Revised TB treatment outcome definitions
<table>
<thead>
<tr>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
</tr>
<tr>
<td>Completed</td>
</tr>
<tr>
<td>Failed</td>
</tr>
<tr>
<td>Default</td>
</tr>
<tr>
<td>Died</td>
</tr>
<tr>
<td>Transfer out</td>
</tr>
<tr>
<td>Not evaluated</td>
</tr>
</tbody>
</table>
Minimal changes, cure only defined for smear positive cohorts
WRD-pos without smears for Dx: completed
Disaggregated by
- Smear or culture pos at Dx
- WRD-pos with no smear/culture at Dx
- Tx history (new vs retreatment)
- HIV
- Sex
Current definition for an MDR 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
Current definition only valid for 20-month regimen
Requires electronic recording and reporting
Unchanged
Disaggregated by
- XDR
- HIV-positive
- Sex
- Children
Option–1, pros

- Builds on existing treatment outcome definitions
Option–1, cons

- Need to disaggregate non-MDR outcomes by smear-pos, XRD-pos and others
- **Cure vs completed** disaggregation not used much, treatment completed is the key indicator used globally
- **Transfer-out** = missing data, separation from other non-evaluated not very useful at national level – but management of transfer-out data essential at peripheral levels
- MDR cure and failure definitions broken when shorter regimen used
- MDR cure and failure definitions convoluted and hard to remember
- MDR outcome computations highly error-prone if done manually using a register
- Change in failing regimen unaccounted for
- Clinical failures unaccounted for
Option 2 – outcomes non-MDR

- **Cured**: Tx completed, no sign of active disease, bacteriological success AND Did not require tx change due to clinical deterioration or lack of bacteriological success
- **Failed**: Signs of active disease or lack of bacteriological success OR Required tx change due to clinical deterioration or lack of bacteriological success
- **Interrupted**: Interruption > 2 months without medical approval
- **Died**
- **Not evaluated**
Option–2, non-MDR implications

- Need for bacteriological monitoring
- Cure requires bacteriological success
  - Smear-neg at end of treatment
  - If bac results not available at end, smear-neg when started on continuation phase
  - No bac results available during treatment but tx completed with no sign of active disease: classify as not evaluated?
Objectives of MDR surveillance

- Assess MDR burden and its trends
- Assess needs for MDR Dx and Care
- Assess performance of MDR care services
Option 2 – outcomes MDR

- **Cured**
  - Tx completed, no sign of active disease, bacteriological success AND
  - did not require tx change due to clinical deterioration or lack of bacteriological success

- **Failed**
  - Signs of active disease or lack of bacteriological success OR
  - Required tx change due to clinical deterioration or lack of bacteriological success

- **Interrupted**
  - Interruption > 2 months without medical approval

- **Died**

- **Not evaluated**
Success
  - Sputum or culture conversion
  - Remains negative

Failure
  - Lack of sputum or culture conversion
  - Revert to positive
  - *Required change of at least 2 classes of SLD*
  - Termination of treatment

Interrupted: > 2mo

Died

Not evaluated
Option–2, MDR implications

- Update PMDT guidelines companion guide
- Cure requires bacteriological success
  - Culture conversion
  - 2 repeat culture pos following conversion define bacteriological failure
Option–2, MDR implications (con’t)

- Treatment change in failures
  - At least 2 classes of SLDs?
## Option 3 ... outcomes subcategories

<table>
<thead>
<tr>
<th>NON-MDR</th>
<th>MDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>- New episodes (incl. recurrences)</td>
<td>- New MDR</td>
</tr>
<tr>
<td>- treatment change</td>
<td>- MDR treatment change</td>
</tr>
<tr>
<td>- HIV+</td>
<td>- HIV+</td>
</tr>
<tr>
<td>- Sex*</td>
<td>- Sex*</td>
</tr>
<tr>
<td>- Children*</td>
<td>- Children*</td>
</tr>
</tbody>
</table>

* If case-based or patient-based electronic recording and reporting in place or operational research
## Complexity of treatment outcomes

<table>
<thead>
<tr>
<th></th>
<th>Core categories</th>
<th>Sub-categories (+ men, women, children)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Option 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>non-MDR</td>
<td>7</td>
<td>40 (58)</td>
</tr>
<tr>
<td>MDR</td>
<td>7</td>
<td>21 (42)</td>
</tr>
<tr>
<td><strong>Option 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>non-MDR</td>
<td>5</td>
<td>15 (30)</td>
</tr>
<tr>
<td>MDR</td>
<td>5</td>
<td>15 (30)</td>
</tr>
</tbody>
</table>
In conclusion

- Option 2 or a variation of option 2 preferred
- Streamline and simplify treatment outcome definitions
- No immediate implication of option 2 with regards to treatment guidelines
- Update recommended paper-based R&R
- Any further simplifications?