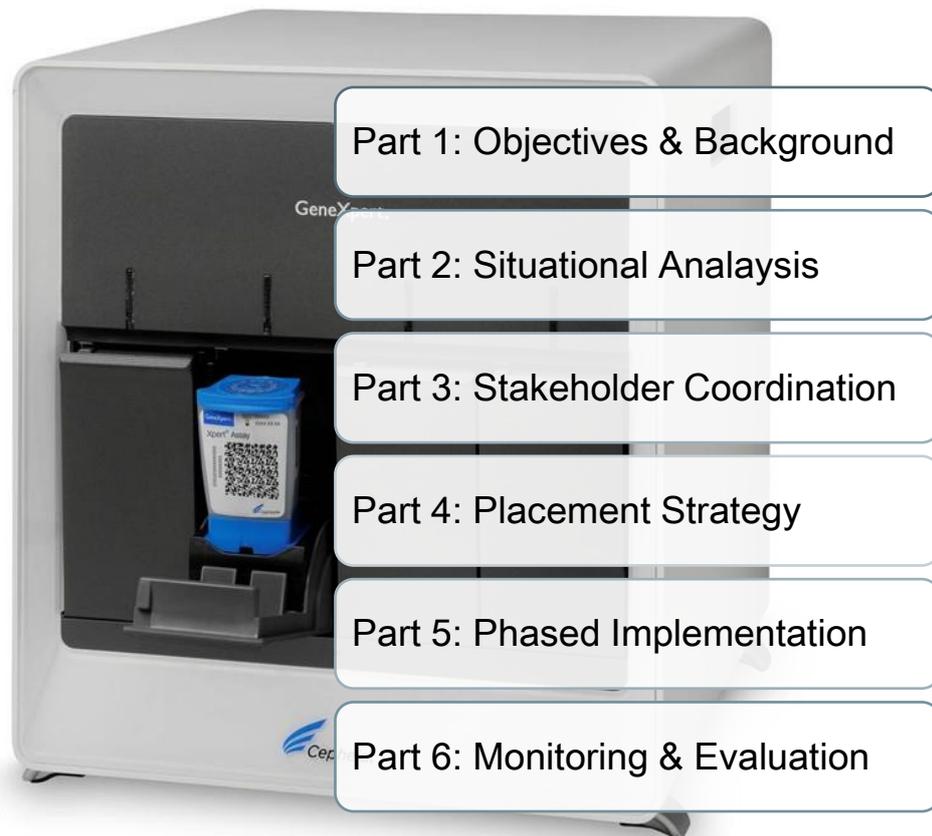


Work Plan Template for Xpert MTB/RIF® Implementation and Scale-up

December 2015



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ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
CDC	Centers for Disease Control and Prevention
DST	Drug sensitivity test
EQA	External quality assessment
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
HIV	Human Immunodeficiency Virus
LED FM	Light-emitting diode fluorescence microscopy
LPA	Line probe assay
M&E	Monitoring and evaluation
MDR-TB	Multidrug-resistant tuberculosis
MOH	Ministry of Health
MTB	<i>Mycobacterium tuberculosis</i>
PEPFAR	US President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV/AIDS
PT	Proficiency testing
QA	Quality assurance
QC	Quality control
RIF	Rifampicin
SOP	Standard Operating Procedure
SWOT	Strengths, weaknesses, opportunities, and threats
TB	Tuberculosis
TWG	Technical Working Group
USAID	US Agency for International Development
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis

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INTRODUCTION TO THIS XPERT MTB/RIF WORK PLAN TEMPLATE

RATIONALE FOR AN IMPLEMENTATION AND SCALE-UP WORK PLAN

Elimination of tuberculosis (TB) is a major global health priority. Multidrug-resistant tuberculosis (MDR-TB) and HIV-associated TB pose enormous challenges to health systems due to the complexity of diagnoses and treatment. The current landscape for TB response underscores the urgent need for rapid diagnosis to control TB, especially in resource-limited settings.

In 2010, the World Health Organization (WHO) endorsed a real-time PCR-based molecular test, the Xpert MTB/RIF assay, which Cepheid developed to detect *Mycobacterium tuberculosis* (MTB) and rifampicin resistance [1]. This automated, fully-integrated system enables molecular testing in settings with high TB burden, providing results within 90 minutes. With its ease of use, this system can be adopted in district and sub-district settings, where the impact of testing on the clinical decision-making process is greatest.

Due to the growing body of evidence showing the successful clinical impact of Xpert MTB/RIF, many national ministries of health have implemented or are considering implementation of the system. As a result, FIND has developed this template to facilitate country work planning.

PURPOSE OF THE XPERT MTB/RIF WORK PLAN TEMPLATE

The purpose of this document is to provide step-by-step instructions for completing an implementation and scale-up work plan for the Xpert MTB/RIF assay in your country. Completion of this template will yield a clear Xpert MTB/RIF work plan in accordance with national policy and plan requirements of your country. The work plan template is intended to guide the implementation of Xpert MTB/RIF testing in facilities providing clinical services.

If an Xpert MTB/RIF work plan already exists for your country, you can use this guide as a reference to update, revise or complement the existing plan.

RESOURCES

The following resources were used in development of this work plan template:

1. Xpert MTB/RIF implementation manual: technical and operational 'how-to': practical considerations. WHO. 2014. [2].
http://apps.who.int/iris/bitstream/10665/112469/1/9789241506700_eng.pdf
2. Xpert MTB/RIF assay for the diagnosis of pulmonary and extra pulmonary TB in adults and children: Policy Update. WHO. 2013. [3].
http://apps.who.int/iris/bitstream/10665/112472/1/9789241506335_eng.pdf
3. TB Planning and Budgeting Tool. WHO. Updated 2014. [4]
http://www.who.int/tb/dots/planning_budgeting_tool/download/en/
4. FIND resources, as referenced: FIND Roadmap to Xpert MTB/RIF Implementation, checklists, standard operating procedures (SOP) and job aids.
5. Xpert MTB/RIF Rollout and Implementation Plan, Ministry of Health and Social Welfare. National Tuberculosis and Leprosy Programme. 2015. First edition.
http://ctrl.ntlp.go.tz/index.php?option=com_content&view=article&id=66&Itemid=73
6. Implementation Guideline for Xpert MTB/RIF Assay, Ethiopia MOH/EPHI, June 2014 [5].

WHO SHOULD USE THE XPERT MTB/RIF WORK PLAN TEMPLATE

The Xpert MTB/RIF assay work plan template is intended for use by individuals responsible for planning implementation and scale-up at the national level (e.g. national TB programme

managers and implementation consultants). Those completing the template are responsible for obtaining input from key stakeholders and ensuring dissemination of the work plan:



Policy Makers

Stakeholders at the ministry level and individuals involved in national and global policy should be sensitized to the importance of Xpert MTB/RIF implementation, its relation to global and national policy, and its accessibility among target populations. It is important that policy makers are part of the work plan process to ensure global policy recommendations are incorporated into the plan and are reflected in existing or new versions of national health and laboratory strategy.



Public Health Programme Managers

Managers of public health programmes involving HIV/AIDS, TB, women and children's health, and vaccinations should be engaged in the development of the work plan. Health care entry points for potentially infected TB individuals must be identified as part of the placement strategy. Furthermore, public health managers are important to the development and communication of new algorithms in collaboration with clinical managers and staff. Bridging communication between laboratory personnel and clinicians is critical to ensure continuity of care post-test.



Procurement and Logistics Officers

Procurement officers must understand the impact of sole sourcing Xpert MTB/RIF equipment and reagent cartridges on existing supply chain processes. Some countries place restrictions on the procurement of laboratory equipment and supplies in an attempt to ensure procurement of lowest cost products, non-branded items, supplies from specific distributors, or open systems. Lack of available substitute products necessitates sole sourcing of both equipment and cartridges, for which parallel procurement processes may need to be developed.

Logistics officers tasked with determining required quantities and coordinating customs entry, delivery and distribution will require advice from laboratory managers on shipping requirements, storage conditions and placement.

Procurement officers and logisticians need to be advised on product regulatory requirements to ensure the development of appropriate specifications including capacity and quality (the latter being especially important for procurement, customs clearance and shipment quality control [QC]). Furthermore, procurement officers and logisticians may be responsible for verifying the appropriate installation of equipment and training of staff.



Quality Assurance (QA) Officers

QA officers responsible for organizing QA schemes, post-market surveillance, training and supervision will require guidance on the implementation of an Xpert MTB/RIF-specific QA programme. Furthermore, the individual overseeing implementation must understand supervision and training limitations of the QA officer, as resources may not be sufficient to cover the required sites.



Clinical Managers and Staff

Together with public health programme managers, clinical managers and staff (including physicians, nurses, and clinic and community health workers) must be consulted during every phase of the implementation process. Input from this group of stakeholders is critical to ensure that patients are appropriately triaged and counselled for Xpert MTB/RIF testing; that high-quality samples are obtained, stored and transported appropriately; and that the test result is communicated to the appropriate health care professional in a timely manner. Clinical managers and staff require assurance of the quality of the test result, and must be empowered to provide appropriate clinical advice, referral (where required) and medical intervention.



Laboratory Managers

Laboratory managers must be consulted at each phase of implementation. Background information on facility infrastructure and location, human resource capacity, patient populations, test turn-around time and supply chain processes are essential during situational analysis, placement and phased implementation. Laboratory managers must also be engaged in QA and monitoring and evaluation (M&E) programme development, as they will be required to contribute key indicators of implementation success.



Partners and Donors

Partners and donors include stakeholders invested in Xpert MTB/RIF success such as national ministry officials, private sector leaders, multi-lateral organization officers, non-governmental organization staff and internal governmental organizations that have contributed intellectual input and financial resources. This group of stakeholders is responsible for authorization of activities, advocacy, fundraising, supporting implementation at the policy and field level, verifying implementation and communicating success. For the benefit of partners and donors, the individual leading the implementation effort must develop a process to obtain input from all stakeholders.

HOW TO USE THE XPERT MTB/RIF WORK PLAN TEMPLATE



Figure 1: Work through six stages of this template to complete an Xpert MTB/RIF assay implementation work plan

This template provides six stages, as depicted in Figure 1, which are to be completed using the text in the document and the tools indicated in the annexes. Instructions and resources are provided at the beginning of each stage. The instructions and resources are indicated in **blue text (Figure 2)**. You can copy and or modify the black text directly into your work plan. If any guidance in this document is not in compliance with existing national TB policies in your country, the language should be modified prior to use. Brackets [] indicate where to insert the text relevant to your country policies.

Certain stages provide data collection tables (in the annexes) to ensure adequate information is available to complete subsequent sections. Each section contains commonly-used work plan components:

- **Goal:** Identifies the overall expected impact of the project (e.g. to increase the number of TB patients receiving anti-TB therapy through expanded access to Xpert MTB/RIF testing);
- **Objectives:** Aims that meet the overall goal – these should be SMART (*i.e.* specific, measurable, achievable, relevant and time-bound; e.g. to procure and install equipment and train laboratory personnel on Xpert MTB/RIF in # facilities across # counties by # date);
- **Activities:** Identifies specific and implementable actions required to meet the objectives;
- **Outcomes:** Identifies the expected impact of the objective (e.g. # fully functional Xpert MTB/RIF equipment in # facilities across # counties by # date);
- **Resources:** Identifies human and other resources required to implement each activity;
- **Useful tools** are indicated using links to document annexes and text boxes;
- **Alternative activities** for specific sections are indicated using text boxes.

NOTE: the work plan template begins with section **STAGE 1: INTRODUCTION, OBJECTIVES AND BACKGROUND.**

STAGE 1 INSTRUCTIONS: DETERMINE GOALS AND OBJECTIVES OF THE WORK PLAN

National policies describing strategic and/or operational issues for TB control likely already exist in your country. However, it is possible the policies will need to be reviewed and updated.

Use the following resources to complete the policy section of this template:

- National policy / plan for health services
- National policy / plan for TB
- National policy / plan for HIV
- [others]

Instructions are shown in blue text. These are only used to guide work plan content. You will not include these in your final work plan.

SECTION 1: GOALS AND OBJECTIVES OF THE WORK PLAN

The goals and objectives for implementation and scale-up of Xpert in [insert country] are stated in the [insert reference document e.g. National strategic plan for TB laboratories] as follows:

1. [To utilize Xpert MTB/RIF to improve detection of MDR-TB, HIV-associated TB, smear-negative TB and for MDR-TB contact and retreatment cases in paediatric and adult patients]
2. [To implement Xpert MTB/RIF to the district level]
- 3.

Groups eligible for Xpert MTB/RIF are as follows:

- 1.

Template text for your work plan is shown in black. Once completed, copy and paste the text and headings into your final work plan document or you can just delete the blue text.

Figure 2: Use the template to create your own work plan, as illustrated in this figure

PART 1: INTRODUCTION, OBJECTIVES AND BACKGROUND

Policies describing recommendations and strategic / operational plans for TB control may already exist in your country. When creating your country Xpert MTB/RIF work plan, ensure it aligns with existing national recommendations. However, consider the need for policy review and update. The following information should be captured in your country Xpert MTB/RIF work plan:

- Global recommendations for Xpert MTB/RIF testing
- National policies and overarching strategy for Xpert MTB/RIF testing
- Groups eligible to receive Xpert MTB/RIF testing
- Xpert MTB/RIF testing algorithm

INTRODUCTION

Instructions: Use a title page followed by a table of contents, acknowledgements and an acronyms section. Copy the following language (in black) into your Xpert MTB/RIF work plan:

Title page: Xpert MTB/RIF® Implementation Work Plan (fill in the
[Insert country and country logo]
[Insert name of programme guiding this document]
[Insert address]
[Insert date])

Table of contents:
TABLE OF CONTENTS
[Insert contents]

Acknowledgements:

Instructions: Modify the text below to include the groups and names of individuals who have played an integral role in the rollout and uptake of Xpert MTB/RIF testing in your country and who contributed to the development of the plan.

ACKNOWLEDGEMENTS

[*National programme name*] completed this National Xpert MTB/RIF assay rollout and implementation work plan in close collaboration with various stakeholders and implementing partners.

The following partners provided extensive support and advice to aid the development of this Xpert MTB/RIF work plan for [country]. Sincere thanks to: [insert names and affiliations]. The [insert national programme name] led the development of this document through a collaborative process with [insert].

The Ministry of Health (MOH) acknowledges technical support from the following donors: [Insert contract numbers and groups if appropriate].

Special appreciation goes to [insert names] for thoroughly and critically reviewing the rollout plan and providing vital feedback. While it is not possible to mention each individual who contributed to this plan, we extend our thanks to all of them.

[Insert name, affiliation, title of person responsible for this plan, and date]

Acronyms

Instructions: Copy any acronyms from this document into your own plan and modify as needed. Include the names of the relevant national TB programmes in your country.

OBJECTIVE

Be clear about the intent of the work plan and reference current guidelines and documents that guide TB testing and/or Xpert MTB/RIF implementation in your country. Refer to the resources listed in [Annex A1](#) that describe the national policies and oversight of Xpert MTB/RIF implementation to:

- Identify the overarching objectives for the utilization of Xpert MTB/RIF in your country;
- Identify and review the existing national documents for Xpert MTB/RIF implementation and laboratory plans;
- Outline key national players, partners and technical working groups that are engaged in the Xpert MTB/RIF implementation in your country.

Instructions: Copy the text below; inserting the missing information into your work plan. Insert requested text in the brackets []:

OBJECTIVES

The aim of this work plan is to define the strategy for implementation of the Xpert MTB/RIF assay for rapid detection of TB and rifampicin resistance in [insert country], within the context of the [insert national programme] strategic plan and other national health guidelines. This work plan is intended to serve as the main guiding document for programme coordinators, National and Regional Reference Laboratories, partners, and all stakeholders involved in TB programmes. The objectives for implementation and scale-up of Xpert MTB/RIF are stated in the [insert reference document, e.g. National strategic plan for TB laboratories] as follows:

- [e.g. To use Xpert MTB/RIF to improve detection of MDR-TB, HIV-associated TB, smear-negative TB, extrapulmonary TB and for MDR-TB contact and retreatment cases in paediatric and adult patients]
- [e.g. To implement Xpert MTB/RIF at the district level]

The following [insert country] national documents currently exist for the guidance of TB and Xpert MTB/RIF testing, and have been used for data collection for this work plan:

- [insert document name and date]
- [insert document name and date]

The MOH has appointed an [insert designation of person responsible for leading implementation (e.g. Xpert MTB/RIF focal person)] and technical partners have been consulted and engaged on Xpert MTB/RIF implementation. A Technical Working Group (TWG), chaired by the MOH, has been convened. The TWG is responsible for ensuring work plan updates and implementation.

Note: If a TWG does not exist in your country, an attempt should be made to convene one with the MOH.

BACKGROUND

Instructions: Copy the following Xpert MTB/RIF background and global recommendations into your work plan. Modify sections to ensure compliance with existing policies in your country.

BACKGROUND

MDR-TB and HIV-associated TB are global priorities for TB control. MDR-TB is an increasing concern worldwide and directly threatens disease-control efforts in many countries. According to World Health Organization (WHO) estimates, 136,000 of 300,000 new cases of MDR-TB were diagnosed and notified in 2013 [6]. Misdiagnosis of TB likely contributed to a rise in nosocomial and community transmission, amplification of drug resistance, and thousands of deaths [7]. The

emergence of extensively drug-resistant TB (XDR-TB) and rapid high mortality in MDR-TB and XDR-TB patients with HIV co-infection is of great concern. The rise of these infections highlights the urgency for rapid diagnostic methods, especially in resource-limited settings where HIV burden is highest.

The Xpert® MTB/RIF assay for the Genexpert® platform is a fully automated, nested real-time PCR system that detects MTB complex DNA in sputum and other sample types (e.g. pleural, lymph node aspirate or tissue, cerebrospinal fluid, gastric fluid and tissue other than lymph node) and simultaneously identifies mutations in the *rpoB* gene that are associated with rifampicin resistance. By fully integrating and automating all processes required for real-time PCR-based molecular testing, Xpert MTB/RIF represents a simple and robust molecular test suitable for use in resource-limited settings where the burden of TB is highest. Xpert MTB/RIF can provide results directly from high-quality sputum samples within 90 minutes.

Tiered, integrated laboratory networks are fundamental to health care system accessibility and equity. Central level services (national reference and central public health laboratories) usually focus on disease surveillance, training, evaluation, quality assurance, and reference testing. Tertiary (e.g. teaching and specialist) hospitals and district (general) hospitals usually offer expanded diagnostic capacity and serve as referral centres for more complex cases transferred from the lower level. At the peripheral level (primary health care facilities), the focus is usually on early detection of diseases of public health importance using simpler diagnostic tools such as microscopy and rapid diagnostic tests (RDTs).

Attaining equitable access to rapid, high-quality TB diagnosis and treatment necessitates the expansion of diagnostic testing. Balancing centralized with decentralized testing to gain maximum efficiency and coverage depends on a range of factors and varies across country, region and facility. For health systems where strong laboratory referral networks are already in place, the appropriate choice may be to strengthen sample referral. In cases where sample referral is weak but linkage to care is strong, there may be a preference for decentralization of Xpert MTB/RIF assay capacity to district and sub-district levels.

In 2010, WHO endorsed the Xpert MTB/RIF assay to detect MTB and rifampicin resistance [1]. The 2010 WHO policy guidelines recommended that Xpert MTB/RIF be used as an initial diagnostic test in individuals suspected of MDR-TB or HIV-associated TB (strong recommendation, moderate quality of evidence). The guidance also provided a conditional recommendation that Xpert MTB/RIF be used as a follow-on test to smear microscopy in settings where MDR-TB or HIV are of lesser concern, especially in further testing of smear-negative specimens.

In 2013, an Expert Group was convened by WHO to review the body of evidence on use of Xpert MTB/RIF. The resulting recommendations from the Expert Group were included in a 2013 WHO Policy update, which widens the recommended use of Xpert MTB/RIF, including for the diagnosis of paediatric TB and on selected specimens for the diagnosis of extrapulmonary TB, and includes an additional recommendation on the use of Xpert MTB/RIF as the initial diagnostic test in all individuals presumed to have pulmonary TB. The Policy update recommends the following:

- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in adults and children suspected of having MDR-TB or HIV-associated TB (strong recommendation).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all adults and children suspected of having TB (conditional recommendation acknowledging resource implications).
- Xpert MTB/RIF may be used as a follow-on test to microscopy in adults suspected of having TB who are not at risk of MDR-TB or HIV-associated TB, especially when further testing of smear-negative specimens is necessary (conditional recommendation acknowledging resource implications).

- Xpert MTB/RIF should be used in preference to conventional microscopy and culture as the initial diagnostic test in testing cerebrospinal fluid (CSF) specimens from patients suspected of having TB meningitis (strong recommendation given the urgency of rapid diagnosis).
- Xpert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, or histopathology) for testing specific non-respiratory specimens (lymph nodes and other tissues) from patients suspected of having extrapulmonary TB (conditional recommendation) [2].

GROUPS ELIGIBLE TO RECEIVE XPERT MTB/RIF TESTING

Instructions: Use the resources listed in [Annex A1](#) to identify populations approved to receive Xpert MTB/RIF testing as per your country national plans and policies. Modify and use the text in brackets [] below.

GROUPS ELIGIBLE TO RECEIVE XPERT MTB/RIF TESTING

[Insert WHO recommendations from Annex A1]

In accordance with the [insert country national plan], the following groups are eligible for Xpert MTB/RIF testing in [insert country]:

1. [e.g. People living with HIV (PLHIV) and those with unknown HIV status, as recommended by WHO guidelines and the National AIDS Programme Policy]
2. [insert brief sentence describing the Xpert MTB/RIF testing protocol for this group]
3. [e.g. Presumptive TB, sputum smear-negative]
4. [insert brief sentence describing Xpert MTB/RIF testing protocol for this group]
5. [e.g. Presumptive MDR-TB]

The [insert appropriate national document, if available or agency] defines the following patient groups as being at high risk for MDR-TB, and therefore eligible for Xpert MTB/RIF as the initial test:

- [Patients who have failed, relapsed, or returned after loss to follow-up who were on a TB retreatment regimen (formerly chronic TB cases).
 - Failure of the first-line regimen (patients who are sputum smear positive at month 2 or 5 during the course of the standard treatment regimen for new patients).
 - Relapses and returns after loss to follow-up from standard treatment for new patients who are smear positive at month 3 of retreatment.
 - Symptomatic close contacts of a known MDR-TB patient]
6. [e.g. Children less than 15 years old]

[Insert brief sentence describing Xpert MTB/RIF testing protocol for this group]

XPERT MTB/RIF TESTING ALGORITHM

Instructions: For your Xpert MTB/RIF work plan, identify the national TB Xpert MTB/RIF testing algorithm. Ensure that the algorithm includes Xpert MTB/RIF testing in relation to other tests such as microscopy, chest x-ray, culture and drug susceptibility testing (DST) and the process for discrepant test results. In the flow diagram, indicate the necessary steps to take when Xpert MTB/RIF gives a RIF resistant result, but a second test (Xpert MTB/RIF or another DST method) gives a RIF susceptible result.

Examples of testing algorithms incorporating WHO-recommended TB diagnostics are provided in [8].

Add your country clinical guidelines on case and patient management after Xpert MTB/RIF testing. A sample algorithm can be found in [Annex A2](#). Copy the following text that is requested in the brackets [].

XPRT MTB/RIF TESTING ALGORITHM

The routine diagnostic algorithms for [insert your country] have been defined. The diagnostic algorithm has been designed to maximize clinical outcomes and to assure appropriate instrument utilization. It is of the utmost importance that all sites offering routine testing follow the national algorithm, and that all implementers are oriented and committed to following the algorithm.

The routine diagnostic algorithm for [country], as per [national document] is shown here:
[Insert algorithm]

PART 2: SITUATIONAL ANALYSIS

An assessment of the epidemiological situation of TB and of TB laboratory diagnostic availability in your country can help form the basis of your GeneXpert placement plan.

EPIDEMIOLOGICAL DATA

Instructions: Copy and use the text below in the relevant section of your work plan. Insert text requested in the brackets []. Refer to [Annex B1](#) for a list of resources to obtain such data.

EPIDEMIOLOGICAL DATA

Epidemiological data and TB-related health system infrastructure impact the placement and optimisation of Xpert MTB/RIF testing to support case detection and shorten test turnaround time.

Recent data from [country] in [year] show [insert number] TB cases of all forms (new and retreatment), an [increase/decrease] from [year], according to the WHO Global Tuberculosis Report [insert reference]. Among the new pulmonary TB cases in [year], [insert number] were bacteriologically confirmed and [insert number] were clinically diagnosed. The number of new extrapulmonary TB cases was [insert number]. HIV is a major contributing factor for developing active TB. [Country] has a [%] TB/HIV co-infection rate [reference]. In [country], the rate of MDR-TB among new and previously treated TB cases is [X% and Y%] respectively. Data were obtained from [insert reference].

[Insert graph of your country's current epidemiological TB data; refer to [Annex B1](#)].

LABORATORY ANALYSIS

This covers an assessment of existing laboratory infrastructure in your country, along with any existing Xpert MTB/RIF testing capacity, and aids determination of scale-up requirements.

Instructions: Perform a qualitative analysis of the TB laboratory capacity in your country by completing a SWOT (strengths, challenges, opportunities, threats) analysis; refer to [Annex B2](#) for a template.

Using country TB reports and data, identify existing TB diagnostic sites and TB tests currently performed at each level of the TB laboratory network; refer to [Annex B3](#) for a template.

Copy the text below and the completed figures from Annex B2 and B3, and use in the relevant section of your work plan. Insert text requested in the brackets [].

LABORATORY ANALYSIS

Though significant improvements have been made in recent years, the laboratory network in [country] continues to face challenges. Primary issues are captured in the following strengths, weaknesses, opportunities, and threats (SWOT) analysis.

[Insert SWOT analysis or refer to the completed SWOT analysis figure in [Annex B2](#)]

[Insert TB test, *i.e.* sputum smear microscopy] is the main TB diagnostic tool used in [insert country] and is available at a total of [insert number] facilities (diagnostic centres) at the district/sub-district level. Xpert MTB/RIF is currently being implemented in [insert number] sites.

The expansion of Xpert MTB/RIF testing requires a strong laboratory network, robust quality assurance system, and adequate culture and drug susceptibility testing capacity at the Central Tuberculosis Reference Laboratory.

[Insert existing TB Testing Sites table or refer to it in the Annex.]

PART 3: COORDINATION OF STAKEHOLDERS

Engaging the appropriate stakeholders before, during and after implementation is necessary to ensure buy-in and standardization of Xpert MTB/RIF rollout. The following steps are recommended to ensure achievement of the objective of full district-level Xpert MTB/RIF coverage:

1. All parties seeking to introduce Xpert MTB/RIF for routine diagnosis should hold an initial consultation with the National TB manager before determining placement.
2. The national TB manager, in collaboration with other stakeholders, should advise on instrument placement based on existing coverage gaps.
3. The national TB manager, in collaboration with stakeholders, should consult with district medical officers regarding site readiness and the availability of care, treatment and referral services post-diagnosis.
4. The national TB manager, in collaboration with stakeholders, must confirm availability of post-placement support for the instrument that includes maintenance and supply of reagents.
5. An agreement is reached between key parties regarding instrument placement.
6. The MOHSW and relevant parties assign a memorandum of understanding (MOU). The MOU should contain information regarding:
 - The introducing party provides information about duration of support.
 - The introducing party quantified the resources being provided, including cartridges, reagents, calibration, warranty, maintenance, staff training, and technical support.
 - Details of the transition plan and how the instruments will continue to be supported after handover date.
 - The introducing party provides indication that they will abide by National TB Programme guidelines for Xpert MTB/RIF use, and agree to hand over a fully functional instrument.

Note: Once an Xpert MTB/RIF placement strategy is finalized, it is recommended that further stakeholder meetings are held to plan for training, site supervision, troubleshooting and sharing of data, and that an Xpert MTB/RIF Introduction agreement ([Annex C1](#)) is signed and approved. It is also important to form linkages to HIV programmes and TB treatment centres when discussing plans with key stakeholders. Therefore stakeholder meetings should have representatives of the National TB Programme, the National TB reference laboratory, the National HIV/AIDS Programme, PMDT services, and all partner organizations involved in the roll-out of Xpert MTB/RIF in the country.

Instructions: Using the suggested steps above, summarize the measures that have been taken to ensure stakeholder coordination and buy-in for Xpert MTB/RIF testing in your country.

COORDINATION OF STAKEHOLDERS

[Insert summary here]

[Insert the parties present at key meetings] convened stakeholder meetings during the initial part of the work plan process in [insert month and year]. The overarching roles of key stakeholders for Xpert MTB/RIF implementation were determined as in the table below.

Stakeholder	Roles / Responsibilities	Communication / Coordination Process

It is important for the above table to be completed before phased implementation proceeds, as this information will enable stakeholders to accurately map resources and allow sufficient time for [insert National TB programme] authorities to conduct sustainability planning.

PART 4: XPERT MTB/RIF PLACEMENT STRATEGY

The following considerations are important for Xpert MTB/RIF placement:

1. Indicate GeneXpert equipment capacity.
2. Map location of existing Xpert MTB/RIF equipment.
3. Determine the total quantity of new instruments required (based upon estimated numbers of patients requiring Xpert MTB/RIF testing) to meet current and future TB diagnostic service needs.
4. Estimate annual scale-up requirements for the next five years.
5. Determine facilities where the new instruments will be placed. Recommendations for consideration include:
 - Burden of TB, MDR or HIV-associated TB in specific districts or regions.
 - Priority for sites with high TB and HIV burden.
 - Priority for health facilities expecting >8-12 specimens per day from the target patient groups, or with >500 cases of TB per year or >1000 patients currently enrolled in HIV Chronic Care¹.
 - Health facilities must meet minimum standards of infrastructure including:
 - adequate infrastructure, and
 - linkage to TB and MDR-TB care and treatment.
6. Link sites with low sample volumes to the closest Xpert MTB/RIF testing facility by establishing robust sputum specimen referral systems.

Once selection criteria have been determined and relevant stakeholders have agreed on selected sites, use the tools in Annex 5 to devise the placement strategy. See [Annex D4](#) for an example of how an Xpert MTB/RIF placement strategy was devised using existing country data.

GENEXPERT TESTING CAPACITY

Instructions: Indicate the number of samples that can be tested per day per GeneXpert module. Consider the number of modules, the number of tests per day per module, the number of tests per day and the number of days per week testing is performed. See [Annex D1](#) for an example. Copy and paste the following information into your Xpert MTB/RIF plan.

GENEXPERT TESTING CAPACITY

To determine acceptable sites for GeneXpert instruments placement in [insert country], epidemiological data on TB, current Xpert MTB/RIF testing centres and testing capacity have been considered. The 4-module GeneXpert instrument testing capacity per year is based on [insert number] analyses/year (12 analyses/day X 5 days/week X 52 weeks per year).

LOCATION OF EXISTING GENEXPERT INSTRUMENTS

Instructions: List the current location of Xpert MTB/RIF instruments in your country. Refer to [Annex D2](#) for a sample table. Copy the text below and the completed table and map from the annex and use in the relevant section of your work plan. Insert text requested in the brackets [].

LOCATION OF EXISTING GENEXPERT INSTRUMENTS

¹ NB. Consideration from Ethiopia national plan for Xpert MTB/RIF implementation. Implementers should determine criteria for each country in coordination with ministry stakeholders.

The first GeneXpert instrument was introduced in [insert country] in [insert year]. GeneXpert instruments are currently placed in [insert number] sites in [insert number] provinces/regions [insert country].

Of a total [insert number] instruments in [insert country], [insert number] are for research use and [insert number] are for routine use:

- [insert number] sites have [insert number] GeneXpert instrument with 4 modules
- [insert number] sites have [insert number] GeneXpert instruments with 8 modules
- [insert number] sites have [insert number] GeneXpert instruments with 16 modules

The complete list (at the time of writing this work plan) illustrating machine placement, supporting partners, and number of modules per machine can be found in the Annex [insert annex number].

BUDGET AND RESOURCE MAPPING

Budgeting and resource mapping may take place during stakeholder coordination, but will need to be revisited periodically during all phases of implementation as many aspects of the work plan may change according to needs identified during rollout.

Determining the required budget and other resources to meet country testing need is an important early step in the planning process. Comparison of required resources to those available will no doubt impact the work plan. Be cautious about moving forward with a plan for which you do not have the resources to accomplish!

Instructions: Describe key financial stakeholders and resources for Xpert MTB/RIF implementation in your country. Include the amount of funds available. Copy and paste the following text into your work plan:

AVAILABLE RESOURCES

Per [insert country] Xpert MTB/RIF testing work plan, [insert number] new GeneXpert machines will be placed in [insert country] by [insert year].

[Insert country] MOH will use funds from the sources below for the [introduction/scale-up/decentralization] of Xpert MTB/RIF testing:

- [Insert domestic sources of support e.g. Ministry of Finance, MOH, private entities, etc., including time frame]
- [Insert international sources of support e.g. Global Fund, etc., including time frame]

[If a significant source of funding is international, insert paragraph here concerning sustainability of programme]

BUDGET ESTIMATION

Instructions: Using information provided in the GeneXpert cost estimation table, populate the Annual Operational Budget table (Figure 11) in [Annex G](#).

Instructions: Copy the completed Figure 11 and the text below into your country Xpert MTB/RIF work plan.

A resource mapping exercise was carried out taking the following into consideration:

- Costs were divided into the following categories:
 - GeneXpert instruments (assumed to be four modules and inclusive of desktop computer), cartridges (inclusive of 15% buffer), UPS
 - Running costs: consumables/reagents, extended warranty (including XpertCheck and calibration), external quality assessment
 - Staff needs: site supervision, new staff
 - Health system: training, minor laboratory infrastructure refurbishments/upgrades.
- A [insert year] horizon was employed, in line with the National TB Laboratory Strategic Plan time frame.
- Information from partners regarding support including number of instruments, period of support, handover plans, and resource commitments within each of the costing categories.

Given the above considerations, the tables below demonstrate the estimated funding required to roll out the Xpert MTB/RIF expansion plan in [insert country].

[Insert completed Xpert MTB/RIF Budget Estimation Tool].

[Insert completed Operation Cost Table from [Annex G](#)].

Instructions: Calculate the total amount of extra funding required by finding the difference between the available funding and the funding required as determined from the Xpert MTB/RIF Budget Estimation Tool. Copy the text below into your country's Xpert MTB/RIF work plan.

Amount of available funding= [insert amount] from [insert year range]

Amount of required funding= [insert total amount calculated from the Xpert MTB/RIF Budget Estimation Tool and the Operation Cost Table]

To execute the Xpert MTB/RIF expansion plan, the amount of funding required is: [insert the difference between the two numbers above].

QUANTITY OF NEW INSTRUMENTS REQUIRED

Instructions: Using the tools from [Annex D3](#), determine the required test capacity in each region. Develop projections for Xpert MTB/RIF demand over the next five years. Copy and paste the following text and data (from [Annex D3](#)) into your work plan.

QUANTITY OF NEW INSTRUMENTS REQUIRED

[insert country] requirements for new GeneXpert instruments were calculated by projecting TB case notifications (total new and relapse cases) anticipated for the next five years. The number of Xpert MTB/RIF instruments required to meet the need is [insert number] in [year] and [insert numbers] for [future years], respectively. The number of instruments already in use has been accounted for in the projected Xpert MTB/RIF instrument requirements.

PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

Although not ideal, procurement of Xpert MTB/RIF instruments may, due to lengthy processes, begin during work plan development. Ideally, sites will have been assessed so that the placement strategy is in line with facility capacity to receive instruments. Infrastructure improvements can impact the placement timeline, therefore it is important that the work plan be updated continually during development and even performance of activities.

Xpert MTB/RIF cartridges have a limited shelf-life. Hence, the national and regional TB control programmes must coordinate the distribution of cartridges from a single central point. Recommendations for an Xpert MTB/RIF supply chain system include:

1. Each site manager requests stock from the regional or district warehouse by a set date, namely two weeks before the start of the new quarter;
2. To avoid stock outs due to delivery delays, the laboratory should have a minimum of two weeks buffer on hand (this needs to be calculated based on workload of laboratory, storage capacity and frequency and reliability of deliveries);
3. An emergency order process should be in place but only used under special circumstances;
4. Emergency orders should be monitored and sites with the highest rates should be investigated;
5. A designated representative should collect logistics data (consumption, losses and adjustments, and stock on hand) from each site or representative sites;
6. A designated representative should check orders against site logistics data.
7. District and regional warehouses should place quarterly (at a minimum) stock orders from the medical supply unit;
8. Depending upon the situation, a minimum of one month buffer stock should be kept on hand at each site;
9. The central cartridge stock should be carefully monitored and maximum and minimum stock levels should be determined;
10. The manager of the central store or a designated representative should work closely with the manufacturer to ensure availability of sufficient supply, including customs clearance procedures.

Refer to [Annex E3](#) for a template for forecasting Xpert MTB/RIF commodities.

Instructions: Copy and paste the following text into your work plan.

PROCUREMENT AND PREPARATION OF SUPPLY CHAIN MANAGEMENT

It is the responsibility of the [insert national TB programme] to incorporate procurement plans for Xpert MTB/RIF instruments and associated consumables into annual forecasting and

quantification activities. Some of the supplies required for using the Xpert MTB/RIF assay are not provided by the manufacturer. When calculating orders of supplies, past consumption rate, stock on hand, shelf-life of the ordered material, lead time, and storage capacity should be considered. Sites should maintain logistic records and perform monthly physical stock counts.

The Xpert MTB/RIF work plan with forecasted quantities and budget details should be aligned with the national TB strategic plan.

In [insert country], Xpert MTB/RIF cartridges are procured by the following channels: [insert procurement process including personnel responsible for each component of the process].

The quarterly indicators (see Monitoring and Evaluation section) should be used to calculate district consumption. The regular TB supply chain should be used for this purpose. Due to transport issues to some sites, it may be necessary to implement a district-level stock buffer to ensure that stock outs do not occur.

All testing centres must establish a strong, transparent and reliable commodity management system at the institutional level. System for regular inventory of cartridges must be in place with updated information on stock levels and expiry dates for all available batches of cartridges. The principle of first expiry first out (FEFO) should be strictly enforced.

PLACEMENT OF NEW INSTRUMENTS

Instructions: Using the total number of new GeneXpert instruments required, determine the location of placement to achieve near full capacity of each. Placement should be made in a phased manner (e.g. over five years). Use the table in [Annex D3](#) to determine the most efficient Xpert MTB/RIF expansion plan. [Annex D4](#) provides an example of Xpert MTB/RIF placement using sample data.

PLACEMENT OF NEW INSTRUMENTS

The Xpert MTB/RIF placement plan for [country] was determined using the following criteria:

- [Insert the criteria you used]
- [Describe how you will attain highest instrument capacity]
- [Describe sample referral networks]
- [Describe plan for priority placement (*i.e.* site with largest TB and HIV burden)]

Proposed targets for Xpert MTB/RIF placement are as follows:

Phase 1:

- districts to be equipped with [insert number] Xpert MTB/RIF instruments from [insert year range]
- [Insert names of Phase 1 districts]

Phase 2:

- districts to be equipped with [insert number] Xpert MTB/RIF instruments from [insert year range]
- [Insert names of Phase 2 districts]

PART 5: ROADMAP FOR PHASED IMPLEMENTATION

FIND developed a Roadmap for Xpert MTB/RIF implementation that is customizable to each country. Stage 5 describes the roadmap steps: pre-installation; installation and training; early implementation and routine implementation.

Instructions: Copy and paste the following text into your work plan.

FIND developed a roadmap for Xpert MTB/RIF implementation (Figure 3). This section of the Xpert MTB/RIF work plan describes the roadmap for implementation in [country].

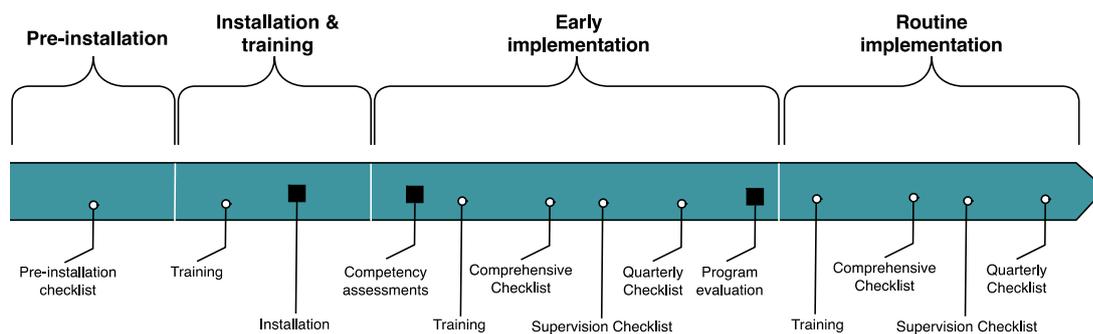


Figure 3: FIND Roadmap to Xpert MTB/RIF Implementation

ROLES AND RESPONSIBILITIES

Instructions: Copy and paste the text below into your work plan. Complete the following table of roles and responsibilities for Xpert MTB/RIF implementation. If necessary, amend the “Responsible individual” column to reflect the appropriate designation (i.e. it may be more appropriate to refer to this individual as “focal person” or “responsible party”). Refer to [Annex E1](#) for examples of roles and responsibilities.

ROLES AND RESPONSIBILITIES

Clearly defining each individual and the activities for which they are responsible will ensure clarity and increase accountability for implementation-related activities. Lines of communication and authority should also be clearly defined. All players should be informed regarding their roles and responsibilities.

[Insert roles and responsibilities for Xpert MTB/RIF implementation activities by completing the table below].

Table 1: Roles and responsibilities for [insert country] Xpert MTB/RIF work plan

Responsible entity	Responsible individual	Role(s)
MOH		
National TB Programme Manager		
National TB Reference Laboratory		
Regional Reference Laboratories		
Health facilities		
Partners		

Regional TB coordinators		
Regional laboratory technologists		
District TB coordinators		
District laboratory technologists		

PRE-INSTALLATION

PRE-INSTALLATION SITE VISIT AND CHECKLIST

Conduct site visits to ensure selected facilities meet selection criteria for Xpert MTB/RIF placement. A major component of the pre-installation visit is to identify required facility upgrades. It is essential to detail required upgrades for each site and to determine responsibilities and timelines for completion of the work. It will be necessary to identify funds for performing important upgrades.

Infrastructure

- Stable electricity supply
- Measures in place to ensure uninterrupted supply (generator, solar panels, battery/UPS backup, etc.)
- Secure premises to prevent theft of the Xpert MTB/RIF instrument and computer/laptop
- Adequate storage space for cartridges at recommended temperature range (2-28°C)
- Measures in place to prevent ambient temperature exceeding 30°C in the room where Xpert MTB/RIF instruments will be installed (e.g. ventilation, air conditioning)

Human resource capacity

- Availability of 1-2 laboratory staff
- Staff have basic computer literacy
- Staff have working knowledge of laboratory registers
- Staff can be trained to perform testing, equipment maintenance and data management

Workload per 4-module Xpert MTB/RIF instrument

- Potential number of samples from target groups at least 5-20 specimens a day or 1,000-3,500 per year, including from existing or potential referral centers

Logistics

- Facility easily accessible by referring facilities (e.g. via public transport or courier service)
- Distribution routes for Xpert MTB/RIF supplies available year-round
- Basic inventory management system in place or facility has capacity to initiate one

Treatment capacity

- Sufficient capacity for treatment of identified TB and MDR-TB patients
- System for patient referral in event care and treatment is unavailable
- Availability of TB therapy (first and second line) and other pertinent drugs

Instructions: Conduct baseline site assessment visit and complete the Xpert MTB/RIF implementation site pre-assessment checklist in [Annex E2](#). It is recommended that district

medical officers participate in the visit to ensure mobilization of funds that may be required to carry out necessary improvements. Copy and paste the following text into your work plan.

PRE-INSTALLATION SITE VISIT AND CHECKLIST

A site is considered eligible for Xpert MTB/RIF if it has met the criteria stipulated in the pre-installation checklist ([Annex E2](#)). The pre-installation checklist must be completed for each facility where an Xpert MTB/RIF instrument will be placed.

A pre-assessment of sites was conducted and results for each facility are in the completed Xpert MTB/RIF Implementation Site Assessment Checklist which is located in [insert location]. The following sites were found to be appropriately prepared for Xpert MTB/RIF placement:

[Insert sites]

The following sites were found currently unsuitable for Xpert MTB/RIF placement: [insert sites].

The following requirements must be fulfilled prior to Xpert MTB/RIF placement (*complete table below*):

Table 2: Site improvements required prior to placement

Site	Infrastructure	Human Resources	Linkage to Care and Treatment	Responsible Party	Est. Date of Completion

INSTALLATION AND TRAINING

STANDARD OPERATING PROCEDURES (SOPS)

Instructions: Xpert MTB/RIF SOPs, job aids and other documentation should be included in your work plan. The Global Laboratory Initiative (GLI) has developed SOPs that can be (or have been) adopted for country use. Refer to [Annex E4](#) for examples. Copy and paste the following text into your country work plan.

STANDARD OPERATING PROCEDURES

The Xpert MTB/RIF programme manager shall oversee the adoption and use of standard operating procedures (SOPs) to ensure highest possible quality and to maintain consistency.

The Xpert MTB/RIF programme manager, in collaboration with other experts, will use the comprehensive suite of SOPs and job aids that the manufacturer and GLI have customized for [insert country]. Compliance with SOPs will ensure standardization of procedures involving biosafety, collection and transportation of sputum specimens, testing processes, results

management, recording and reporting, testing algorithms, instrument maintenance, troubleshooting, quality assurance, and supply management. Refer to [insert annex] for a list of relevant documents and tools and specific SOP considerations.

TRAINING

An Xpert MTB/RIF training curriculum and complimentary competency assessments are required for laboratory and supervisory staff.

Instructions: Copy the text below into your country Xpert MTB/RIF work plan. If your country has not adopted the existing training materials, modify the text to describe national materials used. Note that type and timing of training, and the selected trainees, will vary for different countries. The text below should be edited for your country work plan.

Training methods

Laboratory personnel, clinicians, nurses, TB and HIV programme officers and hospital administrators must be trained on Xpert MTB/RIF algorithms and use prior to service initiation. A minimum of three days training should be conducted for laboratory personnel from Xpert MTB/RIF testing sites using the national standardized training material. One-day on-site sensitization workshops can be conducted for hospital administrators, laboratory supervisors; HIV and TB programme officers, and general health care workers from testing and sample referring centres.

TRAINING

A standardized training curriculum customized to [insert country] has been developed. Master trainers, who will train users during phased implementation, will be identified and trained.

Training materials

Xpert MTB/RIF training materials, developed by GII and the manufacturer, are available at [insert location] and described below. Competency assessment will be performed after training has occurred.

Groups of training participants (*edit as required*):

Users: Xpert MTB/RIF user training enables laboratory personnel to understand the testing algorithms, perform the Xpert MTB/RIF test, interpret Xpert MTB/RIF test results, maintain the Xpert MTB/RIF instrument, and supply the National TB Programme with relevant indicators.

Laboratory Coordinators (also termed Focal Points) perform supervisory visits, competency assessments, troubleshooting and data collection.

Clinicians are to be trained in the fundamentals of Xpert MTB/RIF technology, testing and treatment algorithms, and requesting and interpretation of Xpert MTB/RIF test results.

Regional Tuberculosis Coordinators: Regional TB clinicians are trained in the fundamentals of the Xpert MTB/RIF technology, testing and treatment algorithms, and requesting and interpretation of Xpert MTB/RIF test results. This training also prepares coordinators to perform quarterly supervision visits.

Practical training makes up [insert %] of the course and didactic topics include (*complete the table below*):

Table 3: Training topics, learning objectives and target participants

Training Component	Major Learning Objectives	Targeted Training Participant
TB and TB diagnosis		
Clinical algorithms		
Diagnostic algorithms		
Safety		
Sample collection, transportation, registration, and rejection		
Supply chain management		
Xpert MTB/RIF technology		
Xpert MTB/RIF start-up		
Xpert MTB/RIF assay		
Interpreting, recording, and reporting of results		
Data management		
Instrument troubleshooting, servicing, and maintenance		
Quality assurance		

Timing of training for phased installation

Training will be timed to coincide with installation of Xpert MTB/RIF instruments so that participants are trained within [enter number of weeks – suggest no more than three] of test initiation. Refresher training must be provided in the event of a longer period between training and service initiation.

[Insert the proposed training schedule, by site, here – include the names of available trainers, numbers of days of training and plans for transportation between sites]

INSTALLATION: INSTALLATION CHECKLIST AND INSTRUMENT MAINTENANCE

During installation, testing sites should be provided with installation checklists, equipment manuals, maintenance documents and logs. Xpert MTB/RIF instruments must be cleaned and maintained according to the manufacturer’s instructions and calibration and servicing contracts must be in place. Refer to [Annex E2](#) for the installation checklist and [Annex E4](#) for a list of installation and training documents, tools and SOPs for use with Xpert MTB/RIF testing and a summary of preventive maintenance activities.

Instructions: Copy and paste the following text into your work plan.

INSTALLATION: INSTALLATION CHECKLIST AND INSTRUMENT MAINTENANCE

Installation Checklist

The Installation Checklist enables staff involved in implementation to ensure Xpert MTB/RIF installation and training have been performed correctly. A copy of the completed checklist and any supporting documents must be sent to [insert titles of individuals].

An audit visit will be conducted at each Xpert MTB/RIF placement site within three months of installation and staff training. [Insert the responsible party] will oversee the site audit, ensuring use of the standardized checklist. Corrective actions and retraining must be carried out within [insert time] and prior to site initiation of testing service.

The following items are required for installation:

- GeneXpert system (instrument and computer);
- Xpert MTB/RIF cartridges, printer, UPS and surge protector;
- GeneXpert country-specific installation checklist;
- GeneXpert installation documents [list documents];
- GeneXpert operator manual

Instrument Maintenance

Maintenance includes daily, weekly, monthly and annual procedures. Completion of maintenance processes will be checked during [insert frequency (e.g. monthly, quarterly, biannually)] supervisions. A list of maintenance SOPs and logs can be found in [insert Annex].

Instrument Calibration

Annual calibration using manufacturer-provided XpertCheck (calibration) kits must be performed for each instrument and is a condition of the warranty. The Xpert MTB/RIF laboratory coordinator must maintain calibration schedules and work with regional and district stakeholders to ensure all instruments are calibrated within the required timeframe. Sufficient quantities of calibration kits, [insert time] within date, will be made available. The facility and the laboratory coordinator will keep copies of the calibration reports. If errors are detected, a three-month .gxx file and system log report will be sent to the manufacturer for analysis. The GLI Xpert MTB/RIF training materials provide an Xpert MTB/RIF calibration log to track calibration data [insert location of log].

EARLY IMPLEMENTATION

During the early implementation phase, many activities occur such as training, competency assessment, completion of checklists, programme evaluation and handover. These ongoing activities must be tracked and monitored to ensure proper and efficient Xpert MTB/RIF testing.

COMPETENCY ASSESSMENTS

Each staff member must be assessed for competency after initial training and installation before providing Xpert MTB/RIF testing services. A procedure for competency assessment and an appropriate checklist should be developed. All staff training and determination of competency must be documented and these records must be safely stored.

Instructions: Copy and paste the following text into your work plan

COMPETENCY ASSESSMENT

A competency assessment procedure has been developed and can be found here [insert location of document]. This assessment must be used to ensure proficiency of all staff prior to starting Xpert MTB/RIF testing. Any corrective action or refresher training provided must be documented on the corrective action form provided in [Annex E](#).

TRAINING

Additional training on Xpert MTB/RIF is provided after initial training, installation and competency assessment. The type of training provided will depend on the findings of the competency assessment. Repeated refresher training and more intense mentoring may be required as Xpert MTB/RIF is rolled out in other decentralized facilities.

Instructions: copy and paste the following text into your work plan.

TRAINING

The following standardised trainings are conducted during pre-installation and early implementation phases:

- **Laboratory Coordinator training:** includes orientation on instrument installation and use of the pre-installation checklist; procurement and inventory management; recording and reporting; advanced maintenance and supervision of site maintenance; troubleshooting; and quality assurance.
- **Clinician training:** includes diagnostic algorithm, Xpert MTB/RIF results interpretation and reporting system and follow up of patients for treatment initiation and confirmatory testing.

QUALITY ASSURANCE AND SUPERVISION

The Xpert MTB/RIF testing service must be supported by a quality assurance system consisting of the following components:

- Training and user competence assessment
- Instrument verification
- Quality indicator monitoring
- On-site supervision
- New lot (incoming) QC testing
- Proficiency testing (PT)

Routine monitoring of quality indicators is the most important aspect of quality assurance for the GeneXpert system. Monthly reporting and review of laboratory quality indicators ensure efficient and high-quality use of Xpert MTB/RIF and enable the early identification and correction of issues. Remote monitoring of instrument data may be implemented to assist with data collection for this purpose. However, review of data and instigation of corrective action is the key element, and often neglected.

Instrument verification should be performed on all instruments after installation and after calibration, module replacement or moving an instrument. Verification samples are provided free of charge by the manufacturer.

The Xpert MTB/RIF instrument performs IQC for each sample using controls built into the test cartridge. In addition, every new batch of cartridges should be checked with known positive and negative specimens before using them for patient sample testing. This is usually conducted at the NTRL prior to distribution of cartridges to sites.

EQA may include one or a combination of the following: proficiency testing (PT), site visits and blinded rechecking. EQA should be performed for Xpert MTB/RIF testing alongside existing smear microscopy EQA.

FIND provides the following checklists for the early implementation phase:

- Comprehensive checklist;
- Supervision checklist;
- Quarterly checklist;
- Pre-handover checklist.

These checklists are intended for use by staff and consultants undertaking laboratory monitoring and supervision visits to assess Xpert MTB/RIF test implementation. On-site supervisory visits form a critical part of the quality assurance programme associated with Xpert MTB/RIF implementation, and will be conducted at pre-determined time intervals. More information on Quality Assurance is provided in the GLI Xpert MTB/RIF training package.

Instructions: Copy the following text into your work plan and edit as needed:

Training and user competence. The following standardised training curricula are approved in [country] for training of [name various cadres]

Competence assessment will be conducted at the completion of training, and during on-site supervision. A log of certified users will be kept by [designated authority]. Refresher training will be conducted for all users on a [give period] basis.

Instrument verification. All GeneXpert instruments will be verified using the panel provided by Cepheid after initial installation and following calibration, module replacement or moving of instruments. Data will be forwarded to the GeneXpert focal person.

Quality indicator monitoring. Quality indicators will be monitored on a monthly / quarterly basis. Review of data will be conducted by [name those responsible] and support for corrective and preventive actions will be provided to sites by [explain the mechanism for corrective actions].

On-site supervision. All sites will receive on-site supervision at pre-determined intervals [insert frequency of visits] by [name cadre of staff conducting visits], see Table 4. On-site supervision visits will be documented using the following checklists:

- Comprehensive checklist;
- Supervision checklist;
- Quarterly checklist;
- Pre-handover checklist.

On-site supervision reports will be provided to NTP manager, NTRL manager and regional focal points.

Table 4: Timing of site supervision

Visit	Frequency	Responsible Party
Pre-handover		
Comprehensive		
Supervision		
Quarterly		

Comprehensive site visit assessments will be conducted as an initial assessment of site competency after installation, and annually thereafter.

Proficiency Testing (PT). PT will be used to identify major issues in test quality and will involve the [insert programme description including panels, delivery, return of results and feedback]. [Insert PT provider] will conduct PT [insert frequency] for all Xpert MTB/RIF testing sites, providing panels through regional laboratories [insert number] times per year. [Insert responsible party] will collect PT results from the testing sites, analyse the data and provide summary report to [insert by whom].

RECORDING AND REPORTING

Refer to [Annex E4](#) (case definition, documentation and reporting section) for specific details on reporting Xpert MTB/RIF results.

FIND has developed an Excel-based tracking tool for Xpert implementation http://www.finddiagnostics.org/programs/scaling_up/xpert_implementation/ to capture key Xpert data.

Instructions: Copy and paste the following text into your work plan:

RECORDING AND REPORTING

Standardized recording and reporting formats, adapted from the recommended WHO format [8] will be disseminated to all testing facilities in [insert country]. The format includes laboratory registers, patient registers, treatment cards, laboratory request forms, presumptive TB registers, and MDR registers.

All sites will use the national standardised recording and reporting tools and reporting formats for Xpert MTB/RIF results.

Xpert MTB/RIF-related information will be integrated into the existing TB reporting structures and protocols. All laboratories will be required to contribute to quarterly reports to [insert name of person].

The Xpert MTB/RIF [insert where it is available] is a monthly reporting tool of laboratory quality indicators that can be used at Xpert MTB/RIF sites in [insert country].

Laboratory supervisors will check and confirm statistical accuracy of the most recent quarterly reports directly from Xpert MTB/RIF instruments during supervisory visits and compile them for their district or region to assist with stock management and troubleshooting.

[Insert name of person] will use the information from the quarterly reports to confirm quarterly orders for districts and to assist in stock management at the national level. Quarterly report data will also be used to identify instrument failures to enable appropriate interventions at the site.

PROGRAMME EVALUATION (EARLY IMPLEMENTATION)

Information gathered during the early implementation phase is used to identify successes that can be applied moving into the routine implementation phase. Evaluation is also used to plan measures to mitigate constraints identified early on.

Instructions: Copy and paste the following text into your work plan:

PROGRAMME EVALUATION

Supervisory visits

According to current guidelines, all TB laboratory facilities (peripheral, district, and regional) should receive supervisory visits from a central, regional, or district laboratory technician where appropriate. These cadres will be trained to incorporate supervision for Xpert MTB/RIF alongside their existing supervisory duties for smear microscopy. Supervisors will complete a standardized questionnaire during the visit, which will highlight problems and recommendations. Existing troubleshooting channels will then be used (*i.e.* follow-up intervention visits).

ROUTINE IMPLEMENTATION

Refer to [Annex E2](#) for the routine testing phase checklist.

Instructions: copy and paste the following text into your work plan.

Lessons learned from early implementation will be applied in the routine implementation phase. The same strategy as for early implementation will be employed, namely training, completion of the comprehensive checklist, completion of the supervision checklist and quarterly visits. Feedback, corrective actions and refresher training will be documented and provided as for the previous sections. Data collection and EQA will be employed as per the previous section.

PART 6: CONTINUOUS MONITORING AND EVALUATION (M&E)

Programme evaluation is performed during the early implementation phase as a check point to identify and correct problems before expansion of activities. Stage 6 provides guidance on M&E for the purpose of ensuring continuous quality improvement.

M&E refers to the collection and analysis of specific data, based on predetermined programme objectives and goals using standardized tools and methods [9]. Xpert MTB/RIF data collected from facilities should be evaluated regularly to assess utilization of resources and highlight programme successes and constraints. Consistent M&E provides data to inform programme progress and success and guidance for next steps [2], based on WHO standards [8].

Countries are encouraged to consider implementation of remote monitoring systems to improve effectiveness of M&E of instrument-derived data. However M&E should focus on patient-important outcomes and not only test performance.

Those involved in the implementation of the Xpert MTB/RIF system should consider the following questions for M&E [9]:

- How many instruments are in the country? Where are they located? Who put them there? When? Where should new instruments be placed?
- Have Xpert MTB/RIF users received training? What curriculum? Were they certified as competent?
- Who is responsible for conducting site assessments, training, monitoring, collecting laboratory indicators? Has it been done according to plan?
- How do we ensure uninterrupted cartridge supply and avoid expiry of cartridges?
- Who is responsible for equipment maintenance and calibration? When does it need to be done?
- What level of unsuccessful tests? What are the causes?
- Has the error rate decreased since mentoring and refresher training was given?
- Has use of Xpert MTB/RIF increased the TB and drug resistance detection rate compared with microscopy? What proportion of patients diagnosed with Xpert MTB/RIF are put on appropriate treatment within 7 days? Are data reported to MOH?

For standardized collection tools, refer to [Annex E2](#) and [Annex G](#).

Instructions: Copy and paste the following text into your work plan and edit as appropriate to reflect actual practises.

MONITORING AND EVALUATION (M&E)

Monitoring and evaluation of Xpert MTB/ RIF implementation is necessary to ensure the effective and efficient use of resources and also to measure the impact of Xpert MTB/RIF in order to guide and justify further scale-up. A robust monitoring and evaluation system includes appropriate indicators and support for data collection, reporting, and analysis.

In addition, it is especially important to monitor the effects that Xpert can have on treatment initiation rates and reduced time to treatment. Assessment of these effects requires a system that can link testing site and clinical site data. M&E of Xpert MTB/RIF test implementation activities are coordinated by the GeneXpert Focal Person centrally at the CTRL/NTLP.

Site data will be analysed locally for trends that may inform operational decisions, and centrally to provide an overview of implementation at country level. The GeneXpert Focal Person must report the findings of on-going implementation to the NTLP and provide feedback to sites through the reporting structures.

Testing Site Quality Indicators

Testing site M&E is to monitor that established diagnostic algorithms are being followed, detect whether a particular instrument module is functioning sub-optimally or whether any users require additional training, and allows supplies to be effectively managed. Site-level information will be collected by the [GeneXpert Focal Person] and reported to the NTRL and NTLF quarterly. This will allow guidance on any actions that need to be undertaken to improve effectiveness, efficiency or user performance, and to strengthen the supply-management process to prevent stock-outs or cartridges from expiring by exchanging cartridges among sites. The quality indicator data that will be collected, analysed & reported monthly from testing sites is listed in Table 5. Collection of the quality indicator data can be facilitated by using a GeneXpert Remote Monitoring solution.

Data to collect (edit accordingly)

Table 5: Laboratory quality indicators for Xpert MTB/RIF M&E Plan [9]

Xpert MTB/RIF results	
# Xpert MTB/RIF tests MTB-	# error results
# Xpert MTB/RIF tests MTB+ RIF sensitive	# invalid results
# Xpert MTB/RIF tests MTB+ RIF resistant	# no result
# Xpert MTB/RIF tests MTB+RIF indeterminate	
Total numbers	
# total Xpert MTB/RIF tests	# total Xpert MTB/RIF tests MTB+
# total successful Xpert MTB/RIF tests	# GeneXpert modules in use
# total unsuccessful Xpert MTB/RIF tests	
Analysis	
Error rate	Xpert MTB/RIF - MTB positivity rate (Xpert MTB/RIF MTB positive/all successful Xpert MTB/RIF tests)
Invalid result rate	Xpert MTB/RIF - RIF resistant rate (Xpert MTB/RIF MTB+RIF resistant/all Xpert MTB/RIF MTB positive)
No result rate	Maximum Xpert MTB/RIF testing capacity per month at this site (no. tests)
Total unsuccessful test rate	% Maximum instrument capacity being utilized

In addition, these data may be further disaggregated according to the categories of populations eligible for Xpert MTB/RIF testing and data collected on the request forms. Categorizations may be as follows:

- Presumptive new TB cases
- Presumptive TB cases living with HIV
- Presumptive TB cases who are less than 15 years old (children)
- Presumptive extrapulmonary TB cases
- Presumptive previously treated TB cases

- The number and types of various errors. Identifying the most frequent types of errors can help troubleshoot the process, given that certain errors may be associated with the technique used to process samples; other errors may be related to mechanical problems with the instrument's modules or other issues, such as room temperature
- The number of errors occurring by instrument module. If a particular module produces more errors over time compared with other modules, it may require repair
- The number of errors occurring by user. If a particular user has an unusually high number of errors, further investigation of the specific error types is warranted, since some errors may be caused by the technique used to process samples
- The number of tests lost due to power outages or surges
- The number, duration, and causes of routine interruptions in the Xpert MTB/RIF testing service. Common causes of service interruptions include cartridge stock-outs, expired cartridges, no staff available, instrument breakdown, and computer breakdown
- The number of instrument modules not functioning and the duration (in days) of module failure during the reporting period
- The number of instrument modules overdue for calibration at the end of the reporting period

Monitoring supply management:

- The number of cartridges in stock at the beginning of the reporting period
- The number of cartridges received during the reporting period
- The number of cartridges used during the reporting period
- The number of cartridges that were lost or damaged
- The number of cartridges in stock at the end of the reporting period
- Whether there were any stock-outs during the reporting period, the duration of stock-out (in days)
- Number of cartridges that were lost or damaged before being used

Sources of data (edit as appropriate):

- Main laboratory record keeping (laboratory request form, laboratory report form, laboratory register)
- WHO standardized reporting framework for TB
- An MS Excel-based data collection tool (Xpert MTB/RIF Implementation tracking tool) has been developed to collect site level data on Xpert MTB/RIF quality indicators, site supervision, training and instrument usage. Data collection will be coordinated by NTRL, with reporting to National TB Programme on monthly basis.
- FIND quarterly checklist for M&E tool

Each Xpert MTB/RIF site shall record and compile data using appropriate tools and report to [insert whom] on a [insert frequency] basis. Data shall be compiled, analysed and sent to [insert to whom] and reported to the MOH on a [insert frequency] basis.

Describe plans for remote monitoring of GeneXpert sites

In addition, NTPs should develop appropriate indicators to monitor the impact of Xpert MTB/RIF on linkage of patients to appropriate care and treatment, including proportion of patients diagnosed who are linked to care, and time to diagnosis and time to treatment initiation, particularly for patients with rifampicin resistance.

Programmatic and Clinical Indicators

In order to understand the impact of the Xpert MTB/RIF test on case detection, the management of cases, and other testing site processes, additional data need to be collected from clinical sites at the district or treatment-facility level. The quality indicator data that will be collected, analysed and reported monthly from testing sites is listed in Table.

Other aspects of implementation, in particular data on cost-effectiveness and the impact on diagnostic delays and time to treatment initiation, are best evaluated by operational research studies rather than as part of the routine M&E.

The following indicators are proposed for programmatic and clinical site monitoring, both to monitor progress in the implementation of the programme as a whole (process indicators), as well as to monitor patient important outcomes, including treatment initiation.

Process indicators

- The proportion of projected number of testing sites / number of active testing sites relevant to the projected need
- The number and proportion of notified cases (both new and relapsed) confirmed by bacteriologically (microscopy / culture / Xpert MTB/RIF)
- The number and proportion of individuals found to have rifampicin-resistant TB by Xpert MTB/RIF or DST during the reporting period, disaggregated by patient group
- The number and proportion of individuals found to have rifampicin-susceptible TB by Xpert MTB/RIF or DST during the reporting period, disaggregated by patient group
- The number and proportion of clinical sites with onsite access to GeneXpert
- The number and proportion of clinical sites without onsite access to GeneXpert
- The number and proportion of clinical sites that have access to Xpert MTB/RIF testing through the referral network
- The number and proportion of new testing sites with onsite access to GeneXpert planned and budget secured
- The number and proportion of testing sites participating in Quality Assurance activities including PT/EQA

Clinical indicators

- The number and proportion of rifampicin- resistant cases detected by Xpert MTB/RIF that received further phenotypic DST during the reporting period
- The number and proportion of rifampicin- resistant cases detected by Xpert MTB/ RIF that were initiated on a WHO- recommended treatment regimen for MDR during the reporting period
- The number and proportion of rifampicin- susceptible cases detected by Xpert MTB/ RIF that were initiated on a WHO- recommended treatment regimen for MDR during the reporting period

- Average time from patient presentation (Visit 1) to initiation of treatment, disaggregated by rifampicin susceptible & rifampicin resistance
- Average time from sample collection to initiation of treatment, disaggregated by rifampicin susceptible & rifampicin resistance

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ANNEX A1: NATIONAL POLICIES FOR XPERT MTB/RIF TESTING

Instructions: If applicable, insert the following text into the Global Recommendations section of your work plan:

WHO recommends the following policy on the use of Xpert MTB/RIF to diagnose pulmonary TB and rifampicin resistance in adults and children [2]:

- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in adults suspected of having MDR-TB or HIV-associated TB (strong recommendation, high-quality evidence).
- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in children suspected of having MDR-TB or HIV-associated TB (strong recommendation, very low-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all adults suspected of having TB (conditional recommendation acknowledging resource implications, high-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all children suspected of having TB (conditional recommendation acknowledging resource implications, very low-quality evidence). Xpert MTB/RIF may be used as a follow-on test to microscopy in adults suspected of having TB who are not at risk of MDR-TB or HIV-associated TB, especially when further testing of smear-negative specimens is necessary (conditional recommendation acknowledging resource implications, high-quality evidence).
- Xpert MTB/RIF should be used in preference to conventional microscopy and culture as the initial diagnostic test in testing cerebrospinal fluid (CSF) specimens from patients suspected of having TB meningitis (strong recommendation given the urgency of rapid diagnosis, very low-quality evidence).
- Xpert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, or histopathology) for testing specific non-respiratory specimens (lymph nodes and other tissues) from patients suspected of having extrapulmonary TB (conditional recommendation, very low-quality evidence).

Instructions: As an option, the following text can be inserted into your work plan:

History of recommendations and policy changes for Xpert MTB/RIF test [timeline diagram] [1]:

- May 2006 – FIND and the University of Medicine and Dentistry of New Jersey partner with Cepheid to develop a novel TB test, with funding from the US NIH and the Bill & Melinda Gates Foundation (BMGF)
- May 2009 – Demonstration studies underway
- September 2010 – Expert Group issues strong recommendation to WHO based on scientific evidence; WHO's Strategic and Technical Advisory Group for TB further reviews evidence and makes policy recommendations
- December 2010 – After organization of a Global Consultation, WHO recommends Xpert MTB/RIF
- August 2012 – A public-private partnership between the US President's Emergency Plan for AIDS Relief (PEPFAR), the US Agency for International Development (USAID), UNITAID, and Bill & Melinda Gates Foundation allows for a drop in price of the Xpert MTB/RIF test cartridge from \$16.86 USD to \$9.98 USD
- May 2013 – Expert Group reviews updated evidence base on use of Xpert MTB/RIF for diagnosis of pulmonary, extrapulmonary and paediatric TB and rifampicin resistance, and issues updated recommendations to WHO

- October 2013 – WHO updates recommendations on Xpert MTB/RIF, with an expanded scope of use
- March 2014 – WHO releases updated Xpert MTB/RIF implementation manual, describing technical and operational 'how-to', and practical considerations

Use the following resources to find relevant policy information on Xpert testing in your country:

- Xpert MTB/ RIF Implementation module, WHO, 2014:
http://apps.who.int/iris/bitstream/10665/112469/1/9789241506700_eng.pdf
- National policy/ plan for health services
- National policy/ plan for TB
- National policy/ plan for HIV
- Background information for the utilization on Xpert MTB/RIF assay for the Xpert MTB/RIF platform

ANNEX A2: EXAMPLE XPERT MTB/RIF TESTING ALGORITHM

Instructions: If a national Xpert MTB/RIF algorithm does not exist in your country, you can use the one below as a sample to be modified for your country's recommendations. Be sure that it is in compliance with your country's national policies on TB and Xpert MTB/RIF testing.

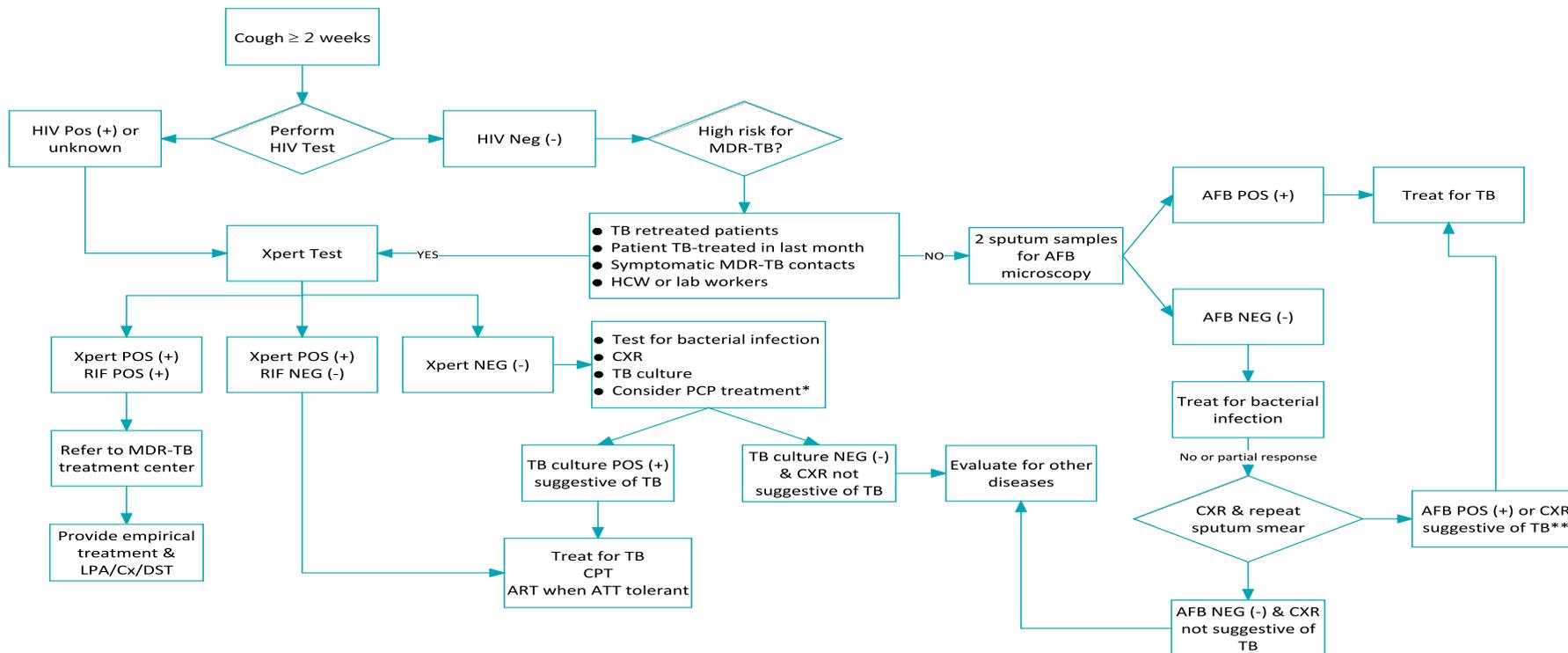


Figure 4: Adapted from [20]: Example national algorithm for TB testing & use of Xpert. *If patient is HIV POS (+) & hypoxic with O2 saturation on room air ≤90% consider treatment for PCP. **Consider Xpert in HIV NEG (-), AFB NEG (-) patient if chest X-ray suggests TB.

ANNEX B1: EPIDEMIOLOGICAL DATA

Instructions: The following resources and data collection variables can be used to inform the Epidemiological Data section of your plan:

Use the following resources to find relevant epidemiological TB data in your country:

- WHO tuberculosis country profiles: <http://www.who.int/tb/country/data/profiles/en/>
- WHO Global Tuberculosis Report, 2014 (country profiles are at the end of the document): http://apps.who.int/iris/bitstream/10665/137094/1/9789241564809_eng.pdf
- WHO Global TB report
- TB Prevalence Surveys
- NTP quarterly and annual reports
- TB treatment registers
- TB Laboratory registers
- Xpert MTB/RIF test indicators
- WHO surveillance reports
- WHO Xpert MTB/RIF Implementation Manual, 2014

Alternative data to capture:

- Number and proportion of bacteriologically confirmed TB cases detected
- Number and proportion of RIF resistant TB cases detected
- TB and MDR-TB related deaths
- Number and proportion of TB cases successfully treated

Below is sample data from Tanzania, obtained from the WHO Global TB Report [10].

Instructions: You can find your country's data and copy it into your Xpert MTB/RIF work plan.

Estimates of TB burden^a 2013		
	NUMBER (thousands)	RATE (per 100 000 population)
Mortality (excludes HIV+TB)	6 (3.4–8.2)	12 (7–17)
Mortality (HIV+TB only)	6.1 (4.8–7.5)	12 (9.8–15)
Prevalence (includes HIV+TB)	85 (45–140)	172 (92–277)
Incidence (includes HIV+TB)	81 (77–84)	164 (157–170)
Incidence (HIV+TB only)	30 (29–31)	61 (58–63)
Case detection, all forms (%)	79 (77–83)	

Estimates of MDR-TB burden^a 2013		
	NEW	RETREATMENT
% of TB cases with MDR-TB	1.1 (0.5–2)	3.1 (0.9–7.9)
MDR-TB cases among notified pulmonary TB cases	530 (240–960)	86 (25–220)

TB case notifications 2013		
	NEW ^b	RELAPSE
Pulmonary, bacteriologically confirmed	24 565	1 101
Pulmonary, clinically diagnosed	23 371	
Extrapulmonary	15 016	
Total new and relapse	64 053	
Previously treated, excluding relapses	1 679	
Total cases notified	65 732	

Among 62 952 new cases:
6 658 (11%) cases aged under 15 years; male:female ratio: 1.4

Reported cases of RR-/MDR-TB 2013			
	NEW	RETREATMENT	TOTAL ^b
Cases tested for RR-/MDR-TB	1 192 (5%)	728 (26%)	2 020
Laboratory-confirmed RR-/MDR-TB cases			64
Patients started on MDR-TB treatment			28

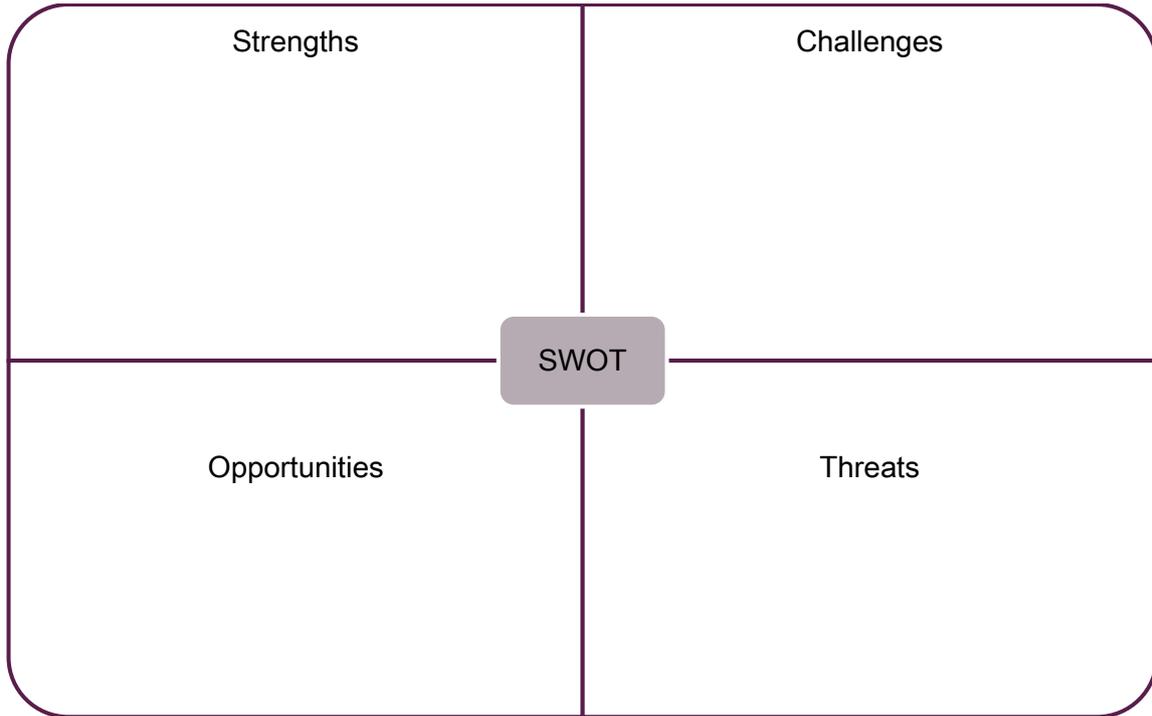
TB/HIV 2013		
	NUMBER	(%)
TB patients with known HIV status	54 504	(83)
HIV-positive TB patients	20 320	(37)
HIV-positive TB patients on co-trimoxazole preventive therapy (CPT)	19 835	(98)
HIV-positive TB patients on antiretroviral therapy (ART)	14 864	(73)
HIV-positive people screened for TB	457 901	
HIV-positive people provided with IPT	166	

Treatment success rate (%)	
New and relapse cases registered in 2012	90
Previously treated cases, excluding relapse, registered in 2012	80
HIV-positive TB cases, all types, registered in 2012	77
RR-/MDR-TB cases started on second-line treatment in 2011	75
XDR-TB cases started on second-line treatment in 2011	

Figure 5: Sample data that can be used for your country's plan: Tanzania country profile from WHO's global TB database. Data are as reported to WHO. Estimates of TB and MDR-TB burden are produced by WHO in consultation with countries. Accessed at <http://www.who.int/tb/country/data/profiles/en/> [10].

ANNEX B2: LABORATORY SWOT ANALYSIS

Instructions: Use this SWOT figure (or a similar one) to describe key strengths, challenges, opportunities and threats of existing TB laboratories in your country. Include information for access and infrastructure; equipment and supplies; human resources for health; TB laboratory M&E; quality management; governance, leadership and coordination; operational research.



ANNEX B3: EXISTING TB TESTING SITES

Instructions: Complete the tables below to describe the number of existing diagnostic centres where the following TB tests are conducted in your country. Refer to your country’s TB reports and data to obtain the following information.

TB test*	Number of facilities test is available as of [insert year] in [insert country]
Sputum smear microscopy (diagnostics centres)	Available at [insert number] at diagnostic centres TOTAL for clinical use: [insert number] TOTAL for research use only: [insert number]
Solid culture	Available at [insert number] at diagnostic centres TOTAL for clinical use: [insert number] TOTAL for research use only: [insert number]
Liquid culture	Available at [insert number] at diagnostic centres TOTAL for clinical use: [insert number] TOTAL for research use only: [insert number]
Drug sensitivity testing	Available at [insert number] at diagnostic centres TOTAL for clinical use: [insert number] TOTAL for research use only: [insert number]
Xpert MTB/RIF	Available at [insert number] sites in [insert number of provinces/regions], for a total of [insert number] Xpert MTB/RIF instruments in [country].

Figure 6: Summary of TB testing facilities in [insert country] [insert reference]

* Relevant TB tests should be described within the following categories:

- Smear microscopy: Ziehl-Neelsen, fluorescence microscopy-conventional vs. LED, direct vs. concentrated
- TB culture: Solid culture medium, liquid culture medium
- *Mycobacterium* TB identification tests: MTB complex versus NTM or specific mycobacterial species identification (e.g. via biochemical identification, strip specification, etc.)
- First line DST: by conventional slow methods (e.g. direct or indirect test; solid or liquid culture medium, drugs tested, concentration of drugs tested; proportion, absolute concentration or resistance ratio method)
- Second line DST: by conventional slow methods (e.g. solid culture medium, drugs tested, concentration of the drugs)
- Tests for rapid detection of TB (e.g. Xpert MTB/RIF MTB/RIF test)

ANNEX C1: XPERT MTB/RIF INTRODUCTION AGREEMENT

Instructions: Convene a meeting to obtain written agreement from the National TB Manager for the proposed work plan. The following agreement can be used.

1. Partner name:	
2. Number of Xpert MTB/RIF instruments including: - number of modules per instrument - indicate inclusion of laptop/desktop	
3. Model number	
4. The duration of support (start date and hand over date)	
5. Complete sections a - g with applicable information regarding: -monetary amount -quantities -product specifications	
a. Cartridges	
b. Reagents/consumables	
c. Calibration	
d. Extended warranty	
e. Maintenance	
f. Staff training	
g. Technical support	
6. Agreement reached with National TB Programme for ongoing support for items 5. a – g?	yes / no
7. Provide details regarding how items 5. a – g will be supported after handover date stated in section 4:	
a. Cartridges	
b. Reagents/consumables	
c. Calibration	
d. Warranty	
e. Maintenance	
f. Staff training	
g. Technical support	
8. Indicate agreement to: - follow National TB Programme requirements for Xpert MTB/RIF® placement - follow National TB Programme guidelines for Xpert MTB/RIF® implementation - handover a fully functional instrument	Name: Signature:
National TB Programme Manager (signature):	

ANNEX D1: XPERT MTB/RIF TESTING CAPACITY

Instructions: Determine the number of samples that can be tested per day per Xpert MTB/RIF module. For example, according to the Provision of Xpert MTB/RIF Tajikistan Plan, the estimated maximum annual capacity of a GeneXpert® IV-module instrument is approximately 3120 analyses (12 analyses/day, 5 days/week). Complete the following chart below. The numbers listed are an example.

Number of modules	Number of instruments	Number of tests per day ²	Total number of tests per week	Total number of tests per year
1	1	3	=3X5=15	780
2	1	6	=6X5=30	1,560
4	1	12	=12X5=60	3,120
8	1	24	=24X5=120	6,240
16	1	48	=48X5=240	12,480

Figure 7: Xpert MTB/RIF testing capacity. Values obtained from Tajikistan Xpert MTB/RIF plan [11].

ANNEX D2: CURRENT PLACEMENT OF XPERT MTB/RIF INSTRUMENTS

Instructions: Determine the location and number of current Xpert MTB/RIF instruments that are being used in your country. Enter data for your country into this table.

Site name	Region	Supported by	# modules	# instruments	Research or routine use	Testing capacity (no. tests/year)*
TOTAL tests/year						

*this number can be determined using the table/calculation from Annex D1 (Xpert MTB/RIF Testing Capacity).

² The maximum number of tests per day may be increased depending on the number of working hours per day and workflow considerations.

ANNEX D3: XPERT MTB/RIF EXPANSION PLAN

Instructions: Determine future country need for Xpert MTB/RIF instruments for the next five years, based on an estimate of TB incidence in the population. Note that estimates of TB incidence are preferred because 100% of cases are not diagnosed. One of data sources that can be used for forecasting is the WHO data visualization:

<http://www.who.int/tb/country/data/visualizations/en/>

Population estimates – World Data Bank:

<http://databank.worldbank.org/Data/Views/VariableSelection/SelectVariables.aspx?source=Health%20Nutrition%20and%20Population%20Statistics:%20Population%20estimates%20and%20projections>

Example: Zambia

Step 1: Retrieve incidence data for the last 5 years from WHO data visualization tool, enter in Excel spreadsheet:

	Column A	Column B
	Year (x)	Incidence per 100, 000 population (y)
1	2009	373
2	2010	352
3	2011	343
4	2012	347
5	2013	338

Step 2: Expand column A to include years of interest:

	Column A	Column B
	Year (x)	Incidence per 100, 000 population (y)
1	2009	373
2	2010	352
3	2011	343
4	2012	347
5	2013	338
6	2014	
7	2015	
8	2016	
9	2017	
10	2018	

Step 3: Using Excel function FORECAST, calculate incidence rate for year 2014:
=FORECAST(A6,\$B\$1:\$B\$5,\$A\$1:\$A\$5).

Expand calculation to remaining years:

	Column A	Column B
	Year (x)	Incidence per 100, 000 population (y)
1	2009	373
2	2010	352
3	2011	343
4	2012	347
5	2013	338
6	2014	391.4
7	2015	373.4
8	2016	355.4
9	2017	337.4
10	2018	319.4

Step 4: Using population size estimates and projections: Go to the [World Data Bank](#) to calculate number of forecasted TB cases for 2014-2018:

Number of cases = (Incidence per 100, 000 x population size)/100, 000

	Column A	Column B	Column C
	Year (x)	Incidence per 100000 population (y)	Forecasted number of TB cases
1	2009	373	
2	2010	352	
3	2011	343	
4	2012	347	
5	2013	338	
6	2014	391.4	57066
7	2015	373.4	56010
8	2016	355.4	55087
9	2017	337.4	53984
10	2018	319.4	52701

ANNEX D4: EXAMPLE OF XPERT MTB/RIF PLACEMENT

Below is an example of how country X determines how many Xpert MTB/RIF machines are needed to meet the TB burden in their country over the next five years and where they should be placed.

Step 1: Xpert MTB/RIF Testing Capacity

Instructions: Determine the number of samples that can be tested per day per Xpert MTB/RIF module. Consider the number of modules, the number of tests per day per module, the number of total tests per day and the number of days per week testing is performed.

The daily testing capacity of the Xpert MTB/RIF instruments is based on the following assumption for a 4-module instrument:

- 12 analyses/day, 5 days/week, 52 weeks/year

Therefore, the testing capacity of 2, 4 and 8-module instruments are calculated as follows:

# modules	# instruments	# tests / day	Total number of tests per week	Total number of tests per year
2	1	6	6 x 5=30	30 x 52= 1,560
4	1	12	12 x 5=60	60 x 52= 3,120
8	1	24	24 x 5=120	120 x 52= 6,240

Step 2: Current Placement of Xpert MTB/RIF Instruments

Instructions: List the current location of Xpert MTB/RIF instruments in your country (Table 6). Refer to your country National TB Plan or documents from partners and organizations (WHO tuberculosis country profiles: <http://www.who.int/tb/country/data/profiles/en/>; WHO Global TB report; TB Prevalence Surveys; NTP quarterly and annual reports; TB treatment registers; TB Laboratory registers; Xpert MTB/RIF test indicators; WHO surveillance reports; WHO Xpert MTB/RIF Implementation Manual, 2014) for a full listing and location of current Xpert MTB/RIF instruments that are currently being used in your country.

Table 6: Current placement of Xpert MTB/RIF instruments in country X

Site	Region	Support from	# Modules	# Machines	Testing capacity (no. tests/ year)*
1	A	CDC	4	1	3,120
2	B	World Bank	4	1	3,120
3	C	CDC	4	1	3,120
4	C	FIND	8	1	6,240
5	D	WHO	4	1	3,120
6	E	WHO	4	1	3,120
7	A	CDC	4	1	3,120
8	A	USAID	4	1	3,120
9	D	USAID	2	1	1,560
10	B	USAID	2	1	1,560
Total tests / year				10	31,200

*Number determined using the calculation from Step 1 (Xpert MTB/RIF Testing Capacity)

Country X has:

- 7 sites with 1 x 4-module instruments.
- 2 sites with 1 x 2-module instruments.
- 1 sites with 1 x 8-module instruments.

Step 3: Quantity of New Instruments Required

Instructions: Determine the testing burden in each region (i.e. number of TB suspects screened by microscopy) for the next five years based on available and projected data using WHO TB Country Profiles, found at: <http://www.who.int/tb/country/data/profiles/en/>

X country’s need for the quantity of new Xpert MTB/RIF instruments was calculated by projecting the TB case notification (total new and relapse cases, from the WHO TB Country Profiles that are anticipated over the next five years. Recent prevalence survey results indicate a significant underestimation of TB burden. To balance the trend with potential increased case finding, the number of cases estimated was taken to be constant for the five-year period, based on 2013 data. The model should be readjusted upon new data.

	2016	2017	2018	2019	2020	Total (cumulative)
Total new cases	109,200	109,200	109,200	109,200	109,200	546,000
Estimated number of tests	546, 000	546, 000	546, 000	546, 000	546, 000	2, 730, 000

The number of total new cases can be used to estimate the number of people to be tested. Using an estimate of 5 individuals to be tested for every new TB case detected, a total of 546,000 tests per year is calculated.

The number of GeneXpert instruments to meet the need is estimated by subtracting the testing capacity per year with existing machines (31,200 tests) with total number of projected tests per year (546, 000) and dividing by the annual testing capacity per instrument.

This means, that an additional 165 four-module instruments or equivalent (utilising larger instruments) would needed to meet the maximum projected testing need per year.

Placement of new instruments

Instructions: Using the total number of new Xpert MTB/RIF instruments that are required to meet the expected TB burden need (taking into consideration those instruments that are already in use), determine the location of placement to achieve near full capacity of the instruments. Placement should be done in a phased manner—over five years, for example.

The proposed/target Xpert MTB/RIF expansion plan for country X was determined using the following criteria:

- Obtaining near full capacity of instrument].
- Linking sites with low sample volume to the closest Xpert MTB/RIF facility.
- Prioritising sites with high TB and HIV burden (health facilities with annual TB diagnosis per facility of >500 or patients currently enrolled in HIV Chronic Care >1000).
- Laboratory infrastructure, human resources, and TB burden data was used.

It was determined that 25 4-module instruments would be phased into X country as follows:

Units required

	2016	2017	2018	2019	2020
Phase 1 districts	1	2	3	1	1
Phase 2 districts	1	2	2	1	1
Phase 3 districts	1	2	3	4	0

ANNEX E1: ROLES AND RESPONSIBILITIES

Assignment of staff responsible for Xpert MTB/RIF implementation is necessary to reduce confusion regarding the responsibilities and duties at all levels in relation to Xpert MTB/RIF implementation. It is recommended that existing lines of responsibility for the national TB program are extended to Xpert MTB/RIF operations. All relevant staff should be sensitized regarding their roles and responsibilities. Below are example of roles and responsibilities for Xpert MTB/RIF testing at testing sites for consideration into your work plan.

National TB Programme Manager

- Make programmatic Xpert MTB/RIF decisions, including decisions regarding instrument placement
- Delegate an Xpert MTB/RIF focal person responsibility for coordination of Xpert MTB/RIF implementation
- Provide support to the Xpert MTB/RIF focal person
- Coordinate partners, the TB program, and promote information sharing
- Liaising with the HIV/AIDS program
- Oversee instrument handover process

National Tuberculosis Reference Laboratory Manager / GeneXpert laboratory focal person

- Liaise with the National TB Programme manager, director of diagnostic services, head of CTRL, partners, district TB and leprosy coordinators (DTLC), and regional TB and leprosy coordinators (RTLCS)
- With the support of assistants: collate countrywide indicators, undertake remote and onsite troubleshooting, liaise with the manufacturer, and coordinate stock management

Regional tuberculosis and leprosy coordinators and regional laboratory technologists

- Stock management at the regional level
- Support DTLCs and district laboratory technologists (DLT) to troubleshoot Xpert MTB/RIF-related issues, collate reports regarding unusual errors from district staff, and report to Gene Xpert MTB/RIF Focal Person and Head of the CTRL
- Collate indicator data
- Include Xpert MTB/RIF oversight in laboratory supervisory visits
- Provide support to the CTRL Xpert MTB/RIF focal person and respond to requests from CTRL
- Immediately report all rifampicin resistance detected through Xpert MTB/RIF
- Provide quarterly indicator reports

District TB and leprosy coordinators and district laboratory technologists

- Stock management at the district level
- Troubleshoot Xpert MTB/RIF-related issues, report unusual errors from facility staff to RTLCS and regional laboratory technologists (RLTs)
- Collect indicators from Xpert MTB/RIF sites via the laboratory supervisors, providing the information to the RTLCS/RLTs
- Include Xpert MTB/RIF oversight in laboratory supervisory visits
- Support the CTRL Xpert MTB/RIF focal person and RTLCS/RLTs as required, and respond to requests

- Immediately report all rifampicin resistance detected through Xpert MTB/RIF
- Provide quarterly indicator reports

Facilities with Xpert MTB/RIF at any level

- Designate a specific focal position responsible for Xpert MTB/RIF including operations, reporting, and troubleshooting
- Facility-level management and ordering
- Immediately report all rifampicin resistance detected through Xpert MTB/RIF
- Troubleshoot Xpert MTB/RIF-related issues, report unusual errors to DTLC/DLTs
- Provide quarterly indicator reports

ANNEX E2: CHECKLISTS: PRE-INSTALLATION, INSTALLATION AND EARLY IMPLEMENTATION

[Pre-installation Checklist 10-2014](#)

[Installation Checklist 10-2014](#)

[Comprehensive Checklist 10-2014 \(18pp\)](#)

[Supervision Checklist 10-2014](#)

[Quarterly Checklist 10-2014](#)

[Pre-handover Checklist 10-2014](#)

[Clinical Checklist 10-2014](#)

Checklists are available in English and French at:

http://www.finddiagnostics.org/programs/scaling_up/xpert_implementation/checklists/

ANNEX E3: PROCUREMENT OF XPERT MTB/RIF COMMODITIES

Instructions: This table shows an example of a forecast plan for a country that aims to have 11 Xpert MTB/RIF instruments in operation. Use this table to make forecasts for Xpert MTB/RIF cartridges for your country.

Partner	Number of instruments	Number of cartridges	Procurement period	Cartridges per year
Partner A	2	8000	01/2013-09/2015	4000
Partner B	4	12250	Q2/2013- Q3/2015	5000
Partner C	3	19800	2013-2015	9900
Partner D	1	0		0
Partner E	0	0		0
Partner F	1	11590	2013-??	900
Partner G	(1)	2840	2013-2015	(1420)
TOTAL	11 (+1)			19800 (+) / year

ANNEX E4: SOP CONSIDERATIONS

The following is a list GLI/FIND installation and training documents, tools and SOPs for use with Xpert MTB/RIF testing:

Package 1 documents (provided)	Package 2 documents (in-country tools)
Xpert MTB/RIF country- specific installation checklist	TB suspect screening tool
Xpert MTB/RIF installation accompanying documents	Sputum testing national testing algorithm
Xpert MTB/RIF Manual	Sputum sample testing request form for Xpert MTB/RIF
Xpert MTB/RIF SOP	Laboratory Sample register
Xpert MTB/RIF MSDS	Results reporting procedures
Xpert MTB/RIF equipment maintenance SOP	Sample TAT records
Xpert MTB/RIF equipment maintenance records	Patient tracing procedure
Xpert MTB/RIF sputum sample collection SOP	Patient initiation onto treatment procedure
Xpert MTB/RIF WHO reporting codes	RIF detected reporting to National TB Programme procedures
Xpert MTB/RIF patient ID recording codes	Stock ordering protocols
Xpert MTB/RIF error records and corrective action log	Stock cards
Xpert MTB/RIF monthly indicator reporting form	Incidence occurrence records
Xpert MTB/RIF equipment calibration log	Waste management procedure
Xpert MTB/RIF equipment error code list	Sample collection for culture
Xpert MTB/RIF equipment user training package	Sputum transport procedure
Xpert MTB/RIF clinical training package	Spill management procedure
Sputum rejection criteria	Temperature monitoring records
PPE donning instructions	

Consider including the following information in the appropriate SOPs.

Case Definition, Documentation and Reporting

The following information is captured in the SOP for Case Definition, Documentation and Reporting.

Based on WHO recommendations [8], all patients diagnosed to have TB by Xpert MTB/RIF shall be defined as a TB case:

- A bacteriological confirmed TB case: one from whom a biological specimen is positive by smear microscopy, culture, or Xpert MTB/RIF. All such cases should be notified to TB control programme.

- Rifampicin resistance TB (RR-TB) case: resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether mono-resistance, multidrug resistance, poly-drug resistance or extensive drug resistance.

The new standardized reporting and reporting formats released by WHO capture Xpert MTB/RIF information and include revised quarterly reports, laboratory registers, patient registers, treatment cards, laboratory request forms, presumptive TB registers, and MDR registers. In this sense, Xpert MTB/RIF-related information will be integrated into the existing TB reporting structures and protocols. All laboratories will be required to contribute to quarterly reports for the National TB programme and Central TB Reference Laboratory. The laboratory supervisors should check and confirm statistical accuracy of the most recent quarterly reports directly from the Xpert MTB/RIF equipment during supervisory visits and compile them for their district or region to assist with stock management and troubleshooting. Quarterly case finding should be reported by the Xpert MTB/RIF testing site while the enrolment of patients in to care should be reported by the treatment initiating centre. To facilitate this activity, the Referral Samples Logbook, Postal TB Sample Logbook and Sample Referral SOP will be used.

Xpert MTB/RIF results reported as follows:

T	MTB detected, rifampicin resistance not detected
RR	MTB detected, rifampicin resistance detected
TI	MTB detected, rifampicin resistance indeterminate
N	MTB not detected
I + error number	invalid / no result / error

Laboratory infrastructure requirements

- Uninterrupted power supply (UPS with minimum capacity of 2 hours and/or a Generator with fuel supply)
- Closed room with temperatures no higher than 30°C and Air Conditioning system in hot areas
- Closed room with temperatures not higher than 30°C and Air Conditioning system in hot areas
- Adequate storage room for cartridges with temperatures not higher than 28°C
- Secured location to protect Xpert MTB/RIF machine and computer from theft
- Adequate space for specimen receipt and preparation for testing
- At least one 2-8°C refrigerator for specimen storage as needed
- Reliable water supply with sink
- Lab chairs and desks for paper work and documentation activities

Refer to the following documents for information:

- Definitions and Reporting Framework for Tuberculosis- 2013 revision. WHO: http://apps.who.int/iris/bitstream/10665/79199/1/9789241505345_eng.pdf
- FIND sputum collection for TB Testing Job Aid, January 2013: <http://www.cdc.gov.tw/professional/downloadfile.aspx?fid=708C99BB946AED0F>

Bio-safety requirements

- Waste disposal system for cartridges. Example: Incineration
- Biosafety level equivalent to smear microscopy (cross ventilated room)
- Gloves for specimen handling

- Containers for triple packaging of referral specimens
- Standard laboratory safety precautions and practices must be followed

The following laboratory SOPs are required for the Xpert MTB/RIF implementation:

Sample referral system requirements

- The laboratory networking for specimen referral shall be based on geographic proximity to the Xpert MTB/RIF MTB/RIF testing centre and specimens will be transported using the current available courier system
- The available transport system [insert description here]
- The expected turn-around times: [insert description here. i.e. delivery of test results for patients from the same facility should be within same day of sample collection. Test results for samples from outside of the testing site (referral samples) should be delivered within five working days from the day of receipt]

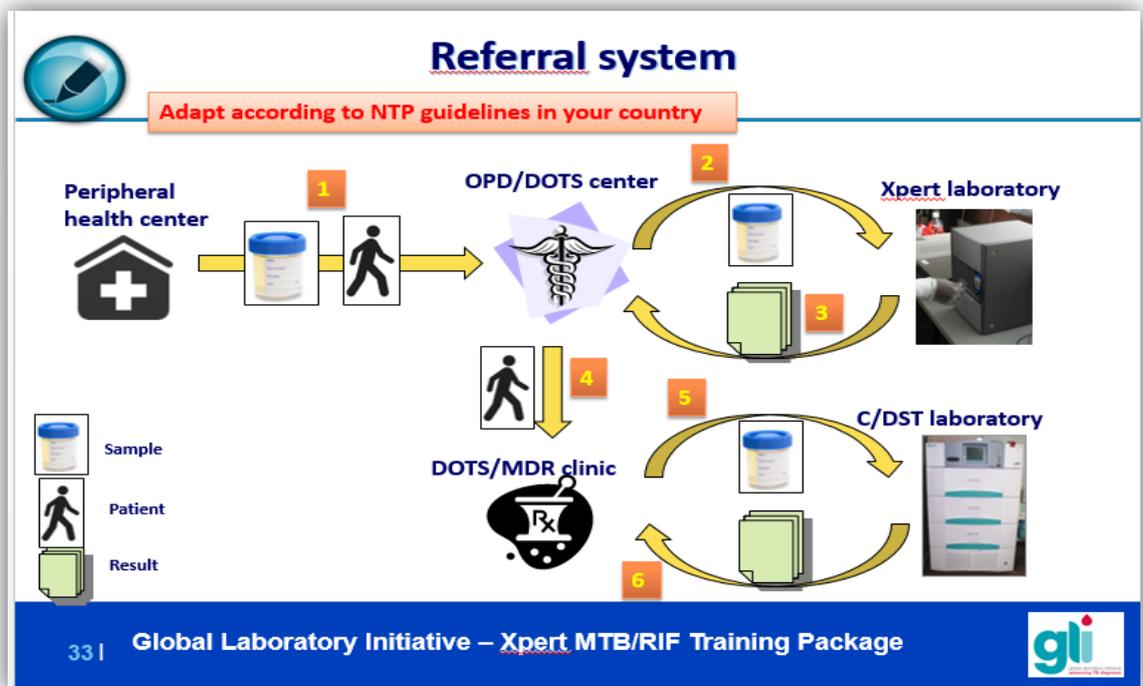


Figure 8: Example of a Referral system (taken from GLI Xpert MTB/RIF training package)

Preventive maintenance:

Frequency	Task
Daily	<ul style="list-style-type: none"> • Remove and properly dispose of cartridges • Clean and disinfect work area • Ensure 10cm clearance around instrument • Put on dust cover when instrument not in use
Weekly	<ul style="list-style-type: none"> • Disinfect the interior of the cartridge bay • Restart the GeneXpert instrument and computer
Monthly	<ul style="list-style-type: none"> • Disinfect plungers • Disinfect the instrument's surfaces • Clean the instrument's filter (this applies only to newer model (GeneXpert instruments, which have a white cover) • Archive and back-up test results
Annually	Run XpertCheck cartridges (calibration) and swap modules if needed

Figure 9: A list of maintenance activities for the Xpert MTB/RIF instrument. Refer to the Maintenance SOP for a complete list of activities.

CORRECTIVE ACTION FORM

Date	Corrective Action Description and Resolution	Signature of person reporting Corrective Action	Corrective Action Completed (Y/N)	Signature of Supervisor	Date Correction Action was Completed

TRAINING ATTENDANCE LOG

Name of Training	
Location	
Date	

	Name	Institution	Title/Position	Telephone	Email	Signature
1						
2						

Refer to the following documents for information:

- From the Implementation Guideline for Xpert MTB/RIF Assay in Ethiopia, June 2014, refer to the following sample forms for your SOPs:
 - Laboratory Register for smear microscopy and Xpert MTB/RIF
 - TB Laboratory Requesting and reporting Form
 - Health Facility TB Sample Referral Log Book
 - Post office Quarterly Report Format
 - Xpert MTB/RIF Quarterly Reporting Format
- The Xpert master file that is in use and data collected on a monthly basis

Below is an example of the indicators recommended by WHO (http://www.finddiagnostics.org/export/sites/default/programs/scaling_up/xpert_implementation/hecklists/XpertMTB-RIF_implementation_manual_2014.pdf). See p. 28. Design an M&E tool using these and any other relevant indicators:

- Number of tests performed per month per module
- Number and proportion of MTB positive results
- Number and proportion of MTB positive rifampicin resistant results
- Number and proportion of errors (disaggregated by type of error)
- Number and proportion of indeterminate results
- Number and proportion of invalid results

ANNEX G1: BUDGET AND RESOURCE MAPPING

GENEXPERT COST ESTIMATE

Instructions: Determine the amount of funds required using information provided in the table below (taken from [2]). Populate Figure 11 using this information, as well as any additional costs for implementing the programme, including specimen transport, remote monitoring, quality assurance (e.g. proficiency testing).

Table 1. Sample annual itemized budget

Row label	Category	Item	Cost, number of days, tests or cartridges	Comment ^a
A		GeneXpert 4 module unit with laptop	US\$ 17 500.00	US\$ 17 000 if desktop computer is selected; preferential pricing for selected countries (see Annex 1).
B	Equipment	Shipping	US\$ 1 000.00	Average cost, actual cost depends on destination
C		Uninterrupted power supply unit and external batteries	US\$ 1 200.00	Local purchase; price depends on the market and back-up capacity of UPS
D		Printer	US\$ 200.00	Local purchase, price depends on the market, optional
E	Maintenance	Calibration kit after 1st year	US\$ 450.00	Can be included in shipment with test cartridges to reduce price of shipping
F		Annual warranty after 2 nd year (includes calibration kit)	US\$ 2 900.00	3-year extended warranty available for US\$ 6 900
G		Cost per cartridge	US\$ 9.98	Preferential pricing for selected countries (see Annex 1)
H		Shipment cost per cartridge	US\$ 1.20	Average cost, actual cost depends on destination
I		Number of working days per year	250	Number can vary depending on local context
J	Consumables	Average number of tests per instrument /day: Year 1	6	Number may vary depending on working hours
K		Average number of tests per instrument /day: Year 2 and beyond	12	Number may vary depending on working hours
L		Number of cartridges to order: year 1	1 500	I*J
M		Number of cartridges to order: year 2 and beyond	3 000	I*K
N	Human resources	Annual salary for technician		To be added; depends on the country
O	and technical assistance costs	Training and monitoring		To be added; depends on the country
		Installation costs: year 1	US\$ 19 900.00	A+B+C+D
		Running costs: year 1	US\$ 17 220.00	E+[(G+H)*(I)]+(N+O)
		Running costs: year 2 and beyond	US\$ 36 440.00	F+[(G+H)*(M)]+(N+O) (Extended warranty purchased at end of year 2 for year 3, etc.)

^a The calculations for selected items are described using the letters assigned to the rows

ANNUAL OPERATIONAL BUDGET

Instructions: Determine the amount of funds required for operating the Xpert MTB/RIF instrument by completing the table below.

	2015	2016	2017	2018	2019	Total (cumulative)
TOTAL (US\$)						
TOTAL existing funding						
TOTAL funding gap						

Figure 11: Operation costs rollout of Xpert MTB/RIF in [insert country]—funding requirements taking into account existing obligations