



CLINICAL GUIDE TO XPERT MTB/RIF (ULTRA)

Facilitator Guide (FG1)

SUMMARY OF MODULE AT A GLANCE

Purpose of module:	To provide clinicians with sensitization training for the Xpert MTB/RIF and Xpert MTB/RIF Ultra tests	
Total time of module	1 hour 50 minutes	
CONTENT OUTLINE		
Power point: TB Diagnostics Global Policies and Strategies	Aim: provide clinicians with sensitization to Xpert MTB/RIF (Ultra)* tests Learning objectives: <ul style="list-style-type: none">▪ Describe the role of Xpert MTB/RIF (Ultra) testing in diagnosis of TB and MDR-TB▪ Explain and discuss your country TB diagnostic algorithm (or the WHO preferred algorithms) for diagnosis and management of TB and MDR-TB▪ Understand the use of the WHO reporting codes for Xpert MTB/RIF (Ultra)	1 hour
Exercise 1: PT Report analysis	Aim: To review Xpert MTB/RIF clinical case studies suggest actions to address the situations presented	50 minutes
Handout and exercise/practicals in module	1. Worksheet (W1:M8)	
Additional resources or references:	<ol style="list-style-type: none">1. World Health Organization. Global Tuberculosis Programme. http://www.who.int/tb2. World Health Organization. (2016). Framework of indicators and targets for laboratory strengthening under the End TB Strategy http://www.who.int/tb/publications/labindicators/en/3. World Health Organization. (2015). Implementing tuberculosis diagnostics: A policy framework http://www.who.int/tb/publications/implementing_TB_diagnostics/en/4. Global Laboratory Initiative, Stop TB Partnership. (2017). GLI Model TB Diagnostic Algorithms. http://stoptb.org/wg/gli/assets/documents/GLI_algorithms.pdf	

* Refers to either Xpert MTB/RIF and/or Xpert MTB/RIF Ultra

5. World Health Organization. (2015). WHO End TB Strategy
http://www.who.int/tb/post2015_strategy/en/

MODULE NOTES

This Clinical Guide serves as sensitization to Xpert MTB/RIF (Ultra) testing for clinicians and other healthcare workers. The module should be used to supplement existing clinician training. Where possible, use country algorithms, request and reporting forms to familiarize clinicians to the tools at their disposal. In addition, review the Programmatic Modules for additional materials for diagnostic network strengthening.

Slide 8 This slide needs to be customized to the country TB diagnostic algorithm(s). Discuss the algorithm(s) with the participants to ensure understanding of how Xpert MTB/RIF (Ultra) can be used in TB diagnosis.

Slide 8-11 (hidden) In the event that country algorithms are not available or under development, the WHO recommended algorithms can be presented. It is important to stress that these are ideal examples and may differ as circumstances and resources are taken into account. See the Programmatic Module 1: TB Diagnostics- Global policies & strategies for more information.

Slide 15 This slide needs to be customized to the country TB diagnostic algorithm for Xpert MTB/RIF Ultra. This; and the following slides, can be skipped if Xpert MTB/RIF Ultra is not being used.

Slide 16-17 (hidden) In the event that country algorithm for Xpert MTB/RIF Ultra is not available (or under development), this WHO recommended algorithm can be presented. It is important to stress that this is an ideal example and may differ as circumstances and resources are taken into account.

Slide 19-21 These slides need to be customized to include the countries request and reporting forms

Slide 29 The scenarios presented are examples, and the exercise should be modified to address clinical situations common to the country and those that highlight actions described in the country's TB diagnostic algorithm(s). If Xpert MTB/RIF Ultra is available, ensure one or more scenarios that include the use of, or interpretation of results from this test

EXERCISE 1: CLINICAL CASE STUDIES

Purpose of exercise:	To review Xpert MTB/RIF clinical case studies suggest actions to address the situations presented
Preparation:	<ul style="list-style-type: none"> ▪ Work in groups of four ▪ Worksheet- Clinical case studies (W1:M8) ▪ Handout- Clinical case studies (H1:M8)
Materials required:	Full list of materials participants need: <ul style="list-style-type: none"> ▪ Pens (Red and black / blue) ▪ Worksheet- Clinical case studies (W1:M8) ▪ Handout- Clinical case studies (H1:M8)
Total time of exercise:	50 minutes
Feedback expected:	Select a someone to report your findings & suggestions

CONDUCTING THE EXERCISE

Break into groups of four	2 minutes
Review the supplied case studies & suggest actions to address the situations presented	15 minutes
Select one group to provide feedback and discuss their findings	30 minutes

DEBRIEFING EXERCISE/PRACTICAL

Discuss the answers and feedback. Do all groups have the same or similar responses? What is different? Where response link to the TB diagnostic algorithm(s) discuss.

Worksheet (W1:M8)

Time: 15 minutes

Instructions: Review the case studies and answer the questions or select the one correct answer from the multiple-choice questions.

Case study 1:

Q1. A 20-year old female is on TB treatment at your facility. At 23 weeks of treatment, she is asymptomatic. What do you do?

1. Collect one sputum specimens. Request smear microscopy.
2. Collect one sputum specimen. Request a Xpert MTB/RIF test and send to the laboratory.
3. Collect two sputum specimens. Request a TB culture on the first and LPA on the second. Submit both samples to the laboratory.
4. Register the patient as cured.

Q2. How does the patient being identified as a new case or a retreatment case affect the timing of sputum sample collection during treatment?

Case study 2:

Q1. A 29-year old male is on TB treatment at your facility. At seven weeks, he is asymptomatic. What do you do?

1. Collect two sputum specimens. Request a TB culture on the first and LPA on the second. Submit both samples to the laboratory.
2. Collect one sputum specimen. Request a Xpert MTB/RIF test and send to the laboratory.
3. Collect one sputum specimens. Request smear microscopy.
4. Register the patient as cured.

Case study 3:

Q1. A 20-year old female, New TB case and on TB treatment. At 23 weeks, she is asymptomatic. A sputum is submitted to the laboratory for smear microscopy. The patient is found to be smear positive. What do you do?

1. Register the patient as a treatment failure. Collect one sample for smear microscopy.
2. Register the patient as a treatment failure. Collect sample for Xpert MTB/RIF and a second for culture and DST
3. Register the patient as cured.

4. Refer immediately the patient to a MDR-TB unit

Q2. In this case the GX result comes back as MTB detected Rif sensitive what do you do next?

Case study 4:

A 21-year old female is on retreatment TB regime. At 12 weeks, she remains symptomatic. A sputum is submitted to the laboratory for smear microscopy. The patient is found to be smear positive. The patient admits not taking her medication for eight weeks. What do you do?

1. This patient has MDR-TB. Refer the patient to a MDR-TB Unit.
2. Register the patient as a treatment interrupter. Collect one sample for smear microscopy.
3. Register the patient as a treatment interrupter. Collect sample for Xpert MTB/RIF and a sample for culture and DST
4. Register the patient as cured.

Case study 5:

A Xpert MTB/RIF test result is received from the laboratory. The Xpert MTB/RIF test result is negative. What do you do?

1. The test result is invalid, and should be repeated on a second sputum specimen.
2. This patient is unlikely to have TB. The patient should be reassessed and consider other diagnosis
3. This patient has TB, and must be treated with a standard MDR-TB regimen.
4. This patient has TB, and must be treated with a standard TB regimen.

References and resources:

- WHO Global Tuberculosis Report 2016
- Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis (2014)
- WHO policy on collaborative TB/HIV activities- Guidelines for national programmes and other stakeholders (2012)
- WHO- Definitions and reporting framework for tuberculosis - 2013 revision (updated December 2014)
- WHO International standards for tuberculosis care (2014)

Handout (H1:M8)

Answers are in bold.

Case study 1:

Q1. A 20-year old female is on TB treatment at your facility. At 23 weeks of treatment, she is asymptomatic. What do you do?

5. Collect one sputum specimens. Request smear microscopy.
6. Collect one sputum specimen. Request a Xpert MTB/RIF test and send to the laboratory.
7. Collect two sputum specimens. Request a TB culture on the first and LPA on the second. Submit both samples to the laboratory.
8. **Register the patient as cured.**

Q2. How does the patient being identified as a new case or a retreatment case affect the timing of sputum sample collection during treatment?

New case: 2 months; 5 / 6 months (if smear positive- culture & DST)

Retreatment case: 3 months; 5 months & 8 months (if smear positive- culture & DST)

Case study 2:

Q1. A 29-year old male is on TB treatment at your facility. At seven weeks, he is asymptomatic. What do you do?

5. Collect two sputum specimens. Request a TB culture on the first and LPA on the second. Submit both samples to the laboratory.
6. Collect one sputum specimen. Request a Xpert MTB/RIF test and send to the laboratory.
7. **Collect one sputum specimens. Request smear microscopy.**
8. Register the patient as cured.

Case study 3:

Q1. A 20-year old female, new TB case and on TB treatment. At 23 weeks, she is asymptomatic. A sputum is submitted to the laboratory for smear microscopy. The patient is found to be smear positive. What do you do?

5. Register the patient as a treatment failure. Collect one sample for smear microscopy.
6. **Register the patient as a treatment failure. Collect sample for Xpert MTB/RIF and a second for culture and DST**
7. Register the patient as cured.
8. Refer immediately the patient to a MDR-TB unit

Q2. In this case the GX result comes back as MTB detected Rif sensitive what do you do next?

For patients who meet criteria for treatment failure, the possible reasons must be addressed promptly.

NB: A fundamental principle in managing patients who have failed treatment is that a single new drug should never be added to a failing regimen; so doing may lead to acquired resistance to the added drug. In such cases, it is generally prudent to add at least three new drugs to which susceptibility could logically be inferred to lessen the probability of further acquired resistance.

Case study 4:

A 21-year old female is on retreatment TB regime. At 12 weeks, she remains symptomatic. A sputum is submitted to the laboratory for smear microscopy. The patient is found to be smear positive. The patient admits not taking her medication for eight weeks. What do you do?

5. This patient has MDR-TB. Refer the patient to a MDR-TB Unit.
- 6. Register the patient as a treatment interrupter. Collect one sample for smear microscopy.**
7. Register the patient as a treatment interrupter. Collect sample for Xpert MTB/RIF and a sample for culture and DST
8. Register the patient as cured.

Case study 5:

A Xpert MTB/RIF test result is received from the laboratory. The Xpert MTB/RIF test result is negative. What do you do?

5. The test result is invalid, and should be repeated on a second sputum specimen.
- 6. This patient is unlikely to have TB. The patient should be reassessed and consider other diagnosis.**
7. This patient has TB, and must be treated with a standard MDR-TB regimen.
8. This patient has TB, and must be treated with a standard TB regimen.

References and resources:

- WHO Global Tuberculosis Report 2016
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