Assessment of the fraction of cases being missed by routine TB notification data, based on the "Onion" model

Objective
- To provide an expert opinion of the number of cases that are being missed in each layer of the onion model and of the fraction of TB cases accounted for in TB notification data in your country
- To enumerate possible reasons why TB cases are being missed in each layer of the onion model in your country
- To discuss possible methods to assess the extent of TB cases missed in each layer of the onion model, and to increase the fraction of TB cases accounted for in TB notification data

Background
Analysis of available TB notification data is an essential component of any assessment of TB incidence and trends in TB incidence. However, on its own it is not sufficient to estimate TB incidence in absolute terms, because it will not identify how many TB cases exist but are not accounted for in TB notification data.

A framework that can be used to understand where and why incident TB cases might not be accounted for in TB notification data, to investigate and quantify the proportion of incident TB cases that are captured in TB notification data, and to identify the kind of programmatic or health system interventions that might be required to increase the fraction of incident TB cases being recorded in TB notification data, is shown in Figure 1. This framework was first presented to the international TB community in 2002, and has been termed the "onion" model. In the onion model, only TB cases in the first inner ring are found in TB notification data. The relative size of rings 2 to 6 determines the proportion of TB incident cases being accounted for in TB notification data. The major reasons why cases are missed from official notification data include laboratory errors, lack of notification of cases by public and private providers, failure of cases accessing health services to be identified as TB suspects and lack of access to health services.

Although conceptually simple, quantification of the fraction of TB cases that are missing from TB notification data (Rings 2 to 6) is challenging. For example, although the number of TB cases that are left undiagnosed (Rings 4 to 6) can only be estimated by capture-recapture studies, there might be information in the countries about the proportion of the population that have no access to health care, or even more specifically to health care facilities able to provide TB diagnoses. There might also be information at national and sub-national level about the distribution of health care providers (private, public NTP, public non-NTP) and about the proportion of private and public non-NTP providers that routinely notify their TB cases (Ring 3).

Table 1 shows examples of studies in which the analysis of the notification data per se (Ring 1) was used to provide a preliminary assessment of its completeness and reliability, and of studies in which TB incidence was estimated following in-depth analysis of TB and HIV notification data and programmatic data. Examples of operational research (such as capture-recapture studies) as well as supporting evidence (such as the knowledge and practices of health-care staff related to definition of TB suspects, the extent to which regulations about notification of cases are observed and population access to health services) that could be used to assess how many cases exist in rings 2 to 6 are also provided in Table 1.
## Exercise

1) Please complete the table below by making a list of the possible reasons why TB cases are being missed from the routine TB notification data in your country, and by providing an estimate for the proportion of TB cases that might be missed in each layer of the onion model.

<table>
<thead>
<tr>
<th>Onion layers</th>
<th>Reasons for missing cases</th>
<th>% of missing cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Patients that have no access to health care</td>
<td></td>
<td></td>
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<tr>
<td>5. Access to health care facilities, but do not present themselves</td>
<td></td>
<td></td>
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<tr>
<td>4. Presenting to health care facilities, but not diagnosed</td>
<td></td>
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<tr>
<td>3. Diagnosed by public non-NTP or private providers, but not notified</td>
<td></td>
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<tr>
<td>2. Diagnosed by NTP or collaborating providers, but not notified</td>
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<tr>
<td>Participants estimates of CDR (sum of missed cases: layers 2 to 6)</td>
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<td></td>
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<tr>
<td>WHO estimates of CDR (all cases - 2007)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference (participants - WHO estimates)</td>
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</tbody>
</table>

* Global TB report 2009

2) Please make a list of the available sources of data and the possible methods that could be used to assess the extent of TB cases missed in each layer of the onion model, and to increase the fraction of TB cases accounted for in TB notification data.
Figure 1. The “onion” model: a framework for assessing the fraction of TB cases accounted for in TB notification data, and how this fraction can be increased

1. Cases recorded in TB notification data

2. Cases diagnosed by the NTP or by providers collaborating with the NTP, but not recorded/reported

3. Cases diagnosed by public or private providers, but not reported

4. Cases presenting to health facilities, but not diagnosed

5. Cases with access to health services that do not go to health facilities

6. Cases with no access to health care

HSS to minimize access barriers

Communication and social mobilization; contact tracing, active case-finding

Improve diagnostic quality or tools

Supervision and investment in recording and reporting systems

Health system strengthening (HSS) Practical Approach to Lung Health (PAL)

Public-Public and Public-Private Mix

Public-Private Mix

HSS to minimize access barriers

Communication and social mobilization; contact tracing, active case-finding

Improve diagnostic quality or tools

Supervision and investment in recording and reporting systems

Health system strengthening (HSS) Practical Approach to Lung Health (PAL)

Public-Public and Public-Private Mix
Table 1: Examples of data and methods that could be used to assess how many TB cases are missing from TB notification data

<table>
<thead>
<tr>
<th>Possible reason for cases to be missing from TB notification data</th>
<th>Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data</th>
<th>Examples of published studies</th>
<th>Examples of analysis and supporting evidence that could be used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases recorded in TB notification data (Ring 1)</td>
<td>Analyse of available TB notification data and trends could provide indirect evidence of its completeness, timeliness and validity. Analysis of trends in notification data could be used to assess the extent to which they reflect trends in rates of TB incidence (which may be influenced by HIV prevalence, for example) and the extent to which they reflect changes in other factors (such as programmatic efforts to find and treat more cases).</td>
<td>Suarez et al (Peru)(^1), Dye et al (Morocco)(^2), Mansour et al (Kenya)(^3), Vree et al (Viet Nam)(^4)</td>
<td>The number of notification data reports expected to arrive from reporting health care units or lower level administrative levels can be compared with the number of reports actually received for a given period. Assessment of whether there is duplication or misclassification of data, exploration of variability geographically and over time (to check for internal consistency). HIV prevalence in the general population. HIV prevalence among TB cases. Changes in diagnostic efforts over time: number of mycobacterial labs, number of trained clinical and lab staff, number of sputum smear slides performed per TB suspects, …</td>
</tr>
<tr>
<td>Cases diagnosed by NTP but not recorded in notification data (Ring 2)</td>
<td>Operational research can be used to study the number of cases that are missing from TB notification data. These studies typically involve prospectively collecting data from places where TB cases may be (i) diagnosed but not notified (ii) seeking care but not being diagnosed and (iii) experiencing symptoms but not seeking care. To assess the number of cases whose diagnosis is being missed at health care facilities and to assess the number of cases that are being correctly diagnosed and treated but not notified, a common approach is to introduce study registers at health facilities (including laboratories), in which TB suspects and TB cases are listed. These lists can then be compared with lists of notified cases. If 3 or more lists can be generated, it may be possible to use capture-recapture methods(^17) to estimate total incident cases (i.e. to estimate not only cases that are missing from notifications, but also to estimate the number of cases that are missing from all lists i.e. cases that are not in contact with health facilities at all).</td>
<td>Botha E et al (S. Africa)(^5)</td>
<td>Drugs sales in the private sector. Health expenditures in private/NGO sectors, out-of-pocket expenditures. Number of health facilities/private practitioners and proportion that are not collaborating with the NTP. Prescriptions in pharmacies. Regulations regarding prescribing and availability of drugs and their application in practice. Knowledge and use of the international standards for TB care.</td>
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<td>Cases diagnosed by non-NTP providers that are not notified (Ring 3)</td>
<td></td>
<td>Migliorisi et al (Italy), Maung et al, (Myanmar), Lonroth et al (Viet Nam), Ambe et al (India), Arora et al (India), Dewan et al (India)(^6)(^\text{11})</td>
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<tr>
<td>Cases presenting to health facilities that are not diagnosed (Ring 4)</td>
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<td>Cases that have access to health services but do not seek care (Ring 5)</td>
<td></td>
<td>Gasana et al (Rwanda), Espinal et al (Dominican Republic), Lee et al (Hong Kong)(^14)(^16)</td>
<td>Data on population knowledge, attitudes and practice (KAP) from TB-related KAP surveys.</td>
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<tr>
<td>Cases that do not have access to health services (Ring 6)</td>
<td></td>
<td>Van Hest et al (the Netherlands), Baussano et al, Crofts et al (UK)(^17)(^20)</td>
<td>Population access to health services e.g. % population living within a certain distance of a health facility. Number of laboratories doing smear microscopy per 100 000 population. Number of nurses and doctors per 100 000 population compared with international norms of what is required. Data from major household/demographic surveys. Vital registration data showing what proportion of TB deaths never accessed TB diagnosis and treatment.</td>
</tr>
<tr>
<td>All reasons listed above</td>
<td></td>
<td>Prevalence survey from Myanmar</td>
<td>Prevalence of TB disease survey in which questions about health-seeking behaviour and contact with health services are asked.</td>
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</tbody>
</table>
References


