).^{15,16} Specify the year of the baseline data.
 - **Cell N:** Fill in the number of previously treated patients who have been tested for MDR-TB in your baseline year.
 - **Cell O:** Fill in the total number of retreatment cases notified in the baseline year. This is the sum of patients who have relapsed, whose treatment has failed, who are returning after treatment interruption, or who are classified as “other retreatment.”
 - **Cell P:** Express the number in cell N as a percentage of all retreatment notifications.^h (Excel will do this by dividing cell N by cell O and multiplying by 100.)

2. **Target.** Replace 20xx with the final year of your plan. In order to diagnose the target number of MDR-TB cases you set in cell H, you will need MDR-TB testing of a certain number of previously treated patients (cell Q).
 - **Cell Q:** You can calculate this by dividing the number of MDR-TB patients to diagnose (cell H in Worksheet 2A) by the proportion of previously treated patients found to have MDR-TB in your country’s most recent drug resistance survey (DRS).^{15,21} (To do this calculation, express the proportion from your DRS as a decimal, i.e., 10 percent would be 0.10.)

⁹ WHO recommends that Xpert[®] MTB/RIF be used as the initial diagnostic test in individuals at risk of MDR-TB (including all previously treated patients).^{22,23}

^h One hundred percent is not feasible since some retreatment patients will not have a positive culture on which to perform drug susceptibility testing.

Discuss whether MDR-TB testing of this number of retreatment patients is achievable for the final year of your plan, given your MDR-TB case-finding strategy. For example, some countries start with an MDR-TB case-finding strategy limited to patients whose treatment is failing. Since this is a small subset of all retreatment patients, this case-finding strategy may not yield sufficient MDR-TB cases to meet the target for the final year of your plan.ⁱ Even testing all retreatment patients may not be sufficient to reach your target for MDR-TB cases to detect. In this situation, you will also need to test new TB patients (see Worksheet 2C) or lower your preliminary target for detecting MDR-TB cases (cell H).

- **Cell R:** Express the number in cell Q as a percentage of previously treated patients notified in the baseline year (cell O).* (Excel will do this by dividing cell Q by cell O and multiplying by 100.)

Worksheet 2B: Preliminary Targets for MDR-TB Testing of Previously Treated TB Patients

	Cells
Baseline number of previously treated TB patients tested for MDR-TB in 20xx	N
Number of previously treated TB patients notified in baseline year	O
Number of patients tested as a percentage of all previously treated TB notifications	$P = N/O \times 100$
Target number of TB patients to test for MDR-TB in 20xx	Q
Target as a percentage of all previously treated TB notifications that year*	$R = Q/O \times 100$

**It is difficult to estimate the number of previously treated TB cases that will be notified in the final year of the plan. For simplification, this worksheet assumes the same number as in the baseline year.*

Overview of Worksheet 2C: Preliminary Targets for MDR-TB Testing of New and Previously Treated TB Cases

Limiting MDR-TB testing to retreatment patients will miss MDR-TB cases among new TB patients, who comprise a significant fraction of MDR-TB cases in some countries.¹⁵ To reach universal access, countries will need to broaden their MDR-TB case-finding strategy to include new TB patients. WHO recommends prioritizing MDR-TB testing of **new** TB patients who:

ⁱ The target also depends on what laboratory method your country is using and what proportion of samples yield a result. For example, conventional drug susceptibility testing can only be performed when a culture is found to be growing.

- Have been in contact with a known MDR-TB case.
- Are living with HIV.
- Remain sputum smear-positive at month three of treatment.²⁰

The Global Plan 2011–2015 target¹³ is MDR-TB testing of at least 20 percent^j of all new patients, but some countries plan to test all new cases. Modeling found that rapid testing for both isoniazid and rifampicin resistance at the time of TB diagnosis is the most cost-effective testing strategy for any patient group, even at very low levels of resistance among TB patients (i.e., MDR-TB in greater than one percent of patients and isoniazid resistance other than MDR-TB in greater than two percent).¹ These levels of drug resistance are found in new TB patients in many countries.

Instructions for Worksheet 2C: Preliminary Targets for MDR-TB Testing in New and Previously Treated TB Cases

Fill in the cells of Worksheet 2C below using these instructions or use the downloadable Excel version from <http://www.path.org/publications/details.php?i=1678>, which will use built-in formulas to make the calculations in the light gray cells, based on the data you enter in the white cells.

1. **Baseline.** In the heading of the worksheet, write your baseline year. Use your country's data or the most recent data your country reported to WHO^{15,16} to fill in the worksheet using these instructions:
 - **Cell N:** Insert the number of previously treated cases notified in your baseline year. This is the sum of patients who have relapsed, whose treatment has failed, who are returning after treatment interruption, or who are classified as “other retreatment.”
 - **Cell O:** Insert the number of previously treated TB patients tested for MDR-TB. In the cell below, express this as a percentage of all retreatment notifications. (Excel will do this by dividing cell O by cell N and multiplying by 100.)
 - **Cell P:** Insert the number of new TB cases notified in your baseline year. This is the sum of pulmonary, extrapulmonary, and “other new cases.”
 - **Cell Q:** Insert the number of new TB cases tested for MDR-TB in your baseline year. In the cell below, express this as a percentage of all new notifications in your baseline year. (Excel will do this by dividing cell Q by cell P and multiplying by 100.)

^j Twenty percent is a global estimate of the proportion of new cases that have a high risk of harboring MDR-TB bacilli and therefore need to be prioritized for MDR-TB testing.¹³

2. Targets. In the heading of the worksheet, fill in the final year of the plan (year by which the target will be achieved). Then:

- **Cell R:** Write the number of previously treated TB cases to be tested for multidrug resistance in the final year of your plan. In the cell below, express this as a percentage of retreatment notifications.* (Excel will do this by dividing cell R by cell N and multiplying times 100.) This should be close to 100 percent given the WHO recommendation for MDR-TB testing of all retreatment patients.²⁰
- **Cell S:** Insert the number of new TB cases to be tested for multidrug resistance in the final year of the plan. In the cell below express this as a percentage of new notifications.* (Excel will do this by dividing cell S by cell P and multiplying times 100.)
- **Cells T and U:** Insert your country's most recent drug resistance survey results. For example, if 20 percent of previously treated TB patients were found to have multidrug resistance, insert 20 in cell T.
- **Cell V:** Next, calculate the number of MDR-TB cases you can expect to find by performing MDR-TB testing of the previously treated TB cases in cell R. (Excel will do this by multiplying cell R by cell T and dividing by 100.)
- **Cell W:** Then calculate the number of MDR-TB cases you can expect to find by performing MDR-TB testing of the new TB cases in cell S. (Excel will do this by multiplying cell S times cell U and dividing by 100.)
- Add cells V and W to find the total number of MDR-TB cases to be detected in the final year of the plan. If this sum is not the same as cell H in Worksheet 2A, you will either need to replace cell H with this revised target, or adjust the number of TB cases to test for MDR-TB (cells R and S in Worksheet 2C).

3. Totals. Excel will automatically fill in the rest of the cells. If not using the Excel version, here are the calculations to complete the worksheet:

- Add cells R plus S to find the total number of patients who will need to be tested for MDR-TB in order to detect the MDR-TB cases in cells V + W.
 - Divide this number by cell X and multiply by 100 to get **cell Z**, which is the percentage of notified TB cases to be tested for MDR-TB in the final year of the plan.
- Add cells N and P to get the total number of notified TB cases in the baseline year (**cell X**).
- Add cells O and Q to find the total number of patients tested for MDR-TB in the baseline year.
 - Divide this number by cell X and multiply by 100 to get **cell Y**, which is the percentage of notified TB cases that were tested for MDR-TB in the baseline year.

**It is difficult to estimate the number of TB cases that will be notified in the final year of the plan. For simplification, these calculations assume the same number as in the baseline year.*

Worksheet 2C: Preliminary Targets for MDR-TB Testing of New and Previously Treated TB Cases

	Baseline year: 20xx		Final year of the plan: 20xx		
	Number of notified TB cases	Tested for MDR-TB	Target number of TB patients to test for MDR-TB*	Percentage expected to have multidrug resistance ^k	Target number of MDR-TB cases to detect
Previously treated	N	O	R	T	$V = (R \times T)/100$
Percentage of notified		$O/N \times 100$	$(R/N) \times 100$		
New	P	Q	S	U	$W = (S \times U)/100$
Percentage of notified		$Q/P \times 100$	$(S/P) \times 100$		
Total	$X = N + P$	$O + Q$	$R + S$		$V + W$
Percentage of notified		$Y = (O + Q)/X \times 100$	$Z = (R + S)/X \times 100$		

*It is difficult to estimate the number of TB cases that will be notified in the final year of the plan. For simplification, the calculations in this column assume the same number as in the baseline year.

^k From drug resistance survey, surveillance, or model.¹⁵

Tool 3: Analyze the current situation

Now that you have set preliminary targets for your plan, the rest of the planning process is about how you will achieve them. To decide which activities are necessary to reach your targets, you will first need to examine in more detail your country's progress to date toward achieving universal access to MDR-TB diagnosis and treatment. Key questions at this stage of the planning process include:

- What models of MDR-TB care service delivery are used now, and how are they working?
- What are the gaps in addressing MDR-TB?

The **Checklist of Essential Elements to Address MDR-TB** will help you quantify the gap between your country's current performance and your targets. Once you have determined the gaps in current MDR-TB services, you can decide which gaps are most important to address (Tool 4) and then design activities to address those gaps (Tool 5).

This checklist consists of all relevant WHO recommendations essential for scaling up the detection and treatment of MDR-TB. Each WHO recommendation ("essential element") is phrased as a result to be achieved. Each essential element is displayed as a row, distributed across all components of the global Stop TB Strategy.⁴

Under each Stop TB Strategy component, the checklist breaks down the essential elements into "First steps" and "Next steps" required to achieve universal access to MDR-TB diagnosis and treatment. This division of WHO recommendations is designed to help countries sequence their initiation and scale-up process. In the checklist, "First steps" are designated by numbers, and "Next steps" are designated by letters.

Both first and next steps are considered essential elements as they are all WHO recommendations. "First steps" consist of basic elements that serve as the starting point for countries initiating the diagnosis and treatment of MDR-TB. Once a country's minimum essential elements are in place, the "Next steps" are recommended for phase-in. However, at any step in a country's path toward universal access, the country may choose elements from the "Next steps" that it judges to be high priority and feasible to implement.¹

Ambulatory MDR-TB care is listed as a "First step" (see row 1C.8). While listed in section 1C of the checklist, all the other components of the Stop TB Strategy are needed to support an ambulatory model, so you will see that community-based care is integrated into the rest of the checklist. If countries plan an initial hospitalization, one challenge is how to bridge the gap when the patient is

WHO recommends that patients with MDR-TB be treated using mainly ambulatory care, rather than models based principally on hospitalization.¹ Ambulatory MDR-TB treatment may occur in a health facility near the patient's residence, in the patient's home, or other location convenient to the patient.

¹ For scale-up, countries can also set higher targets for any "First step" element to expand coverage of services and/or improve their quality.

ready to return to the community. For this stage of the planning process, the planning team should describe the current and desired model of care, depending on the country's health system, geographic access, patient preferences, and regulatory issues regarding the training, skills, and responsibilities of health care staff and community workers.¹¹

The elements in this checklist are abbreviated as short phrases. In Annex C, you will find a more detailed version called the **MDR-TB Essential Elements Reference List**, which includes citations to WHO recommendations, applicable global targets, and indicators for most elements. Many of the indicators for the essential elements are based on data that countries are already asked to report to WHO on their annual data collection form.¹⁶ Annex C also includes cross-references, since many essential elements are linked or could be categorized under more than one component of the Stop TB strategy.

The checklist is limited to elements necessary for the detection and treatment of drug-resistant TB. Since it is designed to fit into an overall national TB strategy, this toolkit assumes the rest of the country's TB plan will cover all other TB-related elements. (Other tools are available to help assess the overall TB situation.²⁴⁻²⁶)

Instructions for Worksheet 3: Checklist of Essential Elements to Address MDR-TB

Note: Worksheet 3 follows the instructions and sample checklist.

1. Starting with the first component of the Stop TB Strategy (section 1A of the checklist), fill out each row of the "First steps" with the following:
 - Targets (column 2), using national or regional targets.⁵⁻⁹ Otherwise, you can fill in global targets where available from the MDR-TB Essential Elements Reference List in Annex C.
 - Country's current performance (column 3), using the most recent data available from national, WHO,^{14-16,27} or other sources (such as mission reports).
 - Gaps (column 4), by subtracting current country performance (column 3) from the target (column 2).
 - Check off (tick) any element where there is no performance gap (i.e., the target is already met).
2. Now look at the "Next steps" for this component of the Stop TB Strategy. Circle any rows that you think this round of planning should address. For the "Next steps" you have circled, repeat the bulleted steps above.
3. Repeat steps 1 and 2 for each of the remaining components of the Stop TB Strategy in the checklist.

Checklist of Essential Elements to Address MDR-TB—Sample

In the sample checklist below, WHO targets have been filled in for two essential elements, as have data on the current performance of Country A (a hypothetical country). By subtracting the current performance from the target, you can see which gaps remain. The first element has been achieved (shown by a checked or ticked box), so it may not need to be explored further.^m The second element shows a large gap and might be prioritized (see Tool 4) for further exploration (see Tool 5).

	1. Essential elements	2. Target	3. Current performance	4. Gap (target minus current performance)
<input checked="" type="checkbox"/>	Laboratory capacity to detect isoniazid and rifampicin resistance	1 drug susceptibility testing (DST) laboratory per 5 million population	2 DST laboratories in a country of 10 million population (2009)	None
<input type="checkbox"/>	MDR-TB testing for all previously treated patients	100% of previously treated patients have MDR-TB testing performed (1,000 patients)	10% had MDR-TB testing (2009) (100 patients)	90% (900 patients)

Note: In the sample above, the first row is from element –5” (–First step”) and the second row is element –a” (–Next step”), both under Stop TB Strategy component 1B: Early case detection.

Countries should tailor the checklist to meet their needs. Options include: Revise the wording of an essential element (in the first column) to fit the country situation; add rows and insert any additional elements deemed essential by your team; organize the checklist rows and/or Stop TB Strategy important recent mission recommendations to address particular gaps.

^m If, by contrast, the two laboratories in Country A are located far from the patients needing MDR-TB testing, then the planning team would describe the gap in column 4 (for example, “No system to transport specimens to the laboratories”). The box in column 1 would not be checked off, and the gap might be prioritized for further exploration.

Worksheet 3: Checklist of Essential Elements to Address MDR-TB

Checklist of Essential Elements to Address MDR-TB (For more details, see Annex C.)		Target	Current performance	Gap
1. High-quality DOTS				
1A. Political commitment with adequate, sustained financing				
First steps				
<input type="checkbox"/>	1. MDR-TB scale-up plan and budget endorsed by the government			
<input type="checkbox"/>	2. Broad participation in planning process, including community representatives			
<input type="checkbox"/>	3. Adequate financing and sustainability			
<input type="checkbox"/>	4. Designated individuals responsible for MDR-TB services at central, regional, local levels			
<input type="checkbox"/>	5. MDR-TB care free of charge			
<input type="checkbox"/>	6. Consistency with WHO ethics of TB prevention, treatment, and care			
1B. Early case detection and diagnosis through quality-assured bacteriology				
First steps				
Detect MDR among TB cases				
<input type="checkbox"/>	1. Policy and standard operating procedures for MDR-TB case-finding			
<input type="checkbox"/>	2. MDR-TB testing in patients whose TB treatment is failing			
<input type="checkbox"/>	3. Household contacts of MDR-TB patients (including children) evaluated to find additional TB cases (and if so, perform MDR-TB testing)			
Optimize laboratory network and performance				
<input type="checkbox"/>	4. Adequate capacity and external quality assessment (EQA) performance in identifying <i>M. tuberculosis complex</i>			
<input type="checkbox"/>	5. Adequate capacity and EQA performance in detecting resistance to rifampicin and isoniazid			
<input type="checkbox"/>	6. Results reported to treatment center as soon as available			
<input type="checkbox"/>	7. National Reference Laboratory (NRL) regularly quality-controlled by Supranational Reference Laboratory			
<input type="checkbox"/>	8. Rapid, reliable, safe system to collect specimens from the patient and to transport and refer specimens to the appropriate laboratory			
<input type="checkbox"/>	9. Continuous supply of quality reagents and consumables			
<input type="checkbox"/>	10. Appropriate biosafety measures in place			
Next steps				
MDR-TB testing at start of treatment (or retreatment) for:				

Checklist of Essential Elements to Address MDR-TB		Target	Current performance	Gap
<input type="checkbox"/>	a. All previously treated cases			
<input type="checkbox"/>	b. New TB patients who are HIV positive			
<input type="checkbox"/>	c. Additional groups defined as high priority			
<input type="checkbox"/>	d. All new patients			
	MDR-TB testing during treatment of:			
<input type="checkbox"/>	e. Previously treated patients who remain smear-positive at month 3 of treatment			
<input type="checkbox"/>	f. New patients who remain smear-positive at month 3 of treatment			
	Other case-finding measures:			
<input type="checkbox"/>	g. Clinical follow-up of household contacts			
<input type="checkbox"/>	h. Detect fluoroquinolone and injectable drug resistance (extensively drug-resistant tuberculosis)			
<input type="checkbox"/>	i. Use of rapid tests to detect MDR-TB			
<input type="checkbox"/>	j. Use of liquid medium with rapid species identification			

1C. Standardized treatment and care with supervision and patient support				
First steps				
<input type="checkbox"/>	1. National guidelines on drug-resistant TB			
<input type="checkbox"/>	2. Policy and procedures for enrollment into treatment			
<input type="checkbox"/>	3. Confirmed MDR-TB cases start treatment right after diagnosis			
<input type="checkbox"/>	4. Initial evaluation and periodic monitoring for adverse effects			
<input type="checkbox"/>	5. Management of side effects			
<input type="checkbox"/>	6. Bacteriologic monitoring during treatment			
<input type="checkbox"/>	7. Directly observed therapy			
<input type="checkbox"/>	8. Procedures for ambulatory MDR-TB care (in the home, outpatient clinic, or other convenient location) are implemented, and specify: <ul style="list-style-type: none"> • Roles and responsibilities for providers at each level (see 1A.4) • Mechanisms for timely two-way communication between community providers and specialized center providers • Mechanisms to ensure that second-line drugs (SLDs) for each patient's full treatment course are uninterrupted (see 1D) • Recording and reporting by facility and treatment supporter (see 1E) • Identification, training, supervision, and compensation for community treatment supporters (see 3A) • Infection control (see 3B) 			
<input type="checkbox"/>	9. Socioeconomic and psychological factors identified and addressed (including incentives, enablers)			
<input type="checkbox"/>	10. Patients who miss appointments are promptly retrieved			
<input type="checkbox"/>	11. System to transfer patients (such as hospital discharge to ambulatory care in their community)			
<input type="checkbox"/>	12. Hospitalization if acute level of care is needed			
<input type="checkbox"/>	13. Expert committee routinely provides clinical and programmatic consultation			

Checklist of Essential Elements to Address MDR-TB	Target	Current performance	Gap
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<input type="checkbox"/>	14. Care of MDR-TB patients not receiving treatment, including palliative and end-of-life care			
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Next steps				
<input type="checkbox"/>	a. Policy on empiric MDR-TB regimens ⁿ			
<input type="checkbox"/>	b. Treatment of mono- or poly-drug resistance patterns			
<input type="checkbox"/>	c. MDR-TB Center of Excellence			
<input type="checkbox"/>	d. Surgical interventions are available			

1D. Effective drug supply and management				
First steps				
<input type="checkbox"/>	1. Accurate forecasting of SLD needs			
<input type="checkbox"/>	2. SLDs meet WHO quality standards			
<input type="checkbox"/>	3. SLDs procured to provide regular delivery of adequate quantities			
<input type="checkbox"/>	4. Distribution system from central to peripheral levels ensures SLDs available for complete treatment of all identified MDR-TB patients			

Next steps				
<input type="checkbox"/>	a. TB medications are available by prescription only			
<input type="checkbox"/>	b. Electronic drug management system			

1E. Monitoring and evaluation (M&E), supervision				
First steps				
<input type="checkbox"/>	1. WHO formats for recording and reporting of MDR-TB cases used at district, provincial, and central levels			
<input type="checkbox"/>	2. Data analyzed and used to improve performance of MDR-TB diagnosis and treatment			
<input type="checkbox"/>	3. Supportive supervision improves MDR-TB services at each level			
<input type="checkbox"/>	4. MDR-TB component in NTP's M&E plan, external monitoring			

Next steps				
<input type="checkbox"/>	a. Surveillance of drug resistance in previously treated patients			
<input type="checkbox"/>	b. Continuous surveillance of drug resistance in new TB patients (or at least a drug resistance survey in the past 3 to 5 years)			
<input type="checkbox"/>	c. Cross-checking of laboratory and MDR-TB registers, data quality			
<input type="checkbox"/>	d. Analysis of HIV and MDR-TB concurrence			
<input type="checkbox"/>	e. Analysis of delays in treatment initiation, deaths while waiting			
<input type="checkbox"/>	f. Full drug resistance patterns of a recent MDR-TB cohort			

ⁿ For certain patients while awaiting confirmation of MDR-TB (if laboratory methods are not rapid).

Checklist of Essential Elements to Address MDR-TB	Target	Current performance	Gap
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<input type="checkbox"/> g. Electronic case-based database			
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2. Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations

2A. TB/HIV activities

First steps

<input type="checkbox"/>	1. MDR-TB patients know their HIV status			
<input type="checkbox"/>	2. HIV-positive MDR-TB patients begin antiretroviral therapy as soon as possible			
<input type="checkbox"/>	3. HIV-positive MDR-TB patients begin cotrimoxazole			
<input type="checkbox"/>	4. HIV-positive MDR-TB patients receive HIV care and support			

Next steps

<input type="checkbox"/>	a. HIV testing, counseling offered to possible MDR-TB cases			
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2B. MDR-TB: *These elements are distributed across the relevant Stop TB Strategy components.*

2C. Address the needs of TB contacts and of poor and vulnerable populations

First steps

<input type="checkbox"/>	1. Prisons linked to NTP for MDR-TB diagnosis, reporting, and care			
<input type="checkbox"/>	2. MDR-TB diagnosis and treatment in other identified vulnerable populations			

Next steps

<input type="checkbox"/>	a. Evaluate whether access to MDR-TB diagnosis and treatment is equitable (i.e., accessible to subgroups such as migrants, rural residents, etc.).			
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3. Contribute to health system strengthening

3A. Human resource (HR) development

First steps

<input type="checkbox"/>	1. Focal person responsible for MDR-TB HR development			
<input type="checkbox"/>	2. Assessment of HR requirements for MDR-TB services (including decentralized care in the community)			
<input type="checkbox"/>	3. Gaps in numbers of staff with requisite skills are defined for each level of the health system			
<input type="checkbox"/>	4. Plan for staffing, training, supervision, and support at each level			
<input type="checkbox"/>	5. Key staff in the needed categories are available at each level			
<input type="checkbox"/>	6. Key staff recently trained on drug-resistant TB			

Next steps

<input type="checkbox"/>	a. HR development plan for MDR-TB scale-up is monitored			
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Checklist of Essential Elements to Address MDR-TB	Target	Current performance	Gap
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3B. TB infection control (IC)			
First steps			
Implement managerial measures			
<input type="checkbox"/>	1. A national TB IC plan addresses settings where care is provided to patients with known or possible MDR-TB		
<input type="checkbox"/>	2. Facilities providing care to MDR-TB patients have IC assessment		
<input type="checkbox"/>	3. In priority ^o facilities, focal person develops and implements facility-specific IC plan		
Implement administrative controls			
<input type="checkbox"/>	4. Triage in health facilities of patients with known or possible infectious TB; implement cough etiquette, separation		
<input type="checkbox"/>	5. If infectious MDR-TB patients hospitalized, precautions to prevent airborne transmission		
<input type="checkbox"/>	6. In the household, infectious MDR-TB patients are advised to sleep in a separate room, practice cough hygiene, and minimize contact with infants, children, and people living with HIV		
<input type="checkbox"/>	7. Health workers and treatment supporters trained; HIV testing encouraged		
<input type="checkbox"/>	8. Health workers or treatment supporters with TB symptoms undergo TB diagnostic evaluation		
Implement environmental controls			
<input type="checkbox"/>	9. Natural ventilation maximized where possible in health facilities		
<input type="checkbox"/>	10. Natural ventilation maximized in household rooms where infectious MDR-TB patients spend time		
Implement respiratory protection programs			
<input type="checkbox"/>	11. Health workers and treatment supporters use approved respirators when caring for MDR-TB patients during the time the patients are known or thought to be infectious		
<input type="checkbox"/>	12. Respiratory protection program includes training, fit testing, and sufficient quantities of approved respirators		

Next steps			
<input type="checkbox"/>	a. TB IC policy is part of the country's overall IC policy		
<input type="checkbox"/>	b. National surveillance of TB disease among health workers		
<input type="checkbox"/>	c. Adequate ventilation of patient care areas in health facilities		
<input type="checkbox"/>	d. Supervision of IC measures at the community and household levels		

4. Engage all providers

First steps

^o Countries will prioritize settings depending on the findings of the risk assessments. Higher priority should be given to settings where TB is drug resistant, exposed people are especially vulnerable to developing disease if infected or dying if they develop TB (such as people living with HIV), exposure is of longer duration (due to diagnostic delays or inpatient care), control measures are lacking, or a large number of people are exposed. During the scale-up process, additional settings may be added to the priority list and additional infection control measures may be phased in.

Checklist of Essential Elements to Address MDR-TB	Target	Current performance	Gap
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<input type="checkbox"/> 1. Non-NTP providers linked to NTP for MDR-TB diagnosis, treatment			
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Next steps			
<input type="checkbox"/> a. NTP captures source of MDR-TB patient referral			
<input type="checkbox"/> b. Cohort analysis of MDR-TB patients treated outside the NTP			
<input type="checkbox"/> c. Laboratories outside the NRL network report drug resistance results			

5. Empowerment of people with TB and communities

First steps			
<input type="checkbox"/> 1. MDR-TB patients provided high-quality patient-centered care per the Patients' Charter ²⁸			
<input type="checkbox"/> 2. Community-based DOTS providers support MDR-TB patients via ¹¹ : <ul style="list-style-type: none"> • Reimbursement for transportation costs • Food packages • Rental housing near the hospital or clinic for patients who live in remote areas, need to be monitored closely, or do not have the necessary family support • Opportunities to participate in support groups • Access to income-generating activities 			

Next steps			
<input type="checkbox"/> a. Involvement of community leaders to address community-wide issues such as stigma toward drug-resistant TB patients			
<input type="checkbox"/> b. MDR-TB is included in the country's advocacy, communication, and social mobilization strategy			

6. Research

Next steps			
<input type="checkbox"/> a. Research agenda includes MDR-TB			
<input type="checkbox"/> b. Operational research results used to improve MDR-TB services			

Tool 4: Prioritize gaps

Once you have determined the gaps in the country's current coverage of MDR-TB services using Worksheet 3, you will need to prioritize them.^P The Set Priorities worksheet will help your planning team come to a consensus on the answer to this question:

- Which are the most important gaps to address first?

Instructions for Worksheet 4: Set Priorities

Have your completed Checklist of Essential Elements to Address MDR-TB (from Tool 3) ready.

1. **Column A** of Worksheet 4: Enter the row numbers from the checklist and key words of any essential element that has not yet reached its target (or been checked off). Label each one with the number of the corresponding component of the Stop TB Strategy and the number or letter of the row from the checklist.

To prioritize this list of elements, you will focus on the public health impact of each performance gap and the feasibility of addressing these gaps.

2. **Column B:** For each element, consider the **public health impact** of the gap.

- How big is the gap?
- How significant is the gap in terms of survival, quality of life, and community health?

Describe how the group answered these questions. Assign the number 0 for the smallest impact, 1 for medium-sized impact, and 2 for greatest impact.

3. **Column C:** Consider the **feasibility** of the needed interventions.

- Is there an intervention that works? Has it been shown to be effective in similar settings?
- Is the intervention feasible to implement?
- Is it a wise and efficient use of resources? (A good value for money?)
- Is it the logical next step?

^P Some planning teams may want to set priorities after analyzing the causes of their country's gaps (see Tool 5).

- Is there an agency, partner, or organization that can take responsibility for this activity?

Describe how the group answered these questions. Assign the number 0 if the intervention is not feasible at all, 1 if it is possibly feasible, and 2 if it is very feasible.

4. **Column D:** Add up the numbers in columns B and C. The rows with the highest numbers in column D are the highest-priority gaps for the planning team to consider.
5. Pull out the top-ranked 10 to 15 essential elements. Display them in order from highest to lowest number in column D.
6. Discuss and reach consensus about these questions:
 - Does this ranking match the planning team’s judgment of highest priorities?
 - Should any elements be combined or split?
 - Should any elements be moved up or down the ranking?
 - How many performance gaps do you want to address in this round of the planning process?

Worksheet 4: Set Priorities

A. Essential element Row number from Worksheet 3 (by Stop TB Strategy component)	B. Public health impact of the gap		C. Feasibility of intervention to address the gap		D. Total (B + C)
	Describe	0: Small, not very significant 1: Medium impact 2: Large, significant impact	Describe	0: Not feasible 1: Feasible 2: Very feasible	

(Add lines as needed.)

Note: The planning team may choose to prioritize gaps within each Stop TB Strategy component or across all components.

Tool 5: Design activities to address priority gaps

Once you have decided which performance gaps are the highest priority, analyzing them in more depth will help you design activities to address them. The worksheet in this tool will help you consider these questions:

- Why do the gaps exist?
- What are the causes of each gap?
- What should be done to address the causes?
- Who (which organization) is most appropriate to take responsibility for conducting activities to fill the gap?

Worksheet 5 presents a simple approach to analyzing the gaps you have prioritized.⁹ When you have finished, you will have designed interventions to address each of your priority gaps, and your activities will be directly tied to the causes of these gaps. Each of the tables you create can become a page of your plan. (See the sample plan outline on page 5).

Instructions for Worksheet 5: Design Activities to Address Gaps

Note: The numbers in these instructions correspond to the numbers in the boxes of Worksheet 5 and the sample worksheet below.

You will need completed Worksheets 3 (Checklist of Essential Elements to Address MDR-TB) and 4 (Set Priorities). Create a separate copy of Worksheet 5 for each priority gap listed in Worksheet 4. Fill in each worksheet as follows:

1. Enter the number and key words for the Stop TB Strategy component and the element (row) number from Worksheet 3 (which you listed in row A of Worksheet 4).
2. To analyze the gap, complete the diagram.
 - a. First, fill in the top box (a) with the gap by copying it from column 4 of Worksheet 3. Box (a) should answer, “What is the gap?”
 - b. Next, think about **why** the gap exists. What are the causes of the gap? What are the barriers to achieving the desired result? List those in the boxes in row b.

⁹ There are many approaches your team could use, including the “Cough to cure pathway,”²⁹ the “Onion” model for TB case detection and notification,³⁰ or such methods as the “Why Tree” or “Fishbone diagram,”³¹ quality improvement including the Plan-Do-Study-Act cycle,³² root cause analysis,³³ systems thinking,³⁴ or operational research studies.³⁵

- c. For each cause of the problem, delve a level deeper to consider why these problems exist. List the main obstacles in the boxes in row c below the corresponding cause.

Add more levels (and/or more boxes in each level) to get to the “roots” of each problem.

3. Draft the problem statement to include:

- A description of the gap. Use any data you have to make it specific. (See Worksheet 3.)
- Information about why you have prioritized the gap based on magnitude (from the corresponding row in Worksheet 3) and its public health impact and the feasibility of intervening (from Worksheet 4).
- A summary of your analysis describing the causes of the gap (from the diagram in Worksheet 5).

4. Design activities to fill in the table at the bottom of Worksheet 5.

Look at the root causes you identified in the diagram and described in the problem statement. Consider which root causes are feasible to address. (See Worksheet 4 instructions for feasibility considerations.) Then design activities to address those root causes that are amenable to intervention (i.e., those that you can do something about). Each activity should be specific enough so it is clear:

- What needs to happen by when.
- How to budget for the activity.
- What the implementer will be accountable for accomplishing.

In addition to being feasible, activities should be locally appropriate, equitable,[†] and based on evidence (if available) for effectiveness and sustainability. Be sure to include:

- Activities of all partners and government agencies (in and outside of the MOH) that address the identified causes.
- Any needed technical assistance, which can come from within the country, the region, or internationally.³⁶ (These technical assistance activities can be pulled out to create a technical assistance plan.)

5. Propose a lead organization to implement each activity. (After the draft plan is compiled, you will then need to follow the steps you described in Worksheet 1B to secure these commitments.)

[†] Equitable means the interventions are appropriate to improve the health of the most vulnerable and ensure access to those with greatest need.²

Once a worksheet is completed for each priority gap, the planning team should review them together to identify and resolve any areas of overlap or missing activities. Each worksheet's planned activities should contribute toward achieving one of your plan's objectives, which Tool 6 will help you develop.

Sample Worksheet 5: This is not a thorough analysis; sections are partially completed for illustration purposes only.

1. Stop TB Strategy component #1B. Early case detection. Essential element #1B.a. MDR-TB testing of previously treated patients	
2. Gap analysis diagram	
3. Problem statement: In 2010, 90 percent of the country's 1,000 previously treated patients had no MDR-TB testing at the time of registration. The recent drug resistance survey found MDR-TB in 25 percent of retreatment patients, which means more than 200 MDR-TB cases (900 x 0.25) may have been missed (<i>magnitude</i>). Without diagnosis and proper treatment, these patients face a high risk of mortality, and their communities face the risk of ongoing spread of MDR-TB (<i>public health impact</i>). The main cause of low MDR-TB testing coverage of this high-risk group of patients is poor access to MDR-TB testing. Patients have to travel to the capital city to provide sputum for MDR-TB testing (<i>list additional causes</i>). This cause can be feasibly addressed by revising MDR-TB case-finding guidelines and improving specimen transport (<i>amenability to intervention</i>).	
4. Activities	5. Proposed lead implementer
By 2013, revise MDR-TB case-finding guidelines to include all previously treated TB patients.	National TB program
By 2013, contract with a national courier agency to transport sputum specimens to the MDR-TB testing laboratory.	National reference laboratory

Worksheet 5: Design Activities to Address Gaps

1. Stop TB Strategy component # ___ (key words)_____ Essential element # ___ (key words)_____	
2. Gap analysis diagram	
<pre> graph TD A[a.] --- B1[b1.] A --- B2[b2.] A --- B3[b3.] B1 --- C11[c1.1.] B1 --- C12[c1.2.] B2 --- C21[c2.1.] B2 --- C22[c2.2.] B3 --- C31[c3.1.] B3 --- C32[c3.2.] </pre>	
3. Problem statement:	
4. Activities	5. Proposed lead implementer

Make copies of this blank worksheet so you have a separate worksheet to fill out for each of your prioritized gaps.

Tool 6: Finalize objectives

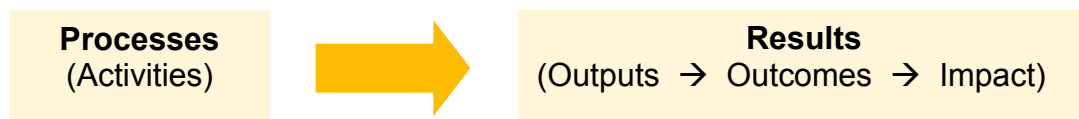
Now that you have designed activities to address your highest-priority performance gaps, you can construct a framework to help you determine if these activities will be sufficient to reach the preliminary targets you set with Tool 2. Then you can finalize your objectives and set yearly targets.

There are three worksheets in this tool: **6A: Results Framework**, **6B: Objectives**, and **6C: Interim Targets During the Life of the Plan**. They will help you answer these questions:

- Will planned activities lead to desired results?
- How will results be measured?
- How much will be accomplished each year?

The Results Framework

Planning should set in motion a sequence of events leading to the desired results.^{17,37}



The *processes* are the activities used to achieve the desired results. The *results* can be immediate/short-term (also called outputs), medium-term (outcomes), or long-term (impact). The short-term results should contribute to the medium-term results, which should contribute to the long-term impact. For example, an activity might include training laboratory staff. This, in turn, will lead to results, such as increased MDR-TB testing of patients (output), which will lead to increased detection of MDR-TB (outcome) so patients can be treated, thus reducing the spread or burden of MDR-TB (impact).^{18,38}

A Results Framework (see Worksheet 6A) shows the causal pathways that lead to the desired impact. Think of this as the logic that underpins the plan (hence the term “logic model”). The Results Framework is also called a monitoring and evaluation (M&E) framework, since it can also be used to manage the implementation process.^{17,37,38}

Here is one way to describe a hierarchy of desired results for addressing MDR-TB:

- **Outputs:** Improved testing (in order to detect MDR-TB) and enrollment of those found to have MDR-TB (so they can be successfully treated).
- **Outcomes:** Improved detection and successful treatment of MDR-TB cases.¹³ These are comparable to the familiar outcome measures of TB case detection and treatment success.
- **Impact:** Reduced burden of drug-resistant TB¹³ in order to save lives and protect communities.¹²

Instructions for Worksheet 6A: Results Framework

Use the worksheet that follows these instructions to develop your Results Framework and check that the planned activities will indeed lead to the target outputs and outcomes and desired impact. You may find you need to revise some of your activities or targets.

1. Under the rows labeled outputs and outcomes, replace “20xx” with the baseline year and final year of the plan.
 - To fill in the targets and baselines for boxes 2.1, 2.2, and 3.2, see the corresponding cell letters in Worksheet 2A.
 - To fill in the targets and baselines for box 3.1:
 - If you used Worksheet 2B, see cell N for baseline and cell Q for target.
 - If you used Worksheet 2C, see cell O + Q for baseline and cell R + S for target.
2. Fill in the main activities you designed in Tool 5, organized by the sections of your national TB strategy (or Stop TB Strategy components as shown in Tool 3).
 - In the top of the Activities column, list the main activities that will contribute to MDR-TB testing.
 - In the middle of the Activities column, list the main activities that will help your country enroll MDR-TB cases into treatment.
 - Fill in the main activities in the “cross-cutting” rows along the bottom of Worksheet 6A. These are the activities that will contribute to both MDR-TB case-finding and treatment and, in fact, are necessary to support both. Examples include other components of the Stop TB Strategy, such as political commitment (component 1A), monitoring (component 1E), health system strengthening (component 3), engaging all providers (component 4), and empowering communities (component 5).
3. Look at the Results Framework.
 - Start with the top row (MDR-TB detection) and consider if the activities lead to improved MDR-TB case detection. Check the causal links to be sure that the activities will lead to more MDR-TB testing (the output), which will improve MDR-TB case detection (the outcome).

- For the middle row of the Results Framework (MDR-TB treatment), consider if the activities will lead to improved enrollment in MDR-TB treatment (the output), and then lead to successful MDR-TB treatment (the outcome).
- Now consider the framework as a whole. If the main activities are fully implemented, will they be sufficient for achieving your targets? If not, you will need to augment the activities and/or lower the targets. On the other hand, you may find that your preliminary targets were not sufficiently ambitious and need to be revised upward.

Note: The Results Framework should be tailored to fit your country's situation and planning process. You can add more output or outcome targets, including those in your national TB strategy, the Global Plan 2011–2015¹³ (see last column of Annex C), or your WHO region's MDR-TB response plan.^{5–9} You can add rows or make a separate Results Framework for decentralization of care to the community,⁸ for preventing acquired drug resistance among TB patients undergoing treatment with first-line medicines, or for offering HIV testing and, if positive, submitting specimens for MDR-TB testing and starting antiretroviral therapy.

Worksheet 6A: Results Framework

Under outputs and outcomes, the numbers (i.e., 2.1, 3.1) correspond to the numbers in Worksheet 6B, and the letters correspond to cells from Worksheet 2A.

	4. Activities ^s	3. Outputs	2. Outcomes	1. Impact
MDR-TB detection	Stop TB Strategy component 1B	3.1. TB patients tested for MDR-TB ^t	2.1. MDR-TB cases notified	Decreased burden of MDR-TB
		Baseline: __ (20xx)	Baseline: __B (20xx)	
		Target: __ (20xx, final year of plan)	Target: __H* (20xx, final year of plan)	
MDR-TB treatment	Stop TB Strategy component 1C	3.2. MDR-TB patients starting treatment (enrolled)	2.2. MDR-TB cases successfully treated ^u	
	Stop TB Strategy component __	Baseline: __D (20xx)	Baseline: __F% (20xx)	
		Target: __J* (20xx, final year of plan)	Target: __L% (20xx, final year of plan)	
Cross-cutting	Stop TB Strategy component __			
	Stop TB Strategy component __			

*Since all confirmed MDR-TB cases need to be treated, these targets should be the same number of MDR-TB patients.

^s This worksheet organizes activities by Stop TB Strategy components as they apply to MDR-TB (see Tool 3). You can replace these with the sections of your national TB strategy.

^t If you used Worksheet 2B, see cell N for baseline and cell Q for target. If you used Worksheet 2C, see cell O + Q for baseline and cell R + S for target.

^u Final treatment outcomes will be available for a cohort of MDR-TB patients who started treatment three years earlier when the plan was not fully implemented or one year before (if a surrogate indicator is used, such as sputum culture conversion at six months). (See Annex C, section 1C.)

Overview of Worksheet 6B: Objectives

This worksheet will help you translate the targets you just finalized into the language of formal objectives so they are ready to insert into your plan. The last column of Worksheet 6B contains language you can use to turn each target from Worksheet 6A into an objective that is SMART:

- **Specific**
- **Measurable**
- **Achievable**
- **Relevant**
- **Time bound** (i.e., by specifying a due date)

The output and outcome objectives use standard indicators from the Global Plan 2011–2015¹³ to allow you to measure your country's performance. On its annual data collection form,¹⁶ WHO asks countries to report all the outcome and output indicators listed in Worksheet 6B. Citations for each indicator appear in column 2 of the MDR-TB Essential Elements Reference List in Annex C.

Instructions for Worksheet 6B: Objectives

Have completed Worksheets 2A, 6A, and either 2B or 2C ready. Fill out Worksheet 6B accordingly:

Column 2 of each box: Replace 20xx with the correct baseline year for each row.

Column 3 of each box: Replace 20xx with the final year of the plan (same for all rows).

Box 1: Impact objective (Goal). A two- or four-year plan may be too short a time frame in which to measure the epidemiologic impact of your activities on the burden of MDR-TB. Furthermore, quantifying the ultimate desired impact is challenging. To be useful as management tools as well as for performance-based funding (i.e., the Global Fund), objectives need to be based on indicators that are measurable.¹⁷ This toolkit uses the percentage of new patients with multidrug resistance,^v which is directly measurable by countries that conduct population-based drug resistance surveys or surveillance.³⁹ The occurrence of MDR-TB in a new TB patient is a warning sign that there has been an infectious MDR-TB case in the community. The larger the number of untreated MDR-TB cases in the community, the more

^v The Global Plan 2011–2015¹³ proposes using declining MDR-TB incidence as an impact indicator. However, most countries cannot directly measure this indicator, and WHO provides these estimates only periodically.²¹ An alternative measure of impact is the proportion of previously treated patients with multidrug resistance.⁵ If there is representative and accurate surveillance of MDR-TB,⁴⁰ then the number of notified MDR-TB cases per 100,000 population (MDR-TB notification rate) may also be a useful impact measure.²⁷

infectious sources for spreading MDR-TB and the more people who will become ill with MDR-TB. For this reason, the percentage of new patients with multidrug resistance can be considered a measure of the burden of MDR-TB in a country.⁵

- In row 1, column 2 of the worksheet, write the baseline percentage of new TB patients with MDR-TB from the most recent drug resistance survey or model. (WHO posts these online for every country.¹⁵)
- Determine how much you aim to lower this percentage to reach the target for the final year of your plan.^w Insert this in column 3.

Box 2: Outcome objectives.

- Fill in the blanks by copying the numbers and percentages from the corresponding cells in Worksheet 2A. Each letter in this section refers to a cell in Worksheet 2A.

Box 3: Output objectives.

- **TB patients tested for MDR-TB:** Annex D shows which cells from Worksheet 2B or 2C you can use.
- **MDR-TB patients enrolled in treatment:** Fill in the blanks by copying the numbers and percentages from the corresponding cells in Worksheet 2A. Each letter in this section refers to a cell in Worksheet 2A. The number of MDR-TB cases to be treated in row 3.2 should be the same as that in 2.1, since all diagnosed MDR-TB patients need to be started on treatment.

You can use the same format to write objectives for any other targets you have included in Worksheet 6A.

^w To assess impact at the end of your plan, you would need to have continuous surveillance of MDR-TB in new TB patients or conduct another drug resistance survey.

Worksheet 6B: Objectives

The uppercase letters refer to the cells in Worksheet 2A. The numbers of the objectives in the last column correspond to the boxes in Worksheet 6A. The denominators for calculating percentages are designated by gray-shaded areas (■).

1. Impact indicator	Baseline (20xx)	Impact objective (Goal)
New TB patients with MDR-TB	___%	1. In the final year of this plan (20xx), less than ___% of new TB patients will be found to have multidrug resistance.

2. Outcome indicators	Baseline (20xx)	Outcome objectives
MDR-TB cases notified	___B (#) ___C%	2.1. In the final year of the plan (20xx), at least ___(H) MDR-TB cases will be notified. This is ___(I) % of the ■(A) estimated MDR-TB cases among TB cases notified that year. ^x
MDR-TB cases successfully treated	___F%	2.2. In the cohort starting treatment in the final year of this plan (20xx), at least ___L% of notified MDR-TB cases will be successfully treated. ^y

3. Output indicators	Baseline (20xx)	Output objectives
TB patients tested for MDR-TB ^z	___%	3.1. In the final year of the plan (20xx), at least ___ TB patients will have MDR-TB testing. This is ___% of the ■ TB cases expected to be notified that year.*
MDR-TB patients enrolled in treatment	___D (#) ___E%	3.2. In the final year of this plan (20xx), at least ___(J) confirmed MDR-TB cases will be enrolled (start) on MDR-TB treatment. This is 100% of the ■(H) MDR-TB cases that will be detected in that year.

*It is difficult to estimate the number of TB notifications in the final year of the plan. For simplification, this assumes the same number as in the baseline year.

^x If the reported TB incidence is expected to change, you can make an estimate for the final year of the plan (and provide a rationale).

^y Since this target cannot be measured until three years after the cohort begins treatment, a surrogate (e.g., conversion at 6 or 12 months) can be used instead. (See Annex C, section 1C.)

^z Annex D shows which cells from Worksheet 2B or 2C you can use to fill in the blanks in this row.

Instructions for Worksheet 6C: Interim Targets During the Life of the Plan

Now that you have set the final targets for your MDR-TB plan, you can set interim targets for each year leading up to the final year. (Later, some implementing agencies may want to set even shorter-term targets, such as for a quarterly work plan.)

1. Display the years your plan encompasses in the table below. To do this, replace “20xx” with the actual years of your plan. (See the example below of a four-year plan.)
2. Refer to the objectives you set in Worksheet 6B for outcomes and outputs. List each of these under objectives. (Add rows as needed.)
3. For each objective, look at the timing of the planned activities to determine how much can be accomplished each year in order to reach the final year’s target.

Example: A planning team reviewed the activities planned for laboratory scale-up and determined it was feasible to increase testing of previously treated TB patients in order to improve MDR-TB case detection. The team set its targets as:

Objective	Baseline			Targets			
	Performance	Year	Data source	2013	2014	2015	2016
By 2016, 80% of previously treated patients notified each year have MDR-TB testing at the start of retreatment.	100 tested of 1,000 previously treated notifications = 10%	2011	TB notifications, laboratory	250 (25%)	400 (40%)	700 (70%)	800 (80%)

Worksheet 6C: Interim Targets During the Life of the Plan

Objective	Baseline			Targets			
	Performance	Year	Data source	20xx	20xx	20xx	20xx

Monitoring MDR-TB scale-up should be part of your country’s overall monitoring and evaluation plan and consistent with the applicable regional MDR-TB response plan.^{5–9} Guidance for developing such a plan is available from the Global Fund and WHO.^{17–19,37,38} See also indicators and citations listed in column 2 of the MDR-TB Essential Elements Reference List (Annex C).

Tool 7: Resources for implementation

Now that you have developed or revised your MDR-TB plan, it is critical to secure adequate resources for implementation. This tool will help you address the following questions:

- How much will it cost to implement each activity?
- Who will take responsibility for implementing which activities?
- Where will the resources come from?
- How could existing resources be optimized to support this plan?
- How will resources be mobilized to fill any funding gaps?

The **Financial Gap Analysis Worksheet** will help you develop the budget and identify commitments and resources needed (both financial and human). Before you complete this worksheet, review the steps you listed for securing commitments in Tool 1. (See section C of Worksheet 1A, as well as Worksheet 1B.)

If the plan is ambitious in meeting the country's needs, budgeting will likely show a funding gap (column F of Worksheet 7 below). This gap can be filled by a combination of optimizing existing resources and mobilizing additional resources (see examples in boxes 1 and 2 below). It usually takes advocacy to accomplish either one. Therefore, the plan should include activities to advocate for needed policy changes or to mobilize the needed resources. There may not be time during the planning process to develop a full-fledged advocacy strategy,⁴¹ but identifying ways to optimize existing resources and/or mobilize new ones are important first steps.

Box 1. Examples of optimizing existing TB resources

- Expand ambulatory treatment (decrease hospitalization).
- Evaluate the cost-effectiveness of current TB practices. Compare costs and benefits of alternatives, such as procuring second-line drugs through the Global Drug Facility if local manufacturers are not yet quality-assured. Other examples include stopping unnecessary tests or procedures.
- Shift or share tasks with ancillary health care workers or trained community workers (e.g., non-nurses provide oral medications to free up nurses to administer injectable second-line drugs).
- Strengthen basic DOTS to prevent MDR-TB from developing in the first place.
- Promptly find and treat MDR-TB patients to prevent transmission and the development of further drug resistance that could lead to extensively drug-resistant TB (XDR-TB).
- Increase collaboration within the health sector (e.g., better integration with primary care, HIV services, maternal and child health).

Box 2. Possible sources for mobilizing additional resources⁴²

- Health reform opportunities.
- Health insurance or social protection schemes.
- Increased collaboration within the health sector (e.g., better integration with primary care, HIV services, maternal and child health).
- Increased collaboration across sectors (such as prisons, social protection, the private sector, faith-based organizations).
- Loans.
- Central MOH budget.
- Provincial or local government budgets.
- Partners.
- Donors.

Instructions for Worksheet 7: Financial Gap Analysis Worksheet

Have Worksheet 6A ready.

Column A: Activities. In column A of Worksheet 7, record each activity from Worksheet 6A, column 4. You can label and group them according to the section of your national TB strategy or by components of the Stop TB Strategy as was done in Worksheets 3, 5, and 6. Add rows as needed.

Column B: Implementer. In column B, list the proposed agency or organization to take lead responsibility for implementing each activity. (You may want to add supporting agencies in parentheses or in a separate column.) Once the plan is budgeted, the first draft can be circulated with a request that organizations reply to confirm their commitments (listed in column B of Worksheet 7) and respond if resources are already secured.

Column C: Total cost. Determine the projected cost of each activity over all years of the plan and record the total in column C. The projected cost can be calculated using the WHO Planning and Budgeting Tool for TB Control.⁴³

Column D: Available resources. Fill in the funding available for each activity in the current year and estimate the funding that will be available for the remaining years of the plan. This requires that the NTP and partners inventory what they are already contributing and what they are planning to contribute over the term of the plan.

Column E: Financial gap. Subtract D (available resources) from C (total cost) to estimate the financial gap for each activity. The gap can also be summed across each Stop TB Strategy component and the plan as a whole.

Column F: Possible funding sources to fill the gap. Write in the names of possible sources of funding to fill the financial gap.

Worksheet 7: Financial Gap Analysis Worksheet

A	B	C	D	E	F
Activity	Implementer	Total cost ^{aa}	Available resources	Financial gap (C – D)	Possible funding sources to fill the gap
Stop TB Strategy component __ ^{bb} :					
Stop TB Strategy component __:					
Stop TB Strategy component __:					

This worksheet can be copied into an Excel spreadsheet.

^{aa} Over all years of the plan.

^{bb} As an example, this tool uses the components of the Stop TB Strategy.⁴ Your plan activities should be grouped by sections of your national TB strategy.

Tool 8: Review the plan

This tool is designed to help you assess an already existing MDR-TB plan or one developed using this toolkit. This tool can be used by the NTP, stakeholders, or independent parties to answer these questions:

- Does the MDR-TB component of the national TB strategy contain the “key ingredients” of a sound plan?
- What are the strengths and weaknesses of the MDR-TB plan?
- What changes are needed in the plan for successful implementation?

The following six ingredients are considered the foundation of any robust national plan²:

1. Planning process: Inclusive process is used to develop the plan; high-level commitment.
2. Situation analysis: Comprehensive analysis covers the context and health sector responses.
3. Programming: Priorities, objectives, and activities are clear and relevant.
4. Finance: Costs and budgetary framework are sound and feasible.
5. Implementation and management: Institutional capacity and systems are in place.
6. Results monitoring and review: Monitoring mechanisms are timely and accurate, and results are used for decision-making and action.

Ideally, all six of these key ingredients would be present for a plan to be considered technically sound. If your plan is still some distance from achieving these ideals, the plan can indicate how the country will make progress toward achieving them.²

Each ingredient has several characteristics, which are listed in Worksheet 8. By checking your MDR-TB plan against these characteristics, you can identify parts of your plan that may need to be strengthened or updated. Worksheet 8 refers you to other relevant tools within this toolkit that you can use to address any areas of weakness. For example, if the worksheet reveals gaps in your plan’s situation analysis, you are referred to the checklist in Tool 3 to revisit and revise this key ingredient.

Assessment of the MDR-TB plan also requires a review of additional documents, such as the overall TB strategy, the national health sector plan, and the country’s TB monitoring and evaluation plan. To help you assess each of the characteristics in Worksheet 8, the Joint Assessment of National Health Strategies and Plans (reference 2) lists additional guidance on which documents to use, what to look for, and “warning signs” that may indicate weaknesses in how the characteristic is addressed in the plan.

Instructions for Worksheet 8: Assess the MDR-TB Component of a National TB Plan

For each of the six key ingredients of a sound plan:

1. Check all boxes that apply.
2. Summarize the strengths and weaknesses of each ingredient and their implications for successful implementation of the plan. Then list changes needed to enhance the quality of the plan.

Worksheet 8: Assess the MDR-TB Component of a National TB Plan

Country:

Plan name:

Date finalized:

Start/End dates for implementation of the plan:

1. PLANNING PROCESS: Inclusive process is used to develop the plan; high-level commitment.

- 1.1. National TB program led the development of the plan.
- 1.2. A transparent mechanism ensured meaningful participation of all stakeholders.
- 1.3. The plan was (or will be) formally endorsed at a high level in government.
- 1.4. Political commitment is shown by maintaining (or preferably increasing) the government’s financing of the MDR-TB component.

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 2.1, 2.4, and 2.5 of reference 2.

Assessment of key ingredient 1: Planning process	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed in the plan	(See Tool 1)

2. SITUATION ANALYSIS: Comprehensive analysis covers the context and health sector responses.

- 2.1. The plan describes the most recent WHO estimates of TB burden,¹⁵ including:
 - Estimated TB incidence (number and rate).
 - Estimated TB incidence in HIV-positive patients (number and rate).
 - Estimated number of MDR-TB cases (total and among notified new pulmonary TB versus retreatment cases).
 - Estimated number of MDR-TB cases among retreatment TB cases.

(If the country uses different estimates, these should be listed and explained.)

(See reference 15.)

- 2.2. The plan includes an analysis of the most recently available country reports¹⁵ on the key MDR-TB indicators in the Global Plan 2011–2015¹³:
 - Number and proportion of new and previously treated TB patients with MDR-TB testing.
 - Number of confirmed MDR-TB cases (total and in notified new TB cases versus retreatment cases); proportion of estimate in 2.1 above.
 - Number of confirmed MDR-TB cases in retreatment notifications; proportion of estimate in 2.1 above.
 - Number and proportion of confirmed MDR-TB patients enrolled in WHO-endorsed treatment protocols.
 - Treatment outcomes of MDR-TB cohort.

(See Worksheets 2A, 2B or 2C, and 6B.)

- 2.3. The plan includes a comprehensive analysis of the current MDR-TB situation, covering the following areas (within and outside the NTP, at the national and provincial levels):
 - Political and financial commitment.
 - Available infrastructure (from both MOH public health and non-NTP sources, including the private sector).
 - MDR-TB case-finding strategy.
 - Laboratory diagnosis and follow-up of MDR-TB.
 - MDR-TB treatment strategy, including regimen and model of care, side effects and follow-up management, treatment delivery (DOTS), adherence, and social support.
 - Second-line drug procurement and supply management.
 - Source and quality of first-line drugs and second-line drugs.
 - Availability and use of TB drugs in the private market, with and without prescription.

- Management and supervision of the program (including partnership and involvement with other stakeholders).
- Public-public and public-private mix.
- Human resource development: program staffing, training, and technical assistance strategy.
- Infection control.
- Monitoring and evaluation (M&E) (including recording and reporting system).
- HIV and high-risk groups (including MDR care for prisoners and migrants).
- Operational research.

(See Worksheet 3.)

- 2.4. Target performance is identified and gaps are quantified (target minus current performance). (See Worksheets 2A, 2B or 2C, 3, 6A–C.)
 - Plan monitors progress toward achieving the recommendations of the most recent MDR-TB monitoring missions and other relevant missions, such as laboratory, infection control, etc.
 - Plan monitors progress toward achieving Global Plan 2011–2015 targets.¹³
- 2.5. Gaps are prioritized. (See Worksheet 4.)
- 2.6. Strategies are planned to mitigate obstacles to successful implementation. (See Worksheet 5.)

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 1.1–1.3, 1.6, and 1.9 of reference 2.

Assessment of key ingredient 2: Situation analysis	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed in the plan	<i>(See Tools 2–6)</i>

3. PROGRAMMING: Priorities, objectives, and activities are clear and relevant.

- 3.1. MDR-TB component is consistent with the country's overall TB strategy. (See Worksheet 1A.)
- 3.2. In decentralized health systems, there is an effective mechanism to ensure subnational plans address national-level goals and targets. (See Worksheet 1A.)
- 3.3. The MDR-TB component describes scaling up MDR-TB diagnosis and treatment, including timeline. (See Worksheets 2A, 6B, 6C.)
- 3.4. Each objective:
 - Is clearly defined.
 - Is SMART (specific, measurable, achievable, relevant, and time bound).
 - Addresses the priority gaps.
 - Clearly states the population target.

(See Worksheet 6B.)

- 3.5. Each objective includes:
 - Background and rationale.
 - Activities.
 - Expected result (output or outcome indicator and target).

(See Worksheets 5, 6A.)

- 3.6. Each planned activity (intervention) is:
 - Feasible.
 - Locally appropriate.
 - Equitable.^{cc}
 - Based on evidence and good practice.
 - Based on considerations of effectiveness and sustainability.
 - Clearly specified.
 - Contributing to at least one objective.

(See Worksheets 5, 6A.)

^{cc} Equitable means the interventions are appropriate to improve the health of the most vulnerable and ensure access to those with greatest need.²

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 1.4–1.6, 2.6, 2.7, and 4.2 of reference 2.

Assessment of key ingredient 3: Programming	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed in the plan	(See Tools 1, 2, 5, 6)

4. FINANCE: Costs and budgetary framework are sound and feasible.

- 4.1. Financial management system and process leading to MDR-TB budget approval is described.
- 4.2. A description is given for how the TB plan and its MDR component integrates with the national planning cycle. (You may want to consult the WHO Country Planning Cycle Database at http://www.internationalhealthpartnership.net/en/about/j_1253621551.)
- 4.3. Estimated funding needs for each objective and activity are included for each year of the plan.
- 4.4. Available funding per activity is broken down by sources, and the funding gap is specified.
- 4.5. If the level of financing is unclear or there is a financing gap, priorities for spending are described.
- 4.6. For any funding gaps, activities to mobilize resources by optimizing existing resources and/or securing additional funding are included in the plan.
- 4.7. Lead and partner implementation agencies are stated for each budgeted activity.
- 4.8. Internal and external funds channelling, management, and reporting mechanisms are described.
- 4.9. WHO planning and budgeting tool reports are used (optional).⁴³

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 3.1–3.5 of reference 2.

Assessment of key ingredient 4: Finance	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed in the plan	(See Tool 7)

5. IMPLEMENTATION AND MANAGEMENT: Institutional capacity and systems are in place.

- 5.1. Annual operational plans translate multiyear objectives into actions and describe the roles and responsibilities of implementing partners.
- 5.2. Plan is updated regularly.
- 5.3. Human resource needs are identified, including staffing levels, skills mix, distribution, training, supervision, pay, and incentives.
- 5.4. Logistics, information, and management system constraints are described, and actions are proposed to resolve the constraints.
- 5.5. Systems and capacity for planning, budgeting, and technical and managerial supervision are in place and properly resourced.
- 5.6. Technical assistance needs are defined;³⁶ activities are specified and budgeted for strengthening national capacity.
- 5.7. Decision-making, oversight, coordination, and reporting mechanisms are described for plan implementation.

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 4.1, 4.5–4.8, and 4.13 of reference 2.

Assessment of key ingredient 5: Implementation and management	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed	<i>(See Tools 1 and 7)</i>

6. RESULTS MONITORING AND REVIEW: Monitoring mechanisms are timely and accurate, and results are used for decision-making and action.

- 6.1. An M&E framework reflects the goals and objectives of the MDR-TB plan and budget and feeds into the national TB plan's M&E framework.
- 6.2. Partners agree to use and contribute to one M&E framework and report to the NTP.
- 6.3. The M&E framework includes clearly defined:
 - Impact indicators (for the overall goals).
 - Outcome and output indicators for the objectives, consistent with the MDR indicators in the Global Plan 2011–2015¹³ (listed in 2.2 of this worksheet).
 - Realistic targets for each indicator.

- Annual milestones that can be used to measure progress and make performance-based decisions.
- Data sources and collection methods.
- Information flows.

- 6.4. Data are analyzed and translated into information for decision-making and are regularly disseminated.
- 6.5. Supportive supervision to subnational levels gives feedback to improve performance.
- 6.6. A multipartner review mechanism regularly assesses program performance against targets.
- 6.7. Gaps and weaknesses are identified in M&E systems, and actions to strengthen capacity are planned and budgeted.

For further guidance on what to look for to assess this key ingredient, where to look, and warning signs, see characteristics 5.1–5.9 of reference 2.

Assessment of key ingredient 6: Results monitoring and review	
Strengths	
Weaknesses	
Implications for successful implementation	
Changes needed	<i>(See Tool 6)</i>

Annexes

Annex A. Acronyms and abbreviations

AFB	acid fast bacilli
AIDS	Acquired Immune Deficiency Syndrome
ART	antiretroviral therapy
DOTS	brand name for WHO-recommended strategy for TB control ⁴ (formerly an acronym for directly observed treatment, short-course)
DRS	drug resistance survey
DST	drug susceptibility testing
EQA	external quality assessment
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HR	human resource
IC	infection control
M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis
MOH	ministry of health
NRL	national reference laboratory
NTP	national TB program
PATH	Program for Appropriate Technology in Health
SLD	second-line drugs
SRL	supranational reference laboratory
TB	tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Annex B. Information to compile for the planning process (Supplement to Worksheet 1B)

1. Plans.
 - a. National TB plan or strategy.
 - b. Other national TB plans (such as M&E, laboratory network strengthening, infection control).
 - c. Other national plans: health sector, human resources, laboratory, HIV.
 - d. WHO regional MDR-TB response plans.⁵⁻⁹
2. The country's MDR-TB guidelines, diagnostic algorithms, and standard operating procedures.
3. TB and HIV data.
 - a. Country reports.
 - a. WHO.^{14,15,27}
 - b. Joint United Nations Programme on HIV/AIDS. (See <http://www.unaids.org/en/>.)
4. Recent mission reports (such as an NTP review, laboratory, Green Light Committee, or Global Drug Facility). See TBTEAM website: <http://www.stoptb.org/countries/tbteam/>.
5. Global Fund proposal, grant performance review. See <http://portfolio.theglobalfund.org/en/Home/Index>.
6. Work plans, budgets, or progress reports of key partner organizations engaged in MDR-TB diagnosis and treatment.
7. Existing terms of reference for a current multi-stakeholder group that can take responsibility for monitoring the plan.
8. Policy for covering MDR-TB in the country's health insurance or social protection schemes.

Annex C. MDR-TB Essential Elements Reference List (Supplement to Checklist 3)

This reference list consists of all relevant WHO recommendations essential for scaling up the detection and treatment of MDR-TB. Each row of the first column is one of the essential elements. More detailed descriptions are provided here than in the checklist in Tool 3. Each element includes the citation to the WHO recommendation, so the reader can see the full context of each WHO recommendation and the evidence base used to develop the recommendation (if available). All the references (with web links) are listed in Annex E. The “First steps” elements are numbered, followed by “Next steps,” which are labelled with letters.

Column 2 contains published global targets for many of the essential elements, their citations, and references to available WHO data for each country.^{14–16,27} For ease of use, many of the indicators for the essential elements are based on data that countries are already asked to report to WHO on the annual data collection form.¹⁶ Where applicable, indicator definitions from WHO,^{19,38} the Global Fund,¹⁸ and the US President’s Emergency Plan for AIDS Relief are also referenced.⁴⁴

Essential Elements	Target, indicators
1. Pursue high-quality DOTS expansion and enhancement	
1A. Secure political commitment with adequate, sustained financing [See also M&E in 1E, advocacy in 5]	
First steps	
1. Country has a current national TB plan approved by the government that includes an assessment, plan, and budget for scaling up the detection and treatment of MDR-TB. ^{4,12,45}	Yes ^{dd}
2. Representatives from civil-society organizations, people living with HIV/AIDS or affected by TB, and health care providers outside the national TB program (NTP) participate in MDR-TB planning. ⁴⁵	Yes
3. The budget for the MDR-TB expansion plan is adequately financed and sustainable. ^{12,45}	___% gap ¹⁵ ___% of MDR-TB budget funded ¹⁶ ___% funded by domestic sources ¹⁶
4. An individual at each level of the NTP (central, regional, and local) is designated to be responsible for planning and implementing MDR-TB scale-up. ⁴⁵	Yes
5. Diagnosis and care of MDR-TB is provided free of charge to patients, including ancillary tests and medications needed to monitor and manage patients’ TB and any adverse TB treatment events. ^{28,45,46}	Yes
6. All activities are consistent with WHO ethics of TB prevention, treatment, and care. ⁴⁶	Yes

^{dd} “Yes” indicates the element is in place.

Essential Elements	Target, indicators
1B. Ensure early case detection and diagnosis through quality-assured bacteriology [See also training in 3B]	
First steps	
Detect MDR-TB among TB cases (outcome objective in Worksheets 2A, 6A, 6B)	<p>≥50% of estimated^{ee} MDR-TB cases are reported¹³</p> <p>___% in new cases^{15,27}</p> <p>___% in previously treated cases^{15,27}</p>
1. Policy and standard operating procedures for MDR-TB case-finding are implemented. ⁴⁵	Yes
2. MDR-TB testing is performed on specimens obtained when TB treatment is determined to be failing in any TB patient. ^{20,39,47}	<p>MDR-TB testing in 100% of patients whose treatment is failing¹⁸</p> <p># of patients with MDR-TB testing as a ___% of those whose first course of treatment is failing^{ff}</p> <p># of patients with MDR-TB testing as a ___% of those whose subsequent course of treatment is failing¹⁹</p>
3. Household contacts of MDR-TB cases (including children) are evaluated to find additional TB cases. (If TB cases are found, MDR-TB testing is obtained.) ^{20,45,47}	Yes
Optimize laboratory network and performance	
4. Laboratory capacity to identify <i>M. tuberculosis complex</i> meets national needs, and laboratories demonstrate acceptable performance during external quality assurance. ^{20,47–49}	<p>≥1 culture laboratory per 5 million population^{13,14,18}</p> <p>≥50% of acid fast bacilli (AFB) smear-negative, new TB cases tested using culture and/or molecular-based test¹³</p> <p>≥90% of AFB smear-negative, previously treated TB cases tested using culture and/or molecular-based test¹³</p>

^{ee} The Global Plan 2011–2015¹³ uses the term “expected.” By contrast, the most recent WHO report¹⁴ and country profiles¹⁵ use estimated MDR-TB cases among TB notifications (new pulmonary and retreatment cases).

^{ff} Formerly called “failures of Category 1.”

Essential Elements	Target, indicators
	<p>___% of new pulmonary cases with laboratory confirmation (smear, culture, or WHO-endorsed rapid molecular diagnostics)¹⁶</p> <p>___% of notified TB cases with positive identification for <i>M. tuberculosis complex</i> (i.e., confirmed by culture, line probe assay, or Xpert[®] MTB/RIF)¹⁶</p> <p>___ (#), ___% of culture laboratories for which external quality assurance was carried out^{16,18}</p>
<p>5. Laboratory capacity for detecting resistance to rifampicin and isoniazid meets national needs, and laboratories demonstrate acceptable performance during external quality assurance.^{4,12,45,49,50}</p>	<p>At least one DST laboratory per 5 million population¹⁴</p> <p>≥95% agreement for isoniazid and rifampicin between the SRL and the NRL^{18,39}</p> <p>___ (#), ___% of DST units for which external quality assurance was carried out^{16,18}</p>
<p>6. Laboratories performing testing for MDR-TB report to the treatment center as soon as results are available.⁴⁵</p>	<p>Yes</p>
<p>7. The country has a national reference laboratory (NRL) that is officially linked and regularly quality-controlled by a supranational reference laboratory (SRL).^{39,45}</p>	<p>NRL implemented a quality management system according to international standards^{13,18}</p>
<p>8. A system of collecting and transferring specimens and cultures from the patient to the appropriate laboratory is rapid, reliable, and safe.^{45,49}</p>	<p>Yes</p>
<p>9. Supply of good-quality reagents and consumables is continuous.⁴⁹</p>	<p>Yes</p>
<p>10. Appropriate biosafety procedures are in place in laboratories performing culture, line probe assays, or DST.^{45,51}</p>	<p>Yes</p> <p>(Appropriate biosafety measures are in place in NRL¹³)</p>
<p>Next steps</p>	
<p><i>MDR-TB testing at start of treatment (or retreatment)</i></p>	
<p>a. MDR-TB testing is performed on specimens obtained at start of retreatment for all previously treated cases, whether their current treatment has failed or they are returning after relapse or after being lost to follow-up (output indicator in Worksheets 2, 6A, 6B).^{20,39,46,47}</p>	<p>100% of previously treated cases are tested for drug resistance^{13-15,18,19,27}</p>

Essential Elements	Target, indicators
b. MDR-TB testing is obtained at the start of TB treatment for new TB patients who are HIV positive. ^{20,22,45-47}	100% of new HIV-positive TB patients tested for drug resistance at the start of TB treatment ^{15,19,20}
c. Country identifies additional groups of TB patients with high levels of multidrug resistance to prioritize for MDR-TB testing at start of treatment. ^{20,45}	___% of TB cases with MDR-TB testing result by each risk category ¹⁹
d. MDR-TB testing is obtained at the start of treatment for all new patients. ^{1,20,46}	20% of new TB cases are tested for drug resistance ^{13-15,27}
<i>MDR-TB testing during treatment</i>	
e. Culture and MDR-TB testing is performed on specimens from <u>previously treated patients</u> who remain smear-positive at month 3 of treatment. ^{20,47}	Yes
f. Culture and DST are performed on specimens from <u>new patients</u> who remain smear-positive at month 3 of treatment. ^{20,47}	Yes
<i>Other case-finding measures</i>	
g. Close contacts ⁹⁹ of MDR-TB patients receive careful clinical follow-up for at least two years. ⁴⁵	Yes
h. If resistance to rifampicin is detected, then susceptibility testing is performed for isoniazid, as well as the fluoroquinolones and second-line injectable agents most often used in the country. ^{39,45}	≥90% of confirmed cases of MDR-TB have a DST result for fluoroquinolones and a second-line injectable drug ^{13,16,19}
i. Rapid tests to detect MDR-TB are available. ^{1,20,45,51} Specifically, Xpert [®] MTB/RIF is used as the initial diagnostic test in individuals with possible MDR-TB. ^{22,23}	≥90% of tests for drug resistance performed on previously treated cases done using rapid tests >50% in new cases ¹³
j. Liquid medium for culture and DST with rapid species identification is integrated into country's laboratory capacity strengthening plan. ⁵²	Liquid culture and rapid speciation test implemented ¹⁶
1C. Provide standardized treatment with supervision and patient support [See also training in 3A]	
First steps	
Successfully treat drug-resistant TB (outcome indicators in Worksheets 2A, 6A, 6B)	Outcomes ≥75% of patients with confirmed MDR-TB are successfully treated ^{13,18,19,27} ___% of each: cure, complete, die, treatment failure, lost to follow-up, no outcome ²⁷
	Interim results ___% of MDR-TB cases registered and started on

⁹⁹ Especially household contacts whose initial evaluation found they did not have active TB.

Essential Elements	Target, indicators
	MDR-TB treatment who have negative culture results during month 6 ^{18,19} ___% died by month 6 ___% lost to follow-up by month 6
1. The national guidelines for drug-resistant TB (including MDR-TB regimens and criteria to change from the intensive to the continuation phase) are consistent with WHO recommendations. ^{1,20,45,47}	Yes
2. NTP has a written policy for selecting which <i>confirmed</i> MDR-TB patients will begin an MDR-TB regimen, who is responsible for applying the selection criteria, ^{hh} and where these patients are referred for treatment. ⁴⁵	Yes
3. Confirmed MDR-TB cases are started on treatment with a WHO-recommended MDR-TB regimen right after diagnosis. ^{1,20,45} (See output indicators in Worksheets 2, 6A, 6B.)	100% of cases with confirmed MDR-TB start on treatment ^{15,18,19,27} in programs that follow international guidelines ¹³
4. MDR-TB patients undergo initial evaluation and standard periodic monitoring for adverse reactions ⁱⁱ as recommended by WHO. ^{1,45}	Yes
5. Algorithms, ancillary drugs, and other therapies are available to manage side effects of MDR-TB treatment. ^{45,53}	Yes
6. The effectiveness of MDR-TB treatment is monitored with sputum bacteriology at least monthly until smear and culture conversion, then at least monthly for smears and quarterly for cultures. ^{1,45}	Yes
7. Directly observed therapy for MDR-TB treatment is provided for the full duration of therapy by a health worker (or trained volunteer functioning under health worker supervision). ⁴⁵	Yes
8. Patients with MDR-TB are treated using mainly ambulatory care (in the home or outpatient clinic) to minimize hospitalization and improve patient access to treatment. ^{1,45,54} Procedures for ambulatory MDR-TB care are implemented and specify ¹¹ : <ul style="list-style-type: none"> • Roles and responsibilities for providers at each level (see 1A.4). • Mechanisms for timely two-way communication between community providers and specialized center providers. • Mechanisms to ensure that SLDs for each patient's full treatment course are uninterrupted (see 1D). • Recording and reporting by facility and treatment supporter (see 1E). 	Yes

^{hh} Some countries have certain exclusion criteria when they are first launching the treatment of MDR-TB.

ⁱⁱ Includes tests for pregnancy and renal, liver, and thyroid function, provided at no cost to the patient.

Essential Elements	Target, indicators
<ul style="list-style-type: none"> • Identification, training, supervision, and compensation for community treatment supporters (see 3A). • Infection control (see 3B). 	
9. Social, economic, and psychological factors that may make patients interrupt treatment are identified and addressed (via incentives, enablers, and other means). ^{4,20,45,47}	Yes
10. Efforts are routinely made and documented to retrieve MDR-TB patients who interrupt treatment or miss appointments. ²⁰	Yes
11. There is a referral system for continuity of care when MDR-TB patients are transferred from one treatment location to another (such as hospital, prison, clinic, region, or to their community). ⁵⁵	Yes
12. Hospitalization is available for MDR-TB patients needing acute level of care due to severity of TB, adverse effects of medications, or concurrent medical conditions. ⁴⁵	Yes
13. An expert committee routinely consults on individual MDR-TB patients and monitors program management for MDR-TB. ⁴⁵	Yes
14. For MDR-TB patients not receiving MDR-TB treatment, a written NTP policy addresses patient education and support, separation if infectious, palliative care, and end-of-life care. ⁴⁵	Yes
Next steps	
a. NTP policy defines which groups of <i>possible</i> MDR-TB cases have a high enough level of multidrug resistance to warrant use of an empiric MDR-TB regimen while awaiting confirmation of MDR-TB (if rapid methods are not yet available). ²⁰	___ #, ___% of eligible patients with presumptive MDR-TB are enrolled in MDR-TB treatment ¹⁹
b. The country's treatment of TB patients with mono- or poly-drug resistance patterns (other than resistance to both isoniazid and rifampicin) is consistent with WHO recommendations. ^{20,45}	Yes
c. An MDR-TB Center of Excellence provides consultation and accepts referrals of difficult cases. ⁴⁷	Yes
d. Surgical interventions are available for MDR-TB patients. ⁴⁵	Yes
1D. Ensure effective drug supply and management [See also training in 3A]	
First steps	
1. Forecasting accurately quantifies the SLD needs for a specific period of time. ^{45,56}	Yes
2. SLDs used to treat MDR-TB meet WHO prequalification standards or Stringent National Medicine Regulatory Authority standards. ^{12,50,56}	Yes
3. Procurement ensures the availability of the right medicines, in the right quantities, of high quality, delivered at the right time. ^{45,56}	Yes
4. Distribution system from central to peripheral levels ensures adequate supplies ^{jj} of high-quality SLDs at each level are available for complete treatment of all identified MDR-TB cases. ^{45,56}	___ (#), ___% of reporting units reporting no stock-out of SLDs on the last day of the quarter ¹⁸

^{jj} With sufficient remaining shelf life. Includes sufficient buffer stock.

Essential Elements	Target, indicators
Next steps	
a. TB medications are available by prescription only, and prescribed and dispensed by accredited public and private providers. ¹²	Yes
b. An electronic system is used to manage SLD forecasting, procurement, supply, and distribution. ^{57,58}	Yes
1E. Monitor and evaluate performance and impact [See also coordination in 1A and training in 3A]	
First steps	
1. NTP uses WHO definitions and WHO formats for recording and reporting MDR-TB cases from facilities to subnational levels to national level to WHO. ⁴⁵	___ (#), ___% of reporting units (at all levels of data flow) that submitted timely case-finding and treatment outcome reports to the NTP in the previous quarter ¹⁸
2. Data on MDR-TB are analyzed and used to improve NTP performance in expanding access to MDR-TB diagnosis and treatment. ¹²	Yes
3. Systematic, supportive supervision from national to subnational to facility levels is used to improve performance in detecting and treating MDR-TB. ^{45,55}	Yes
4. The NTP's M&E plan includes an MDR-TB component, which specifies periodic external monitoring. ^{45,59}	Yes
Next steps	
a. NTP analyzes routine, continuous surveillance of MDR-TB testing of TB patients starting retreatment to determine the proportion of multidrug resistance ^{kk} in each of the following groups: treatment failure, relapse, and return after being lost to follow-up. ^{20,45}	Yes ¹³ ___ (#), ___% of confirmed MDR-TB cases detected among TB patients tested ^{15,19} ___% of MDR in each subgroup of previously treated patients ²⁰
b. Continuous surveillance of drug resistance in new patients or at least a drug resistance survey in new cases conducted in the past 3 to 5 years. If drug resistance surveillance of previously treated patients is not yet routine, retreated patients are also sampled during the DRS. ^{39,45}	Yes
c. Routine practices are in place to ensure the quality of MDR-TB data, to include regular cross-checking of laboratory and MDR-TB registers and supervisory visits. ^{45,49,60}	Yes
d. Data are analyzed to describe the frequency of HIV infection among MDR-TB patients and the frequency of multidrug resistance among HIV-positive TB patients. ⁴⁵	Yes

^{kk} Data are utilized to guide MDR-TB case-finding strategies. If rapid DST methods are not yet available, these data are also used to select which patient groups have high enough levels of multidrug resistance to warrant an empiric MDR-TB treatment regimen while awaiting their DST results for isoniazid and rifampicin.

Essential Elements	Target, indicators
e. Delays between MDR confirmation and the patient starting MDR-TB treatment are measured. Deaths are also recorded among confirmed MDR-TB cases who died before starting treatment. ^{19,45}	Mean number of days between the date of MDR-TB testing results showing resistance to isoniazid and rifampicin and the date the patient started second-line drug regimen ^{18,19}
f. Full DST patterns of a recent MDR-TB cohort are analyzed and the empiric MDR-TB regimen is adjusted accordingly. ^{20,39,45}	Yes
g. Individual MDR-TB patient data are entered or uploaded in an electronic case-based database at the national level. ^{45,58,61}	Yes ¹³
2. Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations	
2A. Scale up collaborative TB/HIV activities [See also TB case-finding in 1B, training in 3A, and infection control in 3B]	
First steps	
1. MDR-TB patients know their HIV status. ^{20,47,62,63}	100% of TB patients know their HIV status ^{13,18,38,44}
2. HIV-positive MDR-TB patients continue or begin antiretroviral therapy (ART) as soon as possible after starting TB treatment. ^{20,48,63,64}	100% of HIV-positive TB patients start (or continue) on ART ^{13,18,38,44}
3. HIV-positive MDR-TB patients begin cotrimoxazole preventive therapy as soon as possible after starting TB treatment. ^{20,63}	100% of HIV-positive TB patients start (or continue) on cotrimoxazole preventive therapy ^{13,18,38,44}
4. HIV-positive MDR-TB patients receive HIV care and support. ^{20,63}	Proportion of HIV-positive TB patients enrolled in HIV care services during TB treatment ³⁸
Next steps	
a. Provider-initiated HIV testing and counseling is offered to all patients with possible MDR-TB. ^{20,47,62}	Yes
2B. Scale up prevention and management of MDR-TB [These elements are distributed across the other relevant Stop TB Strategy components]	
2C. Address the needs of TB contacts and of poor and vulnerable populations [See also 1A for contacts and 1C for social support]	
First steps	
1. Prisons are linked to the NTP for MDR-TB diagnosis, reporting, and treatment (including continuity of care upon transfer between facilities or release to the community). ⁴⁵	Yes
2. Additional vulnerable populations are identified and linked to the NTP for MDR-TB case detection, reporting, and treatment. ⁴	Yes
Next steps	
a. To judge equitable access to MDR-TB diagnosis and treatment, characteristics of detected MDR-TB cases are analyzed and compared to those entering MDR-TB treatment. ¹⁹	___ #, ___ % confirmed MDR-TB cases starting MDR-TB treatment among MDR-TB cases detected ¹⁹ for key subgroups ⁱⁱ

ⁱⁱ Subgroup characteristics may include HIV status, ART status, age, sex, rural/urban, immigrant, migrant, or diagnosis outside NTP.

Essential Elements	Target, indicators
3. Contribute to health system strengthening based on primary care	
3A. Help improve...human resource development.... [See also political commitment in 1A and management and supervision in 1E]	
First steps	
1. A focal person is assigned responsibility for human resource development for the detection and treatment of MDR-TB. ^{3,45}	Yes
2. An assessment of the human resource requirements for MDR-TB includes a task analysis by level of the health system and category of health worker, ^{mm} as well as implications for the existing workforce. ⁴⁵	Yes
3. Gaps in numbers of staff with requisite skills are defined based on the MDR-TB task analysis and the current staffing available at each level of the health system. ^{3,45}	Yes
4. To address the gaps, the country has developed a plan for staffing, training, supervision, and support for MDR-TB services at each level without detriment to other areas of NTP work. ^{3,45}	Yes
5. Key staff in the needed categories are available at each level with the professional competence and support to meet country targets for detection and treatment of MDR-TB. ^{3,45,50}	Yes
6. Key staff members ⁿⁿ have been recently trained on drug-resistant TB. ⁴⁵	Yes
Next steps	
a. Implementation of the human resources development plan for MDR-TB scale-up is regularly monitored, with revision as necessary. ^{3,45}	Yes
3B. Strengthen infection control in health services, other congregate settings, and households [See also supervision in 1E and training in 3A]	
First steps	
Implement managerial measures	
1. A national TB infection control plan addresses settings where care is provided to patients with known or possible MDR-TB. ^{47,54}	Yes (plan for infection control in health facilities providing services to people living with HIV) ¹³
2. Facilities providing care to MDR-TB patients are assessed for risk of TB transmission. ⁵⁴	Yes
3. In priority ^{oo} facilities, a focal person works with a local coordinating body to develop, implement, and monitor a facility-specific infection control plan, to include the administrative, environmental, and respiratory protection controls listed below, to prevent TB transmission. ⁵⁴	Health care facilities that have infection control practices in place ¹⁸

^{mm} Consider clinical, managerial, laboratory, and pharmacy workforce.

ⁿⁿ Country to define which staff and how frequently.

^{oo} Countries will prioritize settings depending on the findings of the risk assessments. Higher priority should be given to settings where TB is drug resistant, exposed people are especially vulnerable to developing disease if infected or dying if they develop TB (such as people living with HIV), exposure is of longer duration (such as hospitals or any setting with diagnostic delays), control measures are lacking, or a large number of people are exposed. During the scale-up process, additional settings will be added to the priority list and additional infection control measures will be phased in.

Essential Elements	Target, indicators
<i>Implement administrative controls</i>	
4. People with known or possible infectious TB are promptly identified, separated, instructed in cough etiquette, and “fast tracked” to receive services (triaged) so their time in the health facility is minimized. ⁵⁴	Yes
5. If hospitalized, patients with known or possible infectious MDR-TB are isolated following WHO recommendations ^{pp} for airborne precautions. ^{54,65}	Yes
6. In the household, infectious MDR-TB patients are advised to sleep in a separate room, practice cough hygiene, and minimize contact with infants, children, and people living with HIV. ⁵⁴	Yes
7. Health workers are given appropriate TB infection control information and encouraged to undergo HIV testing and counseling. ^{54,66}	Yes
8. Health workers who develop signs or symptoms of TB undergo TB diagnostic evaluation. ⁵⁴	Yes
<i>Implement environmental controls</i>	
9. In patient care areas of health care facilities, natural ventilation is maximized where possible. ^{54,67}	Yes
10. Natural ventilation is maximized in household rooms where infectious MDR-TB patients spend time. ⁵⁴	Yes
<i>Implement respiratory protection programs</i>	
11. Health workers and treatment supporters use particulate respirators when caring for MDR-TB patients during the time the patients are known or thought to be infectious. ⁵⁴	Yes
12. A comprehensive respiratory protection program includes training, fit testing, and procuring, distributing, and maintaining sufficient quantities of approved respirators. ⁵⁴	Yes
Next steps	
a. TB infection control is part of the country’s overall infection control policy. ⁵⁴	Yes
b. National surveillance of TB disease among health workers is established. ⁵⁴	Ratio of TB notification rate among health care workers to notification rate among the general population is ~1 ¹³
c. Patient care areas in health care facilities have adequate ventilation. ^{54,67}	Yes
d. Supervision of infection control measures at the community and household level. ¹¹	

^{pp} Including at least 12 air changes per hour.

Essential Elements	Target, indicators
4. Engage all providers [See also MDR-TB planning in 1A and training in 3A]	
First steps	
1. Health care providers outside the NTP (nongovernmental organizations, academic centers, hospitals) referring, diagnosing, or treating MDR-TB patients are formally linked to the NTP. ^{45,50,68}	____% of notified TB cases are reported from non-NTP care providers ^{13,18}
Next steps	
a. The source of MDR-TB patient referral (by major categories of provider) is routinely reported in the laboratory or treatment register. ^{45,68,69}	Yes
b. Outcomes of any MDR-TB patients treated outside the NTP are reported and analyzed as a cohort. ^{59,69}	Yes
c. Laboratories (including private) outside the NRL network that perform first-line and/or second-line DST report results to NRL. ⁶⁹	Yes
5. Empower people with TB and communities through partnership [See also political commitment in 1A, MDR-TB treatment in 1C, and training in 3A]	
First steps	
1. MDR-TB patients are provided high-quality patient-centered care, as outlined in the <i>Patients' Charter for Tuberculosis Care</i> . ^{12,28,45}	Yes
2. Community-based DOTS providers support MDR-TB patients via ^{11,12,45} : <ul style="list-style-type: none"> • Reimbursement for transportation costs. • Food packages. • Rental housing near the hospital or clinic (for patients who live in remote areas, need to be monitored closely, or do not have the necessary family support). • Opportunities to participate in support groups. • Access to income-generating activities. 	Number of TB patients provided directly observed therapy by trained community volunteers ¹⁸
Next steps	
a. Involvement of community leaders to address community-wide issues such as stigma toward drug-resistant TB patients. ²⁹	Yes
b. MDR-TB is included in the country's advocacy, communication, and social mobilization (ACSM) strategy. ¹²	Yes
6. Enable and promote research [See also M&E in 1E and training in 3A]	
Next steps	
a. Research agenda based on country-specific priorities includes MDR-TB. ^{12,35}	Yes
b. Results of operational research are used to improve MDR-TB services. ¹²	Yes

Annex D. Cross-references from preliminary MDR-TB testing targets in Tool 2 to final output objective in Worksheet 6B

This annex shows which cells from the worksheets in Tool 2 you can use to fill in the MDR-TB testing output objective in Worksheet 6B. The denominators for calculating the percentages are designated by gray-shaded blanks.

If your plan's MDR-TB case-finding strategy focuses on **previously treated patients only**, use the cells (corresponding to the upper case letters below) from **Worksheet 2B** to finalize your output objectives below.

3. Output indicators	Baseline (20xx)	Output objectives
TB patients tested for MDR-TB	___P%	3.1. In the final year of this plan (20xx), at least ___ (Q) previously treated TB patients will have MDR-TB testing at the start of retreatment. This is ___ (R)% of the (O) previously treated TB cases expected to be notified that year.*

If your plan includes MDR-TB testing for **both new and previously treated TB patients**, use the cells (corresponding to the upper case letters below) from **Worksheet 2C** to finalize your output objectives below.

3. Output indicators	Baseline (20xx)	Output objectives
TB patients tested for MDR-TB	___Y%	3.1. In the final year of this plan (20xx), at least ___ (R + S) TB patients will have MDR-TB testing. This is ___ (Z)% of the (X) TB cases expected to be notified that year.*

**It is difficult to estimate the number of TB notifications in the final year of the plan. For simplification, this assumes the same number as in the baseline year.*

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