Document flow and data management

Dennis FALZON

TB surveillance and surveys: A training workshop for consultants

Geneva, Switzerland - 26 May 2011
References

WHO/HTM/TB/2009.422

Guidelines for surveillance of drug resistance in tuberculosis

WHO/HTM/TB/2008.402

Guidelines for the programmatic management of drug-resistant tuberculosis
EMERGENCY UPDATE 2008
Objective

Data management in DR surveys aims to:

• Produce good quality data on key features for cases included
• Permit meaningful description and analysis of data
Steps

• Data sources
• Collection
• Handling
• Transfer
• Data validation & checking
  • (Description & analysis)
• Storage
Data flows in a DR survey

Tuberculosis surveillance and surveys: data management

Training workshop for consultants – 26 May 2011

World Health Organization
The Stop TB Department
Data sources & collection (1)

Sputum testing form

Guidelines for the programmatic management of drug-resistant tuberculosis

EMERGENCY UPDATE 2008

Tuberculosis surveillance and surveys: data management
Training workshop for consultants – 26 May 2011

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Data sources & collection (2)

Data on patient details and history

Guidelines for surveillance of drug resistance in tuberculosis

ANNEX 9
Example of a clinical information form

A. IDENTIFICATION OF THE PATIENT
- Name:
- Patient identification number:
- Date registered:
- Sex: [ ] Male [ ] Female
- Age:
- Date of sputum collection:
- Country-specific data (to be decided by the country)
- HIV-status
- Other risk factors: [ ] alcohol use, [ ] diabetes, [ ] other

B. HISTORY GIVEN BY THE PATIENT
- Previously treated for TB?
- If yes: [ ] Yes [ ] No
- For how long have you been sick?
- Did you have the same symptoms prior to this episode?

C. MEDICAL RECORDS
- After extensive checking through the medical files and other documents available in the health center, have you discussed the patient's history mentioned above?
- Previous history of TB?
- Did the patient remember previous treatment for TB after these questions?

D. FINAL DECISION
- Previously treated for TB for more than a month?
- If yes: [ ] Yes [ ] No
- If no: [ ] No
- If yes: [ ] Yes
- (answer to question B1 or B2 and/or C was 'yes')
- If no: [ ] No
- (answer to question B1 and B2 and/or C was 'no')
- Other
- Unknown

Responsible Officer:

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Data sources & collection (3)

Bar coding

- Easy to generate & read
- Barcode label software
- Facilitate data capture
- Reduce error
- Measure of confidentiality
Data handling & transfer (1)

• Check data forms for completion
• Any codes used assigned correctly?
• Cross-check of certain details (eg, treatment history)
• Confidentiality (? anonymization)
Data handling & transfer (2)

- Keep copies at place of origin
- Arrange for transfer to next level
- To accompany laboratory samples
- Storage of forms (policy for destruction)
Data handling & transfer (3)

- Computerization

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**Surveillance of Drug Resistance in Tuberculosis**

**Form 1: Intake, Interview and Shipment**

- **Country**
- **Country Code**
- **Diagnostic Center**
- **Center Code**

**Part A: Patient Information**

- **Pt. Identification No.**
- **Date Registered**
- **Sex**
- **Age**
- **Country of Origin**
- **Age Group**
- **Remarks**

**First Entered: 11/04/2003**
**Last modified: 01/04/2003**
Data handling & transfer (4)

• Special software being developed
Data validation & checking (1)

- Data entry starts soon after launching the survey
- Tabulation of data every 2-3 months to detect problems in enrolment, lab samples and results of DST
- QA of smear and DST
- Double data entry and cleaning routines
Data validation & checking (2)

- Comparison of enrolment by diagnostic centres with expected notification of new smear positive TB cases
- Comparison of database contents with laboratory registers of diagnosed smear positive cases
- Check variables for completeness
- Final description & analysis to be done by epidemiologist
Description of results (1)

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Description of results (2)

### MDR-TB (Resistant to both H and R)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–4</td>
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<tr>
<td>5–14</td>
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</tr>
<tr>
<td>15–24</td>
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<td>25–34</td>
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<td>35–44</td>
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<td>45–54</td>
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<td>55–64</td>
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<tr>
<td>65+</td>
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<td>Unknown</td>
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<tr>
<td><strong>Total</strong></td>
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<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
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<tr>
<td>Sex unknown</td>
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<tr>
<td><strong>Total</strong></td>
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</tbody>
</table>

### Not MDR-TB (Not resistant to both H and R)

<table>
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<th>Age group</th>
<th>Total</th>
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<tbody>
<tr>
<td>0–4</td>
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<td>5–14</td>
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<td>65+</td>
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<td>Unknown</td>
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<td><strong>Total</strong></td>
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<table>
<thead>
<tr>
<th>Sex</th>
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<tbody>
<tr>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Female</td>
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<tr>
<td>Sex unknown</td>
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<tr>
<td><strong>Total</strong></td>
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</table>

### HIV status

<table>
<thead>
<tr>
<th>HIV status</th>
<th>Total</th>
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<tr>
<td>+</td>
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<tr>
<td>–</td>
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<td>Unknown</td>
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<tr>
<td><strong>Total</strong></td>
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<table>
<thead>
<tr>
<th>TB category</th>
<th>HIV status</th>
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<tbody>
<tr>
<td>MDR-TB (Resistant to both H and R)</td>
<td></td>
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<tr>
<td>Not MDR-TB (Not resistant to both H and R)</td>
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<tr>
<td><strong>Total</strong></td>
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pp 60-61
Activities

• Planning & Budgeting
• Updating tools in DRS protocol
• Training
• Piloting
• Supervision during survey
Planning & Budget (1)

- Appoint data manager in Survey coordination team, responsible for all aspects of data collection, validation, entry, storage and transmission
- SOP on data management
- Different materials (stationery) and services (supervision, training, piloting) for data management included in the budget
- Source of funding secured
Planning & Budget (2)

**Detailed budget** drawn up ahead of start (~ 100,000-150,000 US$)

- Human resources
- Laboratory consumables at NRL and diagnostic centres
- Equipment (safety cabinets, computer, etc)
- Trainings
- Supervisory visits of the coordination team to the diagnostic centres
- Domestic and international transport of specimens
- SRL costs- rechecking, proficiency testing, assessment and training mission
- Other administrative (communications, etc) and general consumables (stationary, printing, etc)

[www.who.int/tb/dots/planning_budgeting_tool](www.who.int/tb/dots/planning_budgeting_tool)
Training (1)

Focusing on:

- Enrolment of study subjects
- Eliciting previous anti-TB treatment
- Use of the Clinical Information Sheet
- Laboratory techniques
- Registration of laboratory results
- Data analysis

- Plan ahead and include all members involved
- Train laboratory personnel in peripheral and centre on registration of specimens and results, preparation and reading of slides, DST techniques, transportation ...etc.
There are different levels and roles

Three operational levels:
- Programme management (logistics, clinical information, supervision)
- Laboratory
- Epidemiology / statistics (sampling, data management and analysis)

Survey coordination team:
- National programme manager / P. investigator
- Manager of the central reference laboratory
- Epidemiologist
- Statistician
- Database manager
Routine DR surveillance
Status of routine surveillance, 2009

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

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Routine DR surveillance data (1)

- A surveillance system based on routine DST of all TB cases
- Diagnostic testing
- Could start by targeting previously treated and other risk categories
Routine DR surveillance data (2)

Laboratory Register for culture and DST (p1/3)

<table>
<thead>
<tr>
<th>Date specimen received</th>
<th>Laboratory serial number</th>
<th>Type of specimen received</th>
<th>Referring health facility</th>
<th>Patient issue</th>
<th>Patient address if new</th>
<th>Sex M/F</th>
<th>Registration group</th>
<th>Date specimen collected</th>
<th>Date specimen inoculated</th>
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Routine DR surveillance data (3)

Minimal MDR indicators

<table>
<thead>
<tr>
<th>Risk category (list as many as exist)</th>
<th>Number of TB cases</th>
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<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>With results for H &amp; R</td>
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<tr>
<td></td>
<td>Resistant to both H &amp; R (MDR)</td>
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<tr>
<td></td>
<td>With MDR and tested for FQN &amp; 2nd line inj.</td>
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<tr>
<td>Risk category 1 (specify)</td>
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<td>Risk category 2 (specify) ...</td>
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<td>...</td>
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<td>Total</td>
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<table>
<thead>
<tr>
<th>No. of MDR-TB cases with information on interval</th>
<th>Interval between suspicion and DST results (days)</th>
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<tr>
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<td>Mean</td>
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Routine surveillance data (4)
Each year, each lab sends aggregated report on ...

- Patient groups tested for DST
- Geographic coverage for DST
- QA for H & R
- Range of FLD and SLD tested
- DST methodology

- In each patient group number of cases identified with
  - results for H & R DST known (stratified by HIV status)
  - MDR
  - MDR with DST for FQN & 2\textsuperscript{nd} line inj. known
  - XDR