Xpert MTB/RIF
Preparation to implementation in MSF projects

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Content

- Procurement
- Training
- Info package for the field
- Monitoring
- Operational Research
Procurement overview

Projections for 2011

• 18 projects in 16 countries

• To date: 15 instruments for MSF projects + 1 for Epicentre

• Total number of instruments to be procured in 2011: 27
### 16 projects in diverse contexts

<table>
<thead>
<tr>
<th>High DR TB</th>
<th>Low DR TB</th>
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<tbody>
<tr>
<td><strong>High HIV</strong></td>
<td><strong>Low HIV</strong></td>
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<tr>
<td>Lesotho</td>
<td>Georgia</td>
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<tr>
<td>Swaziland</td>
<td>Uzbekistan</td>
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<td>South Africa (KZN)</td>
<td>Tadjikistan</td>
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<td></td>
<td>Khuristan</td>
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<td></td>
<td>Ukraine</td>
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<td></td>
<td>Colombia</td>
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<table>
<thead>
<tr>
<th>Low DR TB</th>
<th>Low HIV</th>
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<tbody>
<tr>
<td>Kenya</td>
<td>Cambodia</td>
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<tr>
<td>Myanmar</td>
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<td>Malawi</td>
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<tr>
<td>Mozambique</td>
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<td>Uganda</td>
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<td>Zimbabwe</td>
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Training and technical support

- Training of lab advisors and biomed engineers and logisticians conducted by Cepheid at HQ
- Lab advisors of each OC to support their projects for installation and use of the device
- Lab advisors to centralize troubleshooting issues experienced from projects and contact the Cepheid hotline
Info package to the field

- Technical Note (essential info on laboratory procedures and logistical requirements)
- Diagnostic algorithms to be adapted to field conditions
- Xpert Lab register
- Xpert Lab report
- Xpert quarterly report form
Diagnostic algorithms with Xpert MTB/RIF for pulmonary and pleural TB in adult and adolescent

Generic algorithms

- HIV+ patients with low risk of MDR TB and without danger signs
- HIV+ patients severely ill with low risk of MDR TB
- HIV-negative patients with low risk of MDR TB
- Patients with high risk of MDR

Adaptation to field conditions
1. Diagnostic algorithm with Xpert MTB/RIF for pulmonary and pleural TB in adult and adolescent HIV+ patients with low risk of MDR TB.

Day 1

- TB suspect* and no danger signs*
  - 1 sputum for Xpert MTB/RIF and microscopy²
    - Result negative
      - TB, Rif resistance
      - Chest X-Ray + culture⁷
        - Start empiric MDR TB treatment¹⁴
    - CXR suggestive of TB⁸
      - Broad spectrum ATB² or PCP Rx
      - Response¹⁰
        - No response
          - Repeat Xpert MTB/RIF and microscopy
    - CXR not suggestive of TB⁸

Day 5

- Response¹⁰
  - No response
    - Repeat Xpert MTB/RIF and microscopy
  - Result negative
    - TB, no Rif resistance
    - Start empiric MDR TB treatment¹⁵
  - Consider diagnoses other than TB¹⁰
    - Symptoms persist and high index of suspicion for TR¹²
      - Start empiric TB Rx
        - Assess evolution under TB Rx
          - No clinical and CXR improvement¹³
          - Improvement
            - Consider other diagnosis¹⁴
              - Full TB 1st line TB treatment
Monitoring

- Registers

- Standard reports
  - Patients indicators
  - Lab report

- Centralization and recording of technical problems
<table>
<thead>
<tr>
<th>Lab registration number*</th>
<th>Patient name</th>
<th>Age</th>
<th>Sex/F/M</th>
<th>Treatment Unit</th>
<th>Date of collection</th>
<th>Xpert **</th>
<th>Date of exam</th>
<th>Sample appearance (1)</th>
<th>Smear microscopy</th>
<th>MTB (2)</th>
<th>RIF (3)</th>
<th>SPC Control (4)</th>
<th>PC Control (4)</th>
<th>Valid result Y/N</th>
<th>Notes</th>
</tr>
</thead>
</table>

* Also note the cartridge batch number for each new batch
** indicate if 1st, 2nd or 3rd Xpert

(1) Sample appearance: S=Salivary, M=Macouli, P=Purulent, MP=Uncopurulent
(2) MTB: D=Detected, ND=Not Detected, Inv=Invalid, NR=No Result
(3) RIF: D=Detected, ND=Not Detected, Ind=Indeterminate
(4) SPC Control & PC Control: P=Pass, F=Fail, NR=No Result
Patients indicators

**Susceptible TB**

- % of 1\textsuperscript{st} Xpert MTB+ among suspects
- % of patients MTB+ on 2\textsuperscript{nd} Xpert
- % Xpert MTB + among patients started under TB treatment
- % of Xpert MTB+ among smear negative patients
- % of HIV+, - and unknown among Xpert MTB+
- *Median time between Xpert MTB + result and 1st line treatment initiation*
Patients indicators

**Resistant TB**

- % of Xpert RIF+ among Xpert MTB+ patients
- % of Xpert RIF+ among suspect patients
- % of patients under MDR TB treatment who were Xpert RIF+
- % of Xpert RIF+ started under MDR TB
- % of HIV+, - and unknown among Xpert RIF+
- *Median time between Xpert RIF+ result and MDR TB treatment initiation*
### Laboratory report

- **Xpert tests results**

<table>
<thead>
<tr>
<th># Detected</th>
<th># Not Detected</th>
<th># Invalid</th>
<th># No Result</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTB results</td>
<td></td>
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<tr>
<td>RIF results</td>
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</tbody>
</table>

- **Xpert vs culture (when relevant)**
- **TAT from sample collection to sample processing with Xpert**
Operational research

• Multicentric study
  – Assessment of patients outcomes
    • Time to treatment initiation, drop out, detection yield
    • Various epidemiological settings and algorithms
    • District/peripheral level
  – Feasibility in routine conditions
    • Robustness of the instrument
      – Number and cause of error messages
      – Module defection
    • Description of the supply and storage, maintenance, annual calibration, waste management
  – Implementation costs

• Performances according to lead time before test
Operational research

• **Impact study**
  
  – Compare the impact on patients outcome
    • algorithm including testing by Xpert MTB/RIF
    • vs. algorithms based on clinical, CXR with rapid *MTB* culture
    • vs. algorithms based on clinical, CXR without rapid *MTB* culture

  – Measure and compare the incremental cost-effectiveness of different algorithms
Future

- How does it work in real life?
- New case definitions?
- Re-adjust algorithms
- Will the treatment capacity follow the increased detection of MDR TB?
- Complete monopoly of 1 manufacturer…