Update on the global roll-out of Xpert MTB/RIF

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Contents of this presentation

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47 countries have procured at least one GeneXpert, as of Dec 2011 (public sector in eligible countries)

460 machines (2401 modules) procured

Data: FIND
591,450 Xpert MTB/RIF cartridges procured, as of Dec 2011 (public sector in eligible countries)

330,540: South Africa
21,440: Pakistan
20,140: Kenya
17,440: Philippines
16,660: Swaziland
14,140: Tanzania
13,970: Zimbabwe
12,280: Kyrgyzstan
10,590: Mozambique
Xpert MTB/RIF global landscape today

Data: FIND (public sector in eligible countries)
WHO activities to facilitate the global roll-out

December 2010:

- WHO endorsement of Xpert MTB/RIF, following a Global Consultation (recommended by an Expert Group Meeting and endorsed by STAG)
- Issuance of the *Roadmap for rolling out Xpert MTB/RIF*
WHO activities to facilitate the global roll-out

March 2011:
- Issuance of the *WHO Rapid Implementation of Xpert MTB/RIF diagnostic test*
  - Positioning of the test and site selection
  - Selection of individuals to test and patient management
  - Key data elements to collect
  - Operational considerations
WHO activities to facilitate the global roll-out

April 2011:

- Training workshop for Xpert MTB/RIF Early Implementers
  - Focus on the practical application of the *Rapid Implementation* document within country-specific context
  - Mapping of country and technical partner / donor plans for roll-out in order to maximize resources and avoid duplication and overlap
  - Understanding of the additional needs of implementers
WHO activities to facilitate the global roll-out

May 2011:
- Issuance of WHO Policy statement and refined *Rapid Implementation* document
- Impact of Xpert MTB/RIF and other rapid diagnostics on definitions of cases and treatment outcomes for MDR-TB and non MDR-TB: Consultation
WHO activities to facilitate the global roll-out

June 2011:

- Issuance of the Checklist: Prerequisites to country implementation of Xpert MTB/RIF and key action points at country level
WHO activities to facilitate the global roll-out

July 2011 onwards:

- WHO website monitoring the Xpert MTB/RIF rollout
  - Numbers of procured GeneXperts and Xpert MTB/RIF cartridges, by country
  - Sites of GeneXperts in countries
  - Plans of countries and partners for procurements
  - Reported operational problems
WHO activities to facilitate the global roll-out

- July 2011 onwards:
  - WHO website monitoring the Xpert MTB/RIF rollout
  - Numbers of procured GeneXperts and Xpert MTB/RIF cartridges, by country
  - Sites of GeneXperts within countries
  - Plans of countries and partners for procurements
  - Reported operational problems
    - Signal loss errors (5011)
    - Broken thermo-sensor
    - Module out-of-order
    - Recurrent breakage of plastic on lid
    - Syringe errors (2005)
WHO activities to facilitate the global roll-out

- **September, December 2011:**
  - Submission of Letter of Intent (LoI) and proposal to UNITAID for procurement of GeneXperts and Xpert MTB/RIF cartridges
  - Consortium: WHO, Stop TB Partnership, FIND, Global Laboratory Initiative (GLI), TB REACH, African Society for Laboratory Medicine (ASLM), Interactive Research and Development (IRD)
  - Allow for a drop in cartridge price to 9.98USD

Xpert MTB/RIF Early Implementers Meeting: 18-19 April 2012
December 2011 onwards:
- GLI validation panels for Xpert MTB/RIF
  - 5 tubes containing heat-killed bacilli in artificial sputum
  - Results are reported to GLI secretariat and compared with expected results (MTB RIF-, MTB RIF+, not MTB)
  - Intended to be used with new machines and with recalibrated modules
- Requests for panels: gli_secretariat@who.int
Findings of pilot validation panel scheme

- Panels sent to 8 countries, 38 sites funded by TB REACH
- 30 sites: all results as expected (103/103 tests)
- Of the remaining 8 sites (36 tests):
  - 3 tests: false RIF susceptibility
  - 2 tests: false RIF resistance
  - 2 tests: false MTB detection
  - 3 occurrences of errors, plus 1 site in which all 4 tests were invalid
- There is a need to include the panels with shipments of instruments/modules
WHO activities to facilitate the global roll-out

- February 2012 onwards:
  - Launch of website to collect evidence for scale-up, as described in *Rapid Implementation* document
  - Facilities invited to provide data on:
    - Laboratory workload
    - Numbers of tests being performed and results
    - Main logistical and operational problems being encountered
WHO activities to facilitate the global roll-out

- Other ongoing activities:
  - Quarterly updates on the Xpert MTB/RIF roll-out, sent to our mailing list
  - Online list of published literature on Xpert MTB/RIF, updated monthly

http://www.who.int/tb/laboratory/mtbrifrollout
Actions needed for facilitating larger scale-up

- **Price drop!**
  - Ongoing negotiations with UNITAID, FIND, other donors and buyers, with the manufacturer

- Refining of WHO guidance, based on the experiences and data from early implementers
  - Collection of evidence (key laboratory and patient data) by WHO and partners, including TB REACH, TB CARE sites
  - Findings from operational research
Actions needed for facilitating larger scale-up

- Adoption of the technology by the private sector
- Technological innovations to facilitate use in peripheral sites globally
- Review of accuracy data on detection of extrapulmonary TB and paediatric TB for possible endorsement
Expected outcomes of this meeting

- Sharing of up-to-date information and country experiences on use of Xpert MTB/RIF and best practices
- Sharing of country, partner and donor activities and plans for improved coordination
- Greater understanding of the needs of Xpert MTB/RIF implementers

Thank you
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