Revised definitions of TB case and treatment outcomes
New Molecular Tests (WRD*) now recommended for rapid diagnosis of TB in high HIV and high MDR settings

WRD will be used *for diagnosis* in place of conventional bacteriology in high HIV and high MDR-TB settings

Danger of increased complexity in R&R ➔ opportunity to improve systems

*WHO-endorsed Rapid Diagnostics*
STAG recommendations (June 2011) and next steps

- Acknowledged need to update and simplify definitions
- Changes should not compromise trends monitoring
- Allow mechanism for reporting the diagnosis method after registration for culture confirmed cases
- Simplify definitions for MDR-TB (failure/success)
- Pursue consultative process with countries
- Update R&R system in settings rolling out Xpert (start in 2011)
<table>
<thead>
<tr>
<th>Definite</th>
<th>Case</th>
<th>Retreatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Culture-pos</td>
<td>• Definite OR</td>
<td>• After default</td>
</tr>
<tr>
<td>• Smear-pos</td>
<td>• Other cases put on tx</td>
<td>• After failure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Relapse</td>
</tr>
</tbody>
</table>
Proposed case categories

First and recurrent episodes

**Microbiologically diagnosed**
- Culture-pos
- WRD*-pos
- Smear-pos

**Clinically diagnosed**
- Histology-pos (EPTB)
- Others put on tx (incl. CXR, TST)

**Treatment change**
- After interruption
- After failure

* WHO-endorsed Rapid Diagnostics
Main case disaggregations

- Microbio / clinical dx
- HIV status (tested, HIV-, HIV+, ART)
- 4 age groups (0-4, 5-14, 15-49, 50+)
- Sex
- Smear status?
Treatment changed disaggregations

- Treatment change after interruption
  - DR status
    - tested
    - MDR
    - RR confirmed
- Treatment change after failure

+
Predictive values of Xpert MTB/RIF as proxy for MDR in new cases
Predictive values of Xpert MTB/RIF as proxy for MDR in retreatment cases

![Graph showing the predictive values of Xpert MTB/RIF as a proxy for MDR in retreatment cases. The graph includes data points for different regions and number tested, illustrating the relationship between prevalence of MDR and the probability of a positive Xpert result.]
MDR case definition

**MDR-TB Confirmed**
- DST: resistant to R and H

**RR-TB Confirmed**
- DST or LPA: $R^+ H^-$
- WRD: $R^+$ and $RR \geq 15\%$ in same patient group (DRS)
Updated treatment outcomes

NON MDR
- Cured
- Completed
- Failed
- Died
- Interrupted
- Not evaluated

MDR
- Success
- Failed
- Died
- Interrupted
- Not evaluated
Non MDR outcome definitions

- Cure (3 criteria):
  - no signs of continued active disease
  - tx completed
  - bacteriological success documented

- Failed
  - clinical or bact deterioration
  - signs of continued active disease
  - deterioration requiring tx change

- Completed
  - tx completed, no evidence of failure or cure
MDR patient completed tx according to protocol, > 5 consecutive negative cultures from samples at least 30 days apart in final 12 months of tx OR only one culture positive AND no clinical deterioration AND followed with > 3 negative cultures > 30 days apart
Proposed MDR tx outcome definitions

- **Success**  treatment completed as intended without evidence of failure
- **Failure**  termination of tx or need for tx change (≥2 classes)
  - Lack of smear/cult conversion by 2 months after end of intensive phase AND/OR
  - Bacteriological reversion (≥2 pos specimen ≥30 days apart) after conversion to negative AND/OR
  - Adverse drug reactions
Treatment outcome disaggregations

- Option 1
  - New and recurrent
  - Treatment change
  - HIV+ (all together)

- Option 2
  - New and recurrent bacteriologically diagnosed
  - New and recurrent clinically diagnosed
  - Treatment change
  - HIV+ (all together)

Treatment outcomes by sex only in case based eRR systems
## Reducing complexity

<table>
<thead>
<tr>
<th></th>
<th>Current categories</th>
<th>Proposed categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>38</td>
<td>29</td>
</tr>
<tr>
<td>Outcomes non MDR</td>
<td>40</td>
<td>23</td>
</tr>
<tr>
<td>Outcomes MDR</td>
<td>18</td>
<td>15</td>
</tr>
</tbody>
</table>
Next steps

- Discuss and achieve consensus
- Pilot in Xpert settings
- Revise paper-based forms
- Roll-out through 2012-13