Registration and reporting of TB and MDR-TB cases, and key data elements for implementation

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Workshop for Early Implementers

Implementation and roll-out of the Xpert MTB/RIF system for rapid diagnosis of tuberculosis and multidrug-resistance

Geneva, Switzerland

8 April 2011
Topics of presentation

• Registering TB & Rif resistant TB diagnosed by Xpert MTB/RIF

• Reporting TB & Rif resistant TB diagnosed by Xpert MTB/RIF

• Key data for "Generating evidence for scaling-up during Xpert MTB/RIF roll-out"
Interim case definitions (1)

TB case

- Xpert MTB/RIF is diagnostic of TB
- Enumeration as **Xpert MTB/RIF positive**, regardless of smear result
- Monitoring using smear microscopy
- Outcomes "cured" and "failed" apply even if not smear or culture positive at start of treatment
**Interim case definitions (2)**

Rifampicin resistant TB case (1)

- All TB cases diagnosed with Xpert MTB/RIF and rifampicin resistant to be registered as **Xpert MTB/RIF positive with rifampicin resistance**
- Monitoring using smear and culture
- Same outcomes apply as for MDR-TB
Interim case definitions (3)
Rifampicin resistant TB case (2)

In settings where R-resistance is strongly associated with MDR, can Xpert R-resistant cases be a proxy for MDR-TB?

- **Case management**: start on SLD regimen and retest if low prevalence for R-resistance (see other presentation)
- **Notification of MDR**: separate enumeration of Xpert R-resistant cases
- **Surveillance**: (representativity of % resistance) under discussion
Registering TB cases diagnosed by Xpert MTB/RIF
Registering TB cases (1)
TB laboratory register

**TB Laboratory Register**

<table>
<thead>
<tr>
<th>Lab. serial No.</th>
<th>Date specimen received</th>
<th>Name (in full)</th>
<th>Sex</th>
<th>Age</th>
<th>Complete address (patients for diagnosis)</th>
<th>Name of referring facility</th>
<th>Reason for sputum smear microscopy examination</th>
<th>Results of sputum smear microscopy examinations 1</th>
<th>2</th>
<th>3</th>
<th>BMU and TB Register No. (after registration)</th>
<th>Remarks</th>
</tr>
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</tbody>
</table>

"XPERT"
Registering TB cases (2)
District TB register

Basic Management Unit TB Register – Right side of the register book

<table>
<thead>
<tr>
<th>Results of sputum smear microscopy and other examination</th>
<th>Treatment outcome &amp; date</th>
<th>TB/HIV activities</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>2 or 3 months¹</td>
<td>5 months</td>
<td>End of treatment</td>
</tr>
<tr>
<td>Sputum smear microscopy result²</td>
<td>Date/ Lab. No.</td>
<td>HIV result³</td>
<td>X-ray Result⁴</td>
</tr>
<tr>
<td>Date/ Lab. No.</td>
<td>Date/ Lab. No.</td>
<td>Sputum smear microscopy result²</td>
<td>Date/ Lab. No.</td>
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<td>Date/ Lab. No.</td>
<td>Date/ Lab. No.</td>
<td>Sputum smear microscopy result²</td>
<td>Date/ Lab. No.</td>
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<tr>
<td>Date/ Lab. No.</td>
<td>Date/ Lab. No.</td>
<td>Sputum smear microscopy result²</td>
<td>Date/ Lab. No.</td>
</tr>
</tbody>
</table>

"XPERT" result + date

Form 5 (continued)
Registering TB cases (3)

Electronic means, please!

- The advent of new technology should be matched by efficient data management
- The GeneXpert unit is already linked to a computer
- Possibility to export the test result from the inbuilt database
- "Light" in data requirements
- Added benefits of easy transmission of lab results to the clinicians and public health authorities
Registering rifampicin resistant TB cases diagnosed by Xpert MTB/RIF
## Registering R-resistant TB cases (1)

**TB C & DST laboratory register**

<table>
<thead>
<tr>
<th>Reason for examination</th>
<th>Result of smear examination</th>
<th>Result of culture***</th>
<th>Result of confirmatory-test for M. Tuberculosis (pos or neg)</th>
<th>Culture sent for DST (yes or no)</th>
<th>Date DST started/ inoculated</th>
<th>DST method</th>
<th>Date of DST result</th>
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<tbody>
<tr>
<td>Diagnosis*</td>
<td>Follow-up**</td>
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</tbody>
</table>

"XPERT"
Registering R-resistant TB cases (2)
Second line treatment register

<table>
<thead>
<tr>
<th>2 line drugs already received (yes/no)</th>
<th>Date sample taken for DST</th>
<th>Date of result of DST</th>
<th>Result of Drug Resistance Test R= resistant S= Susceptible C = contaminated</th>
<th>Type of resistance (MDR, XDR, polyresistant)</th>
<th>Treatment started with MDR-TB confirmed/unconfirmed</th>
<th>Regimen (in drug initials)</th>
<th>Date treatment started</th>
<th>Smear (S) and Culture (C) Results During Treatment</th>
</tr>
</thead>
<tbody>
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<td>S C S C S C S C S C</td>
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</tbody>
</table>

"XPERT"
Revisions to the reporting format
Work in progress!

- An expert consultation in late May 2011 will discuss this.
- Sound registration of Xpert results in currently recommended format (episode-based) will be useful for future aggregation.
- Again, electronic storage of data will make life easy to generate outputs in future (case detection, enrolment, outcomes).
Key data for "Generating evidence for scaling-up during Xpert MTB/RIF roll-out"

Key data elements for implementation (1)

Rationale

As Xpert MTB/RIF is rolled out, challenges expected as:

- screening and diagnostic practices change
- patient groups to test are prioritized by resources
- laboratory organization and workloads shift
- supply chain management needs increase

Objective:

Key data related to programmatic roll-out (also called "evidence for scaling up") collected to inform wide-scale implementation elsewhere
Key data elements for implementation (2)

Five basic questions

1) How does the introduction of Xpert MTB/RIF testing impact on the number of conventional diagnostic tests (e.g. sputum smear microscopy, culture and DST)?

2) What are the main indications for Xpert MTB/RIF testing being requested?

3) How many Xpert MTB/RIF tests are positive for TB and for rifampicin resistance?

4) How is workload affected after the introduction of Xpert MTB/RIF (e.g. expressed in terms of technician-time)?

5) What are the main logistical and operational issues related to Xpert MTB/RIF implementation (e.g., cartridge supply, downtime of the GeneXpert unit)?
Key data elements for implementation (3)

Minimum dataset (1)

- Core set of variables to allow generation of simple indicators.
- Address the five basic questions.
- Comparison in time (data collected retrospectively for the same laboratory before introduction of Xpert MTB/RIF) or with a comparable laboratory not using Xpert MTB/RIF.
Key data elements for implementation (4)

Minimum dataset (2)

- The use of electronic data collection is strongly encouraged.

- Key laboratory data can be collected with slight modifications to current lab registers to allow the capture of information on Xpert MTB/RIF tests and log of workload and problems with Unit function.
Key data elements for implementation (5)

Other data nice to have

Additional data
- Culture tests
- DST
- Conventional test results: smear, culture, DST

Complementary data on patient management would not usually be available in the lab and would need linkage to information usually kept in a treatment facility. Test out algorithms fully.
Key data elements for implementation (6)

- Placement of unit (NRL, Provincial lab, Hospital lab, District lab...)
- Number of units and type (number of modules)
- Monthly number of days unable to operate Xpert MTB/RIF unit
- Reasons why Xpert MTB/RIF could not be operated
- Total lab-technician hours logged in the TB lab

Number of
- sputum microscopy tests performed for diagnosis
- sputum tests performed for treatment follow-up
- Xpert MTB/RIF tests (disaggregated by the reason for testing)
  - positive Xpert MTB/RIF tests
  - Rif-resistant Xpert MTB/RIF tests
Key data elements for implementation (6)

- Any countries interested to collect data for this exercise are encouraged to contact WHO in advance for better coordination.