Document flow and data management

Dennis FALZON

TB surveillance and surveys: A training workshop for consultants

Geneva, Switzerland - 26 May 2011
References

Guidelines for surveillance of drug resistance in tuberculosis
FOURTH EDITION

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

WHO/HTM/TB/2009.422

WHO/HTM/TB/2008.402
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
# Data sources & collection (1)

## Sputum testing form

### Guidelines for the programmatic management of drug-resistant tuberculosis

**EMERGENCY UPDATE 2008**

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### Sputum testing form

#### Request for sputum examination (to be completed by treatment centre)

- **Treatment unit:**
- **Date:**
- **Patient name:**
- **Age:**
- **Date of birth:**
- **Sex (mark one):** M / F
- **Address (in full):**

#### Reason for examination (mark one):
- ✗ diagnosis
- ✗ follow-up examination
- ✗ test request (mark any that are needed):
- ✗ smear
- ✗ culture
- ✗ drug-susceptibility testing

If DST, specify registration group:

**Signature of person requesting examination:**

#### Smear results

<table>
<thead>
<tr>
<th>No. AFB</th>
<th>Result (mark one)</th>
<th>Reg.</th>
<th>Date collected</th>
<th>Specimen</th>
<th>Laboratory specimen no.</th>
<th>Appearance*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-9</td>
<td>AFB per 100 HPF</td>
<td>+</td>
<td>2</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>10-99 AFB per 100 HPF</td>
<td>++</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100+</td>
<td>AFB per 100 HPF</td>
<td>+++</td>
<td></td>
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</tr>
</tbody>
</table>

*Visual appearance of sputum (blood-stained, mucopurulent, sputum)

**Date:**

**Examined by (signature):**

#### Culture results

<table>
<thead>
<tr>
<th>Date collected</th>
<th>Specimen</th>
<th>Laboratory specimen no.</th>
<th>Reg.</th>
<th>Result (mark one)</th>
<th>Contaminated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td></td>
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</tr>
</tbody>
</table>

**Date:**

**Examined by (signature):**

#### DST results

<table>
<thead>
<tr>
<th>Date tested</th>
<th>Laboratory specimen no.</th>
<th>Reg.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

**Date:**

**Examined by (signature):**

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**Tuberculosis surveillance and surveys: data management**

Training workshop for consultants – 26 May 2011

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**p 227**
Data sources & collection (2)
Data on patient details and history

### ANNEX 9

#### Example of a clinical information form

- **Diagnosis Centre:**
- **Diagnosis Centre Code:**

#### A. IDENTIFICATION OF THE PATIENT

- **Name:**
- **Patient identification number:**
- **Date registered:**
- **Sex:** Male / Female
- **Age:**
- **Date of sputum collection:**
- **Country of origin:**
- **Country-specific data (to be decided by the HIV-status):**
- **History of drug abuse:**
- **Other risk factors (alcohol abuse, diabetes):**

#### B. HISTORY GIVEN BY THE PATIENT

- **B1. Previously treated for TB:**
- **B2. Standardized history**
  - 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 centre, have you identified that the patient has been registered for tuberculosis treatment before?**
- **Previous TB registration number:**

#### D. FINAL DECISION

- **D1. Patient has been previously treated for TB for more than a month:**
- **D2. If yes, what was the outcome of previous treatment?**
  - Cured/treatment completed
  - Failed new patient regimen using first-line drugs only
  - Failed retreatment regimen using first-line drugs only
  - Failed regimen including second-line drugs
  - Defaulted
  - 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 (e.g., 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

Surveillance of Drug Resistance in Tuberculosis

Form 1: Intake, Interview and Shipment

Country Code
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)

<table>
<thead>
<tr>
<th>MDR-TB (Resistant to both H and R)</th>
<th>Age group</th>
<th>0–4</th>
<th>5–14</th>
<th>15–24</th>
<th>25–34</th>
<th>35–44</th>
<th>45–54</th>
<th>55–64</th>
<th>65+</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
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<td>Female</td>
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<td>Sex unknown</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Not MDR-TB (Not resistant to both H and R)</th>
<th>Age group</th>
<th>0–4</th>
<th>5–14</th>
<th>15–24</th>
<th>25–34</th>
<th>35–44</th>
<th>45–54</th>
<th>55–64</th>
<th>65+</th>
<th>Unknown</th>
<th>Total</th>
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<tr>
<td>Male</td>
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<td>Sex unknown</td>
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<thead>
<tr>
<th>HIV status</th>
<th>+</th>
<th>–</th>
<th>Unknown</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR-TB</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Not MDR-TB</td>
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<tr>
<td>Total</td>
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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](http://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 name</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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<tbody>
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</tbody>
</table>

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

World Health Organization

THE STOP TB DEPARTMENT
## 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>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>With results for H &amp; R</td>
<td>Resistant to both H &amp; R (MDR)</td>
<td>With MDR and tested for FQN &amp; 2(^{nd}) line inj.</td>
</tr>
<tr>
<td>Risk category 1 (specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk category 2 (specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of MDR-TB cases with information on interval</th>
<th>Interval between suspicion and DST results (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
</tbody>
</table>

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*Routine DR surveillance and surveys: data management*
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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