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Prerequisites to country implementation of Xpert MTB/RIF and key action points at country level.

Checklist

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Checklist of prerequisites to country implementation of Xpert MTB/RIF and key action points at country level.

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Background

Earlier and improved tuberculosis (TB) case detection - including smear-negative disease often associated with HIV - and expanded capacity to diagnose multidrug-resistant tuberculosis (MDR-TB) are global priorities for TB control. Alarming increases in MDR-TB, the global emergence of extensively drug-resistant TB (XDR-TB), documented institutional transmission, and rapid mortality in MDR-TB and XDR-TB patients with HIV co-infection have highlighted the urgency for rapid diagnostic methods.

In December 2010, WHO endorsed the Xpert MTB/RIF assay and recommended that roll-out of the technology be phased in by country health authorities within the context of national plans for appropriate management of TB, MDR-TB and HIV-associated TB.

A Global Consultation called by WHO in December 2010 discussed the implementation considerations for Xpert MTB/RIF and achieved broad consensus on the way forward. Key outcomes of the consultation were agreement on interim diagnostic algorithms, positioning of Xpert MTB/RIF in risk groups at different levels of health services, and implementation considerations for programmatic roll-out of Xpert MTB/RIF to optimize use and benefits of the technology. These aspects are summarised in a **Rapid Implementation of Xpert MTB/RIF** document[1], aimed at guiding systematic roll-out of Xpert MTB/RIF in varying epidemiological and resource settings, with a view towards large-scale implementation based on programmatic data collected during the roll-out phase.

Current document outlines prerequisites and key actions that need to be considered by countries prior and during roll-out and implementation of the Xpert MTB/RIF assay.

Policy recommendation

The WHO evidence synthesis process confirmed a solid evidence base to support widespread use of Xpert MTB/RIF for detection of TB and rifampicin resistance and resulted in the following main recommendations[2]:

1. **Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having MDR-TB or HIV-associated TB.** (Strong recommendation)
2. **Xpert MTB/RIF may be considered as a follow-on test to microscopy in settings where MDR-TB or HIV is of lesser concern, especially in further testing of smear-negative specimens.** (Conditional recommendation acknowledging major resource implications)

Xpert MTB/RIF technology does, however, not eliminate the need for conventional microscopy culture and DST, which are required to monitor treatment progress and to detect resistance to drugs other than rifampicin. In settings or patient groups where rifampicin resistance is rare, Xpert MTB/RIF results indicating rifampicin resistance should be confirmed by conventional DST or LPA.

In addition, several operational conditions need to be met for successful implementation of Xpert MTB/RIF - stable electrical supply, a maximum ambient operating temperature of 30°C for the GeneXpert device, security against theft, dedicated trained personnel, adequate storage space, annual calibration of the instrument by a commercial supplier, and bio-safety precautions similar to those for direct sputum microscopy should all be in place.

[1] Rapid Implementation of Xpert MTB/RIF. WHO, Geneva WHO/HTM/TB/2011.2, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf

[2] Policy statement: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system. WHO, Geneva WHO/HTM/TB/2011.4, 2011. Available at: http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf

The checklists

Two checklists are presented below. **First** is a checklist of the most important prerequisites countries should meet before introducing the Xpert MTB/RIF assay. **Second** is a list of the key action points to be taken for efficient implementation of this new diagnostic.

1. Key prerequisites before country implementation of the Xpert MTB/RIF assay

	Prerequisite
Epidemiological data	1. Data available on prevalence of MDR-TB and HIV-associated TB to allow for decision making on **prioritizing** placement of the technology and **optimising** use of Xpert MTB/RIF in high-risk patient groups
Diagnostic policy reform	2. Plan to modify existing diagnostic algorithms as part of the NTP strategy to introduce Xpert MTB/RIF testing.
Laboratory network	3. Existing capacity and referral network to provide quality assured laboratory services with: **a)** culture and DST to determine resistance to first- and second-line drugs at central level (at least), quality assured through an established link with a Supranational Reference Laboratory; **b)** sputum smear microscopy for TB testing and treatment response monitoring; **c)** culture to monitor response to MDR-TB treatment.
Laboratory workload	4. Potential number of samples from high-risk groups for Xpert MTB/RIF testing in the facility where implementation is intended ranges 10-20 a day or 2000-4000 annually, in order to ensure optimal efficiency[3]
Infrastructure	5. Stable electricity supply in the facilities where implementation is intended or sufficient measures to ensure uninterrupted supply (generator, solar panels, battery/UPS backup, etc.)
	6. Secure premises for the equipment to prevent theft of the GeneXpert unit and the computer/laptop.
	7. Adequate storage of cartridges at recommended temperature range (2-28°C).
	8. Appropriate measures to prevent ambient temperature exceeding 30°C in the room where equipment will be installed (e.g. ventilation, air conditioning).
Bio-safety	9. Bio-safety requirements similar to sputum smear microscopy.
Personnel	10. 1-2 staff per site with basic computer literacy and knowledge of laboratory registers who can be trained to perform the testing and