An overview of major alternatives to study design of inventory studies

Protocol development workshop for TB inventory studies
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Quantifying gaps in surveillance systems

TB incidence

Under-diagnosed, limited health coverage

Under-reported from non-NTP sector

TB case notifications known to the NTP

Gap
The general idea

- Cases detected by health providers recorded
  - **NTP sector** (e.g. BMU's)
  - **Non-NTP sector**
    - General hospitals
    - Private doctors
    - Health insurance
    - Paediatricians
    - ...

- Match cases in non-NTP list with cases in NTP list
Definition of important terms

Under-reporting: A proportion (that can also be expressed as a percentage) calculated as the number of cases diagnosed and not reported to the national TB surveillance system (often managed by an NTP) divided by the total number of diagnosed cases (the sum of reported and unreported cases).

Health-care providers: Any health-care facility, public or private, including dispensaries, private practitioners, paediatricians, small private clinics, hospitals and laboratories, where TB patients may be diagnosed.

NTP and non-NTP providers: A distinction is made between (i) providers operating directly under the NTP or similar authority responsible for national TB surveillance and (ii) other providers that may be in the private or public sector, e.g. public hospitals that are not linked formally to the NTP (see Chapter 3). These two groups are referred to as NTP and non-NTP providers respectively throughout the chapter.
Objectives of inventory studies

1. To quantify the level of TB under-reporting:
   a) Either with a given precision
      • e.g. 15% 95%CI (10%-20%)
   b) Or that it is of a minimal level
      • e.g. less than 15%

2. To estimate TB incidence using capture-recapture methods
Requirements for inventory studies

1. Electronic, case-based database for TB cases reported to the NTP (available retrospective or prospective)
2. Available identifying information for record linkage (either deterministic – unique ID or probabilistic – when based on a set of variables)
3. Standard TB case definition to be used across all health-care providers
4. Mapping of all health-care providers that diagnose TB
# An overview of study designs

## Retrospective

- **Study design I.** Measure under-reporting with given precision
- **Study design II.** Measure under-reporting and estimate incidence
- **Study design IV.** Measure under-reporting as being of a minimal level

## Prospective

- **Study design III.** Measure under-reporting and estimate incidence using existing electronic records
Study design I (prospective)

Measures the level of under-reporting with a given precision

- Estimation of the sample size (= number of TB cases) required for a chosen precision of under-reporting
- Definition of well-defined geographical areas (e.g. BMU's)
- Random sampling of a certain number of geographical areas
- Mapping of all health-care providers that diagnose TB in sampled areas
- Prospective data collection during a specified time period until sample size is reached
- Record-linkage of case-based study with NTP database (two databases required)
Study design II (prospective)

*Measures the level of under-reporting & incidence (with capture-recapture analysis)*

- Definition of self-contained geographical areas (e.g. provinces)
- Random sampling of a certain number of geographical areas (recommendation is to sample at least 50% of the country)
- Definition of the three (or more) categories of health-care providers required for this design
- Mapping of *all* health-care providers that diagnose TB in sampled areas
- Prospective data collection of *all TB patients diagnosed* during a specified time period
- Record-linkage of study with NTP databases (*at least three are required*)
Study design III (retrospective)

Measures the level of under-reporting & incidence (with capture-recapture analysis)

- Case-based, national electronic NTP database
- Other case-based, national electronic databases (e.g. health insurance, laboratory)
- No sampling required
- Standard definition of TB case to be used in all databases
- Record-linkage between NTP and other databases for a specified period of time in the past
Study design IV (prospective)

Measures the level of under-reporting at a minimal level (based on LQAS sampling)

- Estimation of the sample size (= number of health-care providers) required, including choice of minimal level and decision interval \( (d) \)
- Mapping of all health-care providers that diagnose TB in the country
- Random sampling of required health-care providers
- Prospective data collection during a specified time period until sample size is reached
- Classification of each health-care provider as "acceptable" or "unacceptable" based on their level of under-reporting
- If number of unacceptable health-care providers is less than the pre-defined "decision interval" then under-reporting in the country is less than the minimal level
...and another study design: measuring under-reporting from prevalence surveys

- **Under-reporting** $R$ from 2007 prevalence survey [1]
  - All those reporting to have been on treatment identified from prevalence survey
  - Record linkage with NTP database/records
  - $R$ uncertainty range (7.1% - 20.3%)

1. Nguyen B Hoa et al. IED 2011;17:502-4
## Selected recent studies of incidence & under-reporting

<table>
<thead>
<tr>
<th>Capture-recapture</th>
<th>NO capture-recapture</th>
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</thead>
<tbody>
<tr>
<td>Pakistan</td>
<td>USA (2 States)</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>South Korea</td>
</tr>
<tr>
<td>UK</td>
<td>Taiwan</td>
</tr>
<tr>
<td>Egypt</td>
<td>India (study design not recommended in WHO guidelines)</td>
</tr>
<tr>
<td>Syria</td>
<td>Vietnam (nested in the prevalence survey)</td>
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<tr>
<td>Yemen</td>
<td>Indonesia (?)</td>
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<tr>
<td>Iraq</td>
<td></td>
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Choosing the right design for your country
(Day 1, group work)

• Is there evidence (including anecdotal) that some detected cases are not reported?

• How large is the private sector, is it growing, what are the mechanisms in place to verify that TB surveillance performs well in the private sector, is reporting mandatory?

• What other sectors may not report all cases, including public?

• Is mapping of ALL health-care providers that diagnose TB available? To what extent are PPM activities implemented?

• What are the different types of facilities (possible strata) that diagnose TB to target, including those diagnosing children?

• What are the available databases of TB cases in your country?
Key implementation decisions
(Day 2, group work)

• Investigators/implementing agency
• Timelines
• Technical assistance
• A very draft budget (?)