

Philippe Glaziou
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Revised TB treatment outcome definitions

Treatment outcomes

Cured

Completed

Failed

Default

Died

Transfer out

Not evaluated

Option 1 – outcomes non-MDR

- 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

Option 1 – outcomes MDR

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

Option 1 – outcomes MDR (con't)

- 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

Option-1, cons (con't)

- 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

Option-3 ...MDR outcomes

- 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

NON-MDR

- New episodes (incl. recurrences)
- treatment change
- HIV+
- *Sex**
- *Children**

MDR

- New MDR
- MDR treatment change
- HIV+
- *Sex**
- *Children**

* If case-based or patient-based electronic recording and reporting in place or operational research

Complexity of treatment outcomes

| | Core categories | Sub-categories (+ men, women, children) |
|-----------------|-----------------|--|
| Option 1 | | |
| non-MDR | 7 | 40 (58) |
| MDR | 7 | 21 (42) |
| Option 2 | | |
| non-MDR | 5 | 15 (30) |
| MDR | 5 | 15 (30) |

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?