

- UPDATE -
Implementation and roll-out of Xpert MTB/RIF
May 2011

This document provides an update on the global roll-out of Xpert MTB/RIF, the WHO-endorsed test for the rapid simultaneous detection of TB and rifampicin resistance. Background information on the test, as well as operational considerations, WHO interim recommendations on site selection and positioning of the test, selection of individuals to test and patient management approaches, and key data elements to be collected to inform future scale-up, can be found in the **recently published WHO Policy statement** “Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system” (http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf), and the newly revised WHO Rapid **Implementation document** “Technical and operational ‘How-to’, Practical considerations” (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf).

At the end of April 2011 at least 22 countries were already implementing Xpert MTB/RIF and plans were in place to procure instruments and cartridges for 34 countries (18 additional countries) in collaboration with partners.

Training Workshop for Early Implementers of the Xpert MTB/RIF system

A training workshop was held on 7-8 April in Geneva with the following objectives:

1. To provide country health programmes and their local and international technical partners with the science behind Xpert MTB/RIF, assay performance characteristics and the need to link diagnosis with treatment and care in different epidemiological and resource settings;
2. To discuss with countries and partners the practical considerations for roll-out of Xpert MTB/RIF using the WHO Implementation Document, including interim diagnostic algorithms, patient management approaches, and key data elements to be collected to inform future scale-up;
3. To map country and technical partner plans for roll-out of Xpert MTB/RIF in order to maximize resources and avoid duplication and overlap.

Meeting participants included representatives from country health programmes planning to start implementation of the Xpert MTB/RIF assay, international institutions and agencies, and non-governmental organizations providing support to these country programmes.

All presentations can be found at <http://www.stoptb.org/wg/gli/meetings.asp>

Next steps discussed at the Training Workshop for Early Implementers

- A **checklist will be developed** by WHO to assist countries in deciding where to best place the technology.
- A dedicated **website mapping the rollout** of Xpert MTB/RIF is being developed by WHO. Upon agreement with the manufacturer, the numbers of GeneXpert devices and Xpert MTB/RIF cartridges sold, by country, will be shared. The website will also map country and

partner plans, to facilitate linkages and coordination. A notice will be sent to partners when the website has been launched (expected by end of May 2011).

- **Post-marketing surveillance:** The manufacturer has agreed to share all reports from users about malfunctions in GeneXpert devices and Xpert MTB/RIF cartridges. The follow-up on problems, including root cause analysis, and eventual outcome will also be shared.
- Countries and implementing partners will be invited to **participate in the WHO-coordinated roll-out**. Participants will be requested to:
 - Use the WHO-proposed interim algorithms
 - Submit core data to WHO. Discussions are underway with the manufacturer to allow for the GeneXpert software to easily make summary reports, which could be voluntarily submitted to WHO
- TREAT-TB is developing an online tool for **mapping Xpert MTB/RIF operational research activities**, to provide a comprehensive platform for researchers, policy makers and implementers to link, communicate and collaborate.

Consultation on the impact of WHO-endorsed molecular diagnostics on TB and MDR-TB case- and treatment outcome definitions

Conventional approaches to defining a case of TB and MDR-TB and classifying treatment outcomes depend on bacteriological methods (microscopy, culture, drug susceptibility testing). WHO-recommended molecular methods for the diagnosis of TB, including Xpert MTB/RIF and line probe assays, do not readily fit within the current case and treatment outcome definitions. A consultation was organized by WHO on 12–13 May, 2011 (Geneva, Switzerland), to review and propose refinements to definitions of cases and treatment outcomes for non MDR-TB and MDR-TB and the subcategories for which cases and treatment outcomes should be reported. The proposed revised definitions will be discussed at STAG-TB (June 2011) and later at a second consultation with country representatives and other stakeholders (tentatively October 2011), and piloted at the end of 2011 in sites rolling out Xpert MTB/RIF.

Upcoming events

- Second consultation on TB and MDR-TB case- and treatment outcome definitions, with country representatives and other stakeholders: October 2011 (tentative)
- Early Implementers' Meeting: Q4 2011 or Q1 2012, Geneva

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