

**- UPDATE -**  
**Implementation and roll-out of Xpert MTB/RIF**

## **Background**

On 8 December 2010 the World Health Organization (WHO) endorsed the Xpert MTB/RIF assay, a highly sensitive and specific, automated, real-time molecular diagnostic test which uses state-of-the-art DNA technology for rapid and simultaneous detection of tuberculosis (TB) and rifampicin resistance (a reliable proxy for multidrug-resistant TB, MDR-TB), in both HIV-negative and HIV-positive individuals. The technology is suitable for use at district and sub-district health service level, outside of conventional laboratory settings.

Given its ease of use and speed of diagnosis (in 100 minutes), Xpert MTB/RIF is expected to have a major impact on patient care and disease control by reducing patient and health service diagnostic delays, decentralizing the diagnosis of MDR-TB and HIV-associated TB, and accelerating patient access to appropriate care.

Although technical end-user training requirements for Xpert MTB/RIF are minimal, maximum efficiency and optimal use of the technology requires major overhaul of TB and MDR-TB diagnostic algorithms, changes in patient management approaches, and changes in case definitions and monitoring and evaluation indicators. WHO therefore convened a Global Consultation in December 2010 to discuss the operational considerations for Xpert MTB/RIF implementation.

## **Outcomes from the Global Consultation**

- Agreement on **interim diagnostic algorithms** prepared by the implementation Working Groups of the Stop TB Partnership (Global Laboratory Initiative, MDR-TB, TB-HIV and DOTS Expansion). These algorithms target high MDR-TB burden groups, high HIV-associated TB groups, and groups where MDR and/or HIV is of lesser concern;
- Agreement to pursue Xpert MTB/RIF roll-out in a systematic and coordinated programmatic approach in a so-called '**Evidence for scaling-up**' phase during 2011, with large-scale implementation from 2012 onwards based on the results of the Evidence for scaling-up phase;
- Agreement that the WHO Stop TB Department (STB), providing the secretariats for the abovementioned Working Groups, will develop a '**Rapid Implementation**' document to guide Xpert MTB/RIF roll-out in the 'Evidence for scaling-up' phase, which will outline the interim diagnostic algorithms, patient management approach, practical considerations for implementation, and core indicators for monitoring and evaluation;
- **Monitoring of global sales and market dynamics** by FIND to ensure that previously agreed price reductions based on demand/volumes are effected quickly and communicated to WHO-STB, countries and partners;
- Establishment of a **post-marketing surveillance programme** by FIND to monitor adverse events reported during Xpert MTB/RIF roll-out, including equipment breakdowns and down-times, supply chain problems, etc. with regular reporting to WHO-STB;
- Organization of an **Early Implementers' Meeting** in December 2011 to share experiences from the first phase of Xpert MTB/RIF roll-out in preparation for large-scale implementation from 2012 onwards.

## **Evidence for scaling up - Next steps**

- Member States notified by WHO-STB of Xpert MTB/RIF endorsement via WHO Regional and Country offices in December 2010;

- Detailed WHO policy guidance to be issued in March 2011;
- Rapid Implementation document to be disseminated in February 2011, containing a generic protocol for implementation and outlining interim diagnostic algorithms, patient management approach, and core indicators for routine programmatic monitoring;
- All countries and partners anticipating Xpert MTB/RIF roll-out to be invited to participate in the 'Evidence for scaling up' phase, using the Rapid Implementation document with local adaptation for setting-specific use, and reporting data to WHO-STB;
- WHO-STB to coordinate a systematic approach to roll-out of Xpert MTB/RIF in selected countries over the next 12-18 months, in association with donors and technical agencies, to collect standardized data on operationalisation of the technology under routine programmatic conditions, and to validate and cost the agreed interim diagnostic algorithms,
- WHO-STB to organise a training workshop for Early Implementers participating in the 'Evidence for scaling up' phase in April 2011;
- WHO-STB to establish a dedicated website to map global Xpert MTB/RIF sales (by country and public/private sector differentiation), map implementation progress (by country and partners), and report the post-marketing surveillance data and corrective actions taken;
- WHO-STB to convene a consultation in April 2011 in Geneva with key technical partners to redefine case- and outcome definitions and discuss possible changes in patient monitoring;
- WHO-STB to convene an Early Implementers' meeting in December 2011 in Geneva.

### **Save the date - tentative dates for important events**

- Training Workshop for Early Implementers: 5-6 April 2011, Geneva
- Consultation on changes in case- and outcome definitions: 19-20 April 2011, Geneva
- Early Implementers' Meeting: 7-9 December 2011, Geneva

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