

Assessment of Surveillance data
WORKBOOK

Country _____

Persons filling in this workbook

Name	
Functional title (e.g.)	
Highest educational degree	
Number of years working in TB control programme	
Email address	

Instruction to fill in the exercises

Most of the questions in this workbook are formulated in a structured format with multiple options. Some of the options represent broad categories including various possibilities.

After completing this workbook, you will be asked to prepare a presentation summarizing your main findings. In your presentation, instead of using the broad options provided here, please provide specific answers/descriptions which correspond to the situation in your country.

- 1. 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 all **estimated new** 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 incidence¹ 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**, **failure of cases to access health services**, 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 -e.g. penitentiary system-), 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.

¹ In contrast to the case notification rate, TB incidence refers to the estimated "true" number of new cases that occur annually, regardless of whether or not they are notified

Exercise

1.1 Please complete the table below by providing an estimate for the percentage of TB cases that might be missed in each layer of the onion model for the years indicated.

Onion layers	% of missing cases out of all estimated new and relapse (pulmonary and extrapulmonary) TB cases (0% to 100%)								
	1997			2003			2008		
	Lowest possible value	Most likely value	Highest possible value	Lowest possible value	Most likely value	Highest possible value	Lowest possible value	Most likely value	Highest possible value
1.1.1. Layer 6: Patients that have no access to health care									
1.1.2. Layer 5: Access to health care facilities, but do not present themselves									
1.1.3. Layer 4: Presenting to health care facilities, but not diagnosed									
1.1.4. Layer 3: Diagnosed by public non-NTP or private providers, but not notified									
1.1.5. Layer 2: Diagnosed by NTP or collaborating providers, but not notified									
1.1.6. Sum of % of missing cases: layers 2 to 6									
1.1.7. Participants estimates of case detection rate (CDR) (= 100 minus the sum of % of missing cases: layers 2 to 6)									
1.1.8. WHO estimates of CDR (all cases - 2007)*									
1.1.9. Difference (participants - WHO estimates)									

* Global TB report 2009

1.2 What sources of data or other evidences did you use to complete the table in exercise 1?

1.3 Sources of data that could be used to assess the extent of TB cases missed in each layer of the onion model. Select if the data source is available in your country. You can select more than one.

- | | |
|--|---|
| <input type="checkbox"/> Mortality (vital registration) | <input type="checkbox"/> Health insurance registries |
| <input type="checkbox"/> Laboratory registries | <input type="checkbox"/> Demographic health surveys with TB component |
| <input type="checkbox"/> Separate NTP list (for example, a paper based registry inside NTP primary health care facilities) | <input type="checkbox"/> Other (please, specify) |
| <input type="checkbox"/> Hospital registries | <input type="checkbox"/> Other (please, specify) |
| <input type="checkbox"/> HIV notification data with information on TB diagnoses | <input type="checkbox"/> |
| <input type="checkbox"/> Pharmacy registries (distribution of 1 st line TB drugs) | <input type="checkbox"/> |

1.4 Which of the following types of studies would be more relevant in your country to help assess the number of TB case missing in each layer of the onion model? Please consider the layers of the onion model that you thought contributed more to the proportion of missing TB cases. You can select more than one.

- | | |
|--|---|
| <input type="checkbox"/> Inventory studies (i.e. cross-checking various registers) using existing sources of data (layers 2 and 3) | <input type="checkbox"/> Yield of patients found while contact tracing (layers 4 and 5) |
| <input type="checkbox"/> Inventory studies using newly collected sources (e.g. introducing a TB registry in a private hospital) of data (layers 2 and 3) | <input type="checkbox"/> Yield of patients found because of improvements in diagnostic quality or tools (layer 4) |
| <input type="checkbox"/> Studies of diagnostic procedures performed on TB suspects attending samples of health care facilities (layer 4) | <input type="checkbox"/> Yield of patients found as a result of PPM (layer 3) |
| <input type="checkbox"/> Yield of patients found as a result of advocacy, communication and social mobilization activities (layers 2 and 3) | <input type="checkbox"/> TB disease prevalence studies (all layers) |
| <input type="checkbox"/> Yield of patients found following training staff on Practical Approach to Lung Health (layers 4 and 5) | <input type="checkbox"/> Capture recapture studies (all layers) |
| <input type="checkbox"/> Yield of patients found while screening high risk populations (layers 4 and 5) | <input type="checkbox"/> Studies of post-mortem registration of TB (layers 4, 5 and 6?) |
| | <input type="checkbox"/> Other, please specify |

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.

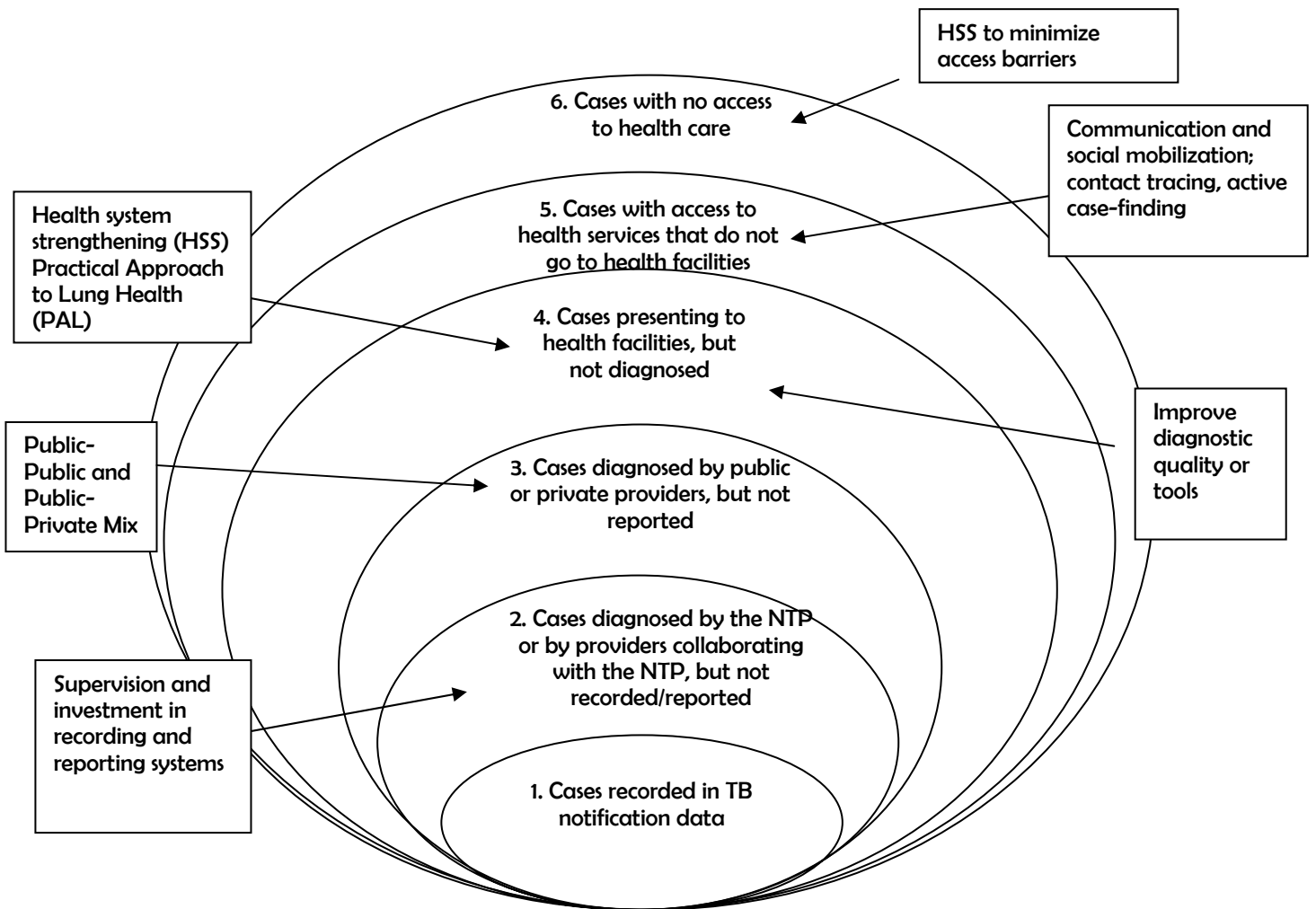


Table 1. Examples of data and methods that could be used to assess how many TB cases are missing from TB notification data

Distribution of cases according to the onion model	Examples of methods that could be used to directly measure how many TB cases are missing from TB notification data	Examples of published studies	Examples of analysis and supporting evidence that could be used
Cases recorded in TB notification data (Ring 1)	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).	Suarez et al (Peru) ¹ Dye et al (Morocco) ² Vree et al (Viet Nam) ³ Mansour et al (Kenya) ⁴	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) Analysis of changes in TB notifications due to changes in HIV prevalence in the general population Analysis of 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, ...
Cases diagnosed by NTP but not recorded in notification data (Ring 2)	Operational research can be used to study the number of cases that are missing from TB notification data. These studies typically involve prospectively	Botha E et al (S. Africa) ⁵	
Cases diagnosed by non-NTP providers that are not notified (Ring 3)	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	Migliori et al (Italy), Maung et al, (Myanmar), Lonroth et al (Viet Nam), Ambe et al (India), Arora et al (India), Dewan et al (India) ⁶⁻¹³	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
Cases presenting to health facilities that are not diagnosed (Ring 4)	lists of notified cases. If 3 or more lists can be generated, it may be possible to use capture-recapture methods ¹⁷⁻²⁰ to estimate total incident cases		Knowledge/attitudes/practices of health staff Suspect management practices Slides examined per TB suspect % laboratories with satisfactory performance (based on EQA)
Cases that have access to health services but do not seek care (Ring 5)	(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).	Gasana et al (Rwanda), Espinal et al (Dominican Republic), Lee et al (Hong Kong) ¹⁴⁻¹⁶	Data on population knowledge, attitudes and practice (KAP) from TB-related KAP surveys
Cases that do not have access to health services (Ring 6)	Since it is not possible to study all health care facilities, a critical issue in study design is the sampling of facilities to make sure that results are representative of the population as a whole. Convincing non-NTP providers to participate in such studies may also be challenging.	Van Hest et al (the Netherlands), Baussano et al, Crofts et al (UK) ¹⁷⁻²⁰	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
All reasons listed above		Prevalence survey from Myanmar	Prevalence of TB disease survey in which questions about health-seeking behaviour and contact with health services are asked.

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2. Are data reliable and complete?

Main questions

2.1 Are TB data complete?

Do the nationally aggregated TB notifications include all the data/reports from the reporting units that were expected to report to NTP?

Were any notification reports missing from the lowest admin levels at any time ?

2.2 Are TB data reliable?

Are reported TB cases actually TB cases?

Are TB cases classified correctly? e.g. new cases are not classified as re-treatment or vice versa. Or smear unknown cases are not classified as smear-negative.

Separate questions

2.3 Do you have data on TB-HIV co-morbidity cases?

2.4 Do you have data on MDR-TB cases?

2.1 Are TB data complete?

Do the nationally aggregated TB notifications include all reports from the reporting units that were expected to report to NTP? Were any notifications reports missing from the lowest admin levels at any time?

Specific questions:

Comparison of reports received versus expected	
2.1.1. Do you have a system to monitor the completeness of reporting from admin 1 to national level? Circle one as appropriate. Admin 1: states, provinces See graph 1	Yes / No / Don't know
2.1.2. If yes, since when? Select as appropriate.	Year _____
2.1.3. Do you have a system to monitor the completeness of reporting from admin 2 to admin 1 level? Circle one as appropriate. Admin 2: districts, municipalities	Yes / No / Don't know
2.1.4. If yes, since when? Select as appropriate.	Year _____
2.1.5. Do you have a system to monitor the completeness of reporting from admin 3 to admin 2 level? Circle one as appropriate. Admin 3: basic management units	Yes / No / Don't know
2.1.6. If yes, since when)? Select as appropriate.	Year _____
Identification of unusual fluctuations	
Trend in notification of new TB cases See graphs 2-17	
2.1.7. Were there unusual fluctuations in the time series? e.g. notifications that differ significantly from one year to the next.	Yes / No / Don't know

<p>2.1.8. If yes, can you list the reasons for these unusual fluctuations in time? You can select more than one.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Sudden improvements or disruptions in the recording and reporting system (for example: absent, delayed or decreased notification reports from certain areas, data cleaning to exclude duplicates and misclassifications, etc.) <input type="checkbox"/> Inclusion of data from new reporting units (e.g. inclusion of data from the penitentiary sector, military hospitals) <input type="checkbox"/> Sudden changes in TB diagnostic capacity (for example: new lab facilities, training of clinical and lab staff, doctors on strike, patients avoiding diagnosis because of rumours of drug shortages, etc.) <input type="checkbox"/> Changes in notified case definitions (for example: including smear negative or extrapulmonary cases in notifications, eliminating misclassifications of TB infection in children as TB cases, etc.) <input type="checkbox"/> Don't know <input type="checkbox"/> Other. Please specify.
<p>2.1.9. Were the fluctuations driven by a certain case type?</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Yes, it was mainly driven by fluctuations in the number of SS+ pulmonary TB cases <input type="checkbox"/> Yes, it was mainly driven by fluctuations in the number of SS- pulmonary TB cases <input type="checkbox"/> Yes, it was mainly driven by fluctuations in the number of extra-pulmonary TB cases <input type="checkbox"/> No, I don't believe the fluctuations were driven by a certain case type. <input type="checkbox"/> Don't know <input type="checkbox"/> Other. Please specify.
<p>Variation in notification rates of new TB cases across admin1 See graph: 39–57</p>	
<p>2.1.10. Is there a lot of variation between notification rates of new (all and by smear) TB cases across admin1?</p>	<p style="text-align: center;">Yes / No / Don't know</p>
<p>2.1.11. If yes, what are the main reasons to explain this variation? You can select more than one.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> True differences in TB epidemic sub-nationally (TB determinants such as HIV prevalence, urbanization and socio-economic situation etc.) <input type="checkbox"/> Differences in TB diagnostic capacity (staff or laboratory capacity, access to health care, etc.) <input type="checkbox"/> Differences in the recording and reporting system (structure, coverage or performance of the notification system) <input type="checkbox"/> Don't know <input type="checkbox"/> Other. Please specify.
<p>2.1.12. Were the fluctuations found for the national data driven by certain admin 1 areas?</p>	<p style="text-align: center;">Yes / No / Not applicable (e.g. sub-national data not provided)</p> <p>Comments:</p>

Comparison notification; workshop template versus reported in WHO TB database	
<p>2.1.13. Was there a difference between the number of notifications reported in the workshop template and those reported in the WHO Global TB database?</p> <p>See graph 18</p>	<p>Yes / No</p>
<p>2.1.14. If yes, can you list the reasons for this difference? You can select more than one.</p>	<p><input type="checkbox"/> Case definition understood as different in each database</p> <p><input type="checkbox"/> Inclusion of reports that arrived late</p> <p><input type="checkbox"/> Don't know</p> <p><input type="checkbox"/> Other. Please specify.</p>
Comparison national and sub-national notification data in the workshop template	
<p>2.1.15. Was there a difference between the national aggregated data with the sub-national data reported in the workshop template?</p> <p>See graph 19</p>	<p>Yes / No / Not applicable (e.g. sub-national data not provided)</p>
<p>2.1.16. If yes, can you explain the reasons for this difference?</p>	<p>Comments:</p>

2.2 Are TB data reliable?

Are reported TB cases actually TB cases? Are cases classified correctly? E.g. new cases are not classified as re-treatment or vice versa.

Specific questions:

National data	
A - Proportion of all TB cases that are new See graph 26 & 27 <i>(Compare with the global and regional averages)</i>	
2.2.1. In the last year, how does the proportion compare with the global and regional average?	Regional: Similar / Higher / Smaller Global: Similar / Higher / Smaller
2.2.2. If the proportion is considerably different from the regional and/or global average, how do you explain this? You can select more than one.	<input type="checkbox"/> Factors that affect the number of retreatment cases, including differences in risk factors, TB control efforts, proportion of drug-resistant TB <input type="checkbox"/> Misclassification problems (i.e. retreatment cases classified as new cases) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
2.2.3. Are there significant variations over time?	Yes / No / Don't know
2.2.4. If yes, how do you explain these variations over time?	<input type="checkbox"/> Variations in the factors that interfere with the number of retreatment cases, including TB control efforts, proportion of drug-resistant TB <input type="checkbox"/> Reduction of misclassification problems (i.e. retreatment cases no longer classified as new cases) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
B - Proportion of new cases that are pulmonary See graphs 21 & 27 <i>(Compare with the global and regional averages)</i>	
2.2.5. In the last year, how does the proportion compare with the global and regional average?	Regional: Similar / Higher / Smaller Global: Similar / Higher / Smaller
2.2.6. If the proportion is higher or smaller than the global average, how do you explain this? You can select more than one.	<input type="checkbox"/> Differences in extra-pulmonary TB diagnostic capacity <input type="checkbox"/> Differences in the age structure of TB cases (higher % of extra-pulmonary TB in children) <input type="checkbox"/> Differences in HIV prevalence (higher % extra-pulmonary TB in HIV-positive cases) <input type="checkbox"/> Differences in notification policy or practice (regulation or lack of knowledge about need to notify EP cases) <input type="checkbox"/> Misclassification problems (i.e. mixed cases are classified as pulmonary or extra-pulmonary) <input type="checkbox"/> Don't know

	<input type="checkbox"/> Other causes - please specify
2.2.7. Are there significant variations over time?	Yes / No / Don't know
2.2.8. If yes, how do you explain these variations over time? You can select more than one.	<input type="checkbox"/> Variations in extra-pulmonary TB diagnostic capacity <input type="checkbox"/> Variations in the age structure of TB cases <input type="checkbox"/> Variations in HIV prevalence <input type="checkbox"/> Variations in notification policy/practice <input type="checkbox"/> Variations in misclassification problems (introduction of measures to correct the misclassification problem) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
C - Proportion of all pulmonary cases that are smear positive <i>See graphs 22 & 27</i> <i>(Compare with the global and regional averages)</i>	
2.2.9. In the last year, how does the proportion compare with the global and regional average?	Regional: Similar / Higher / Smaller Global: Similar / Higher / Smaller
2.2.10. If the proportion is higher or smaller than the global average, how do you explain this? You can select more than one.	<input type="checkbox"/> Differences in capacity to perform smear examination (number of quality assured labs, poor efficiency of labs, referral practices, ...) <input type="checkbox"/> Differences in the age structure of TB cases (lower smear positivity in children) <input type="checkbox"/> Differences in HIV prevalence (lower smear positivity in HIV+ patients) <input type="checkbox"/> Differences in notification policy or practice (regulation or lack of knowledge about need to notify SS- cases) <input type="checkbox"/> Misclassification problems (smear negative / culture positive cases notified as smear positive, because there is no other case category to notify a bacteriologically positive case) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
2.2.11. Are there significant variations over time?	Yes / No / Don't know
2.2.12. If yes, how do you explain these variations over time? You can select more than one.	<input type="checkbox"/> Variations in diagnostic capacity for smear positive cases <input type="checkbox"/> Variations in the age structure of TB cases <input type="checkbox"/> Variations in HIV prevalence <input type="checkbox"/> Variations in notification policy/practice <input type="checkbox"/> Variations in misclassification problems (introduction of measures to correct the misclassification problem) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify

D - Proportion of all re-treatment cases that are 1) relapse, 2) treatment-after-failure, 3) treatment-after-default 4) other re-treatment See graph;23-27	
2.2.13. In the last year, which of the categories contributed most to the total number of retreatment cases?	<input type="checkbox"/> Relapse <input type="checkbox"/> Treatment-after-failure <input type="checkbox"/> Treatment-after-default <input type="checkbox"/> Other re-treatment
2.2.14. Where there significant changes over time in the contribution of each of the categories to the total number of retreatment cases?	Yes / No / Don't know
2.2.15. If yes, how do you explain these changes over time? You can select more than one.	<input type="checkbox"/> Variations in the factors that drive the TB epidemic, including TB control efforts and TB treatment regiments <input type="checkbox"/> Variations in the prevalence of drug-resistant TB <input type="checkbox"/> Variations in notification policy/practice in these categories over time <input type="checkbox"/> Variations in the amount of misclassification between the categories over time <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify

Sub-national data	
A - Proportion of all TB cases that are new <i>See graph 51</i> <i>(Compare with the national average for the latest year)</i>	
2.2.16. In the last year, how do the proportions for each of the admin 1 level areas compare with the national average?	Similar / Considerable variation
2.2.17. If you identified a big variation, how do you explain that?	<input type="checkbox"/> Differences in factors that drive the TB epidemic across admin 1 areas, including risk factors, TB control efforts, proportion of drug-resistant TB <input type="checkbox"/> Misclassification problems across admin 1 areas (i.e. retreatment cases wrongly classified as new cases) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
B - Proportion of new cases that are pulmonary <i>See graph 52</i> <i>(Compare with the national average for the latest year)</i>	
2.2.18. In the last year, how do the proportions for each of the admin 1 level areas compare with the national average?	Similar / Considerable variation
2.2.19. If you identified a big variation, how do you explain that?	<input type="checkbox"/> Differences in extra-pulmonary diagnostic capacity across admin 1 areas <input type="checkbox"/> Differences in the age structure of TB cases across admin 1 areas (higher % of extra-pulmonary TB in children) <input type="checkbox"/> Differences in HIV prevalence across admin 1 areas (higher % extra-pulmonary TB among HIV+ patients) <input type="checkbox"/> Differences in the notification policy or practice across admin 1 areas (regulation or lack of knowledge about need to notify EP cases) <input type="checkbox"/> Differences in misclassification problems across admin 1 areas (i.e. mixed cases classified as pulmonary or extra-pulmonary) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
C - Proportion of all pulmonary cases that are smear positive <i>See graph 53</i> <i>(Compare with the national average for the latest year)</i>	
2.2.20. In the last year, how do the proportions for each of the admin 1 level areas compare with the national average?	Similar / Considerable variation

<p>2.2.21. If you identified a big variation, how do you explain that?</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Differences in capacity to perform smear examination across admin 1 areas (number of quality assured labs, poor efficiency of labs, referral practices, ...) <input type="checkbox"/> Differences in the age structure of TB cases across admin 1 areas (lower smear positivity in children) <input type="checkbox"/> Differences in HIV prevalence across admin 1 areas (lower smear positivity in HIV+ patients) <input type="checkbox"/> Differences in the notification policy or practice across admin 1 areas (regulation or lack of knowledge about need to notify SS- cases) <input type="checkbox"/> Differences in misclassification problems across admin 1 areas (smear negative / culture positive cases notified as smear positive because there is no other field to notify a bacteriologically positive case) <input type="checkbox"/> Don't know <input type="checkbox"/> Other causes - please specify
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2.3 Do you have data on TB-HIV co-morbidity cases?

Specific questions:

TB-HIV				
2.3.1. Is there a national TB-HIV surveillance system?	<input type="checkbox"/> Yes, data on the results of HIV testing of TB patients is collected as part of the main TB surveillance system <input type="checkbox"/> Yes, data on the results of HIV testing of TB patients is collected in a parallel system (e.g. HIV sentinel surveillance system) <input type="checkbox"/> No, there is no system to record results of HIV testing of TB patients <input type="checkbox"/> Don't know			
2.3.2. If yes, since when? Select as appropriate	Since before 1995	1995 to 2000	2000 to 2005	From 2005 onwards
2.3.3. If yes, have there been variations in the proportion of registered TB patients with known HIV+ status over the last 5 years?	<input type="checkbox"/> Yes, and they are mainly due to real changes in the proportion of co-infected patients <input type="checkbox"/> Yes, and they are mainly due to changes in the proportion of TB patients that are tested for HIV <input type="checkbox"/> Yes, and they are mainly due to changes in the recording of this information in the system <input type="checkbox"/> Yes, and they are due to a combination of the above mentioned causes <input type="checkbox"/> No, the proportion has not varied much <input type="checkbox"/> Don't know			
2.3.4. Have you ever done a national survey for the prevalence of HIV positive patients among a representative sample of your registered TB patients?	<input type="checkbox"/> Yes, one survey <input type="checkbox"/> Yes, more than one survey <input type="checkbox"/> No <input type="checkbox"/> Don't know			
2.3.5. What was the result of your last national survey?	Year	% of all new TB cases tested for HIV	Prevalence among new TB cases (%)	

2.4 Do you have data on MDR-TB cases?

Specific questions:

MDR-TB					
2.4.1. Is there a national MDR-TB surveillance system?	<input type="checkbox"/> Yes, data on MDR-TB patients is collected as part of the main TB surveillance system <input type="checkbox"/> Yes, data on MDR-TB patients is collected in a parallel or sentinel system <input type="checkbox"/> No, there is no system to record MDR-TB patients data <input type="checkbox"/> Don't know				
2.4.2. If yes, since when? Select as appropriate	Since before 1995	1995 to 2000	2000 to 2005	From 2005 onwards	
2.4.3. If yes, have there been variations in the proportion of registered TB patients that have MDR-TB over the last 5 years?	<input type="checkbox"/> Yes, and they are mainly due to real changes in the proportion of MDR-TB patients <input type="checkbox"/> Yes, and they are mainly due to changes in the proportion of TB patients that have access to culture and/or drug sensitivity testing <input type="checkbox"/> Yes, and they are mainly due to changes in the recording of this information in the system <input type="checkbox"/> Yes, and they are due to a combination of the above mentioned causes <input type="checkbox"/> No, the proportion has not varied much <input type="checkbox"/> Don't know				
2.4.4. Have you ever done a national survey for the prevalence of MDR-TB patients among a representative sample of your registered TB patients?	<input type="checkbox"/> Yes, one survey <input type="checkbox"/> Yes, more than one survey <input type="checkbox"/> No <input type="checkbox"/> Don't know				
2.4.5. What was the result of your last national survey?	Year	% of new culture-positive cases tested for MDR-TB	Prevalence among new TB cases (%)	% of retreatment culture-positive cases tested for MDR-TB	Prevalence among retreatment cases (%)

3. Do changes in notifications over time reflect changes in TB incidence?

Questions

3.1 Have TB notifications been increasing, decreasing or stable over time?

3.2 Were there any changes in case-finding effort and/or recording and reporting that might have affected notifications over time?

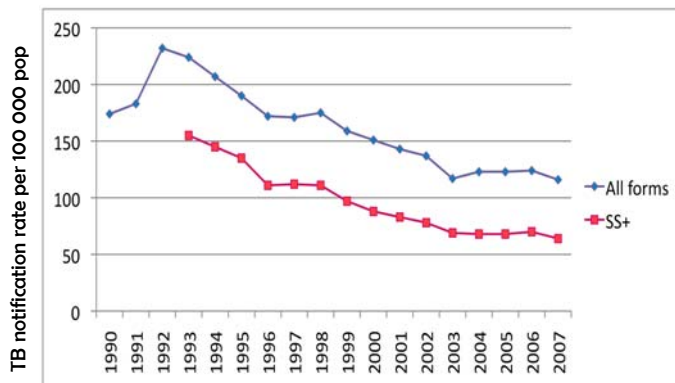
3.3 How have factors that may influence TB incidence changed over time, and have they had an impact on underlying TB incidence?

3.4 Based on the information discussed in questions 3.1 through 3.3, how do you think true underlying incidence has changed over time?

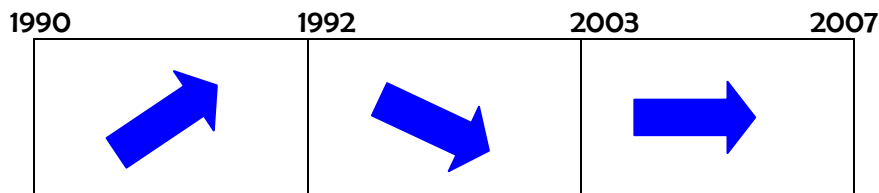
3.1 Have TB notifications been increasing, decreasing or stable over time?

Notifications

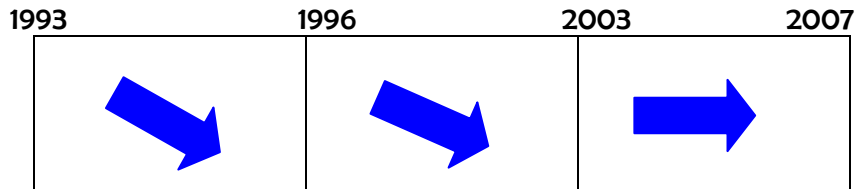
Below is an example of notifications from a country in another region. We have looked at the notifications and how they change over time and indicated the direction and years of the changes in the boxes below.



New all forms notifications



New SS+ notifications



Now do the same using your country's notifications. First look at new pulmonary and new extra-pulmonary notifications. Then, among new pulmonary cases, look at SS+ and SS- notifications. Please note that there may not be much change in direction, in which case the arrows could continue to point in the same direction throughout. You can select different years for SS+ and all forms notifications if they change direction at different times. Don't worry about small single year changes, but focus on general trends over time.

3.1.1. New pulmonary notifications **See graph; 28–30**

Year	(Start)	Year	Year	Year	(End)

3.1.2. New extra-pulmonary notifications **See graph; 28, 29 & 31**

Year	(Start)	Year	Year	Year	(End)

Please discuss the reasons for any differences in trends between pulmonary and extra-pulmonary notifications. These could be changes in the programme, diagnosis or epidemiology.

Now look at new pulmonary cases by smear status. What are the trends in SS+ versus SS- notifications?

3.1.3. New pulmonary SS+ notifications **See graph; 28, 29 & 32**

Year	(Start)	Year	Year	Year	(End)

3.1.4. New pulmonary SS- notifications **See graph; 28, 29 & 33**

Year	(Start)	Year	Year	Year	(End)

Do the notifications trend in the same direction or are SS+ notifications moving in a different direction or pace than SS- notifications? Please describe possible reasons for any divergences.

3.2 Were there any changes in case-finding effort and/or recording and reporting that might have affected notifications over time?

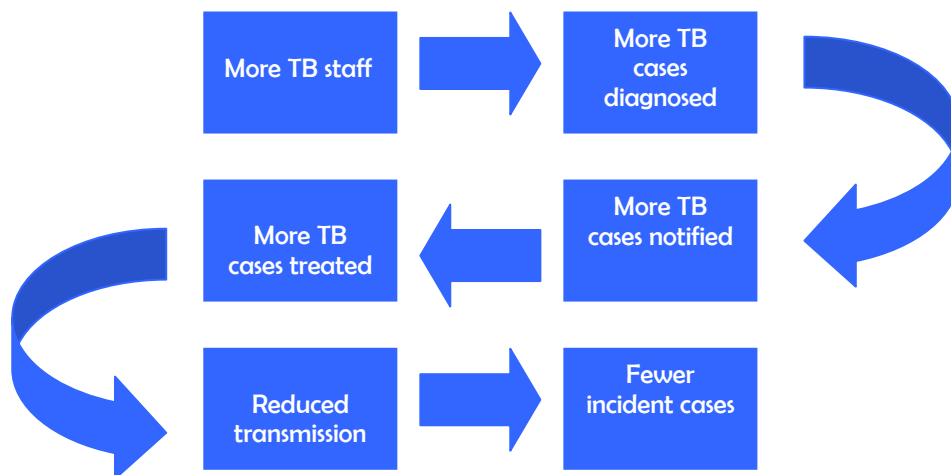
a) Case-finding effort

The following factors are likely to affect **notifications** over time as they have an impact on case detection.

- The number of laboratories doing smear and/or culture
- The number of NTP staff
- Expenditure on TB control
- Suspect ratio (smear-positive cases/TB suspect identified clinically)
- Suspect rate (TB suspect identified clinically/population * 100 000)
- Number of slides per patient to diagnose one TB patient
- Proportion of all pulmonary cases diagnosed through active case finding
- Proportion of population screened for TB through active case finding
- Proportion of all notified cases reported by non-NTP

Although some of these indicators refer to NTP actions that could eventually impact underlying incidence, we believe that *initially* they are more likely to impact the capacity of the NTP to notify TB cases. It may take many years to reduce incidence.

For example:



For each of the above indicators, please describe the impact, if any, you think it has had on notifications considering the time periods reflected in the notifications table on the first page.

Please depict how these factors may have affected notifications in your country in the same way you depicted the changes in notifications in the first exercise.

3.2.1. Number of labs doing smear and/or culture **See graph: 34–35**

Year _____ (Start)	Year _____	Year _____	Year _____ (End)

Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From _____ to _____

Why and how did it impact notifications?

3.2.2. Number of NTP staff **See graph 34**

Year _____ (Start)	Year _____	Year _____	Year _____ (End)

Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From _____ to _____

Why and how did it impact notifications?

3.2.3. Expenditure on TB control

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

3.2.4. Suspect rate **See graph 35**

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

3.2.5. Number of slides per patient to diagnose one TB patient **See graph 35**

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

3.2.6. Proportion of all pulmonary TB cases diagnosed through active case finding **See graph 35**

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

3.2.7. Proportion of population screened through active case finding **See graph 35**

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

3.2.8. Proportion of notified cases reported by non-NTP **See graph 35**

Year ____ (Start) Year ____ Year ____ Year ____ (End)

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Do you think that the indicator has an impact on notifications?

- Yes, increased notifications
- Yes, decreased notifications
- No impact
- Don't know

If yes, during what years? From ____ to ____

Why and how did it impact notifications?

b) Recording and reporting

Changes in recording and reporting systems are another factor that can affect notifications over time, but would not impact true underlying incidence.

3.2.9. Have there been any changes in the recording and reporting system in your country?
Yes/No/Don't know

Check those that apply to you.

3.2.10. Recording and reporting change	If yes, indicate the exact year(s)
<input type="checkbox"/> Expanded coverage of recording & reporting system	
<input type="checkbox"/> Began notifying retreatment cases	
<input type="checkbox"/> Began notifying SS- cases	
<input type="checkbox"/> Began notifying extra-pulmonary cases	
<input type="checkbox"/> Began notifying SS+ cases in children	
<input type="checkbox"/> Began notifying SS-/extra-pulmonary cases in children	
<input type="checkbox"/> Stopped notifying tuberculin positive individuals (including children) as active TB cases	
<input type="checkbox"/> System changed from paper to electronic or electronic to internet-based	
<input type="checkbox"/> Began checking for and correcting duplications and misclassifications	
<input type="checkbox"/> Other (please specify)	
<input type="checkbox"/> Other (please specify)	

3.3 How have factors that may influence TB incidence changed over time, and have they had an impact on underlying TB incidence?

These are some indicators that may affect or be affected by changing the **underlying TB incidence**, and therefore notifications, over time.

- HIV prevalence in the general population - as HIV prevalence increases we would expect to see TB incidence increase
- Gross Domestic Product (GDP) - as GDP increases, we would expect to see TB incidence decrease
- Trend in age distribution of notified cases over time - in areas of persistently high TB transmission, we see peak incidence rates among young adults; in areas of lower recent transmission (declining TB incidence), we see more cases among older individuals due to reactivation, so the mean age of cases tends to increase over time.
- Other risk factors for TB such as malnutrition, smoking, alcoholism, diabetes, indoor air pollution can also impact TB incidence, and you may know of others in your country that we have not listed here. Please indicate them in the table below.

Has the indicator had an affect on incidence?	If yes, during what time period?	If yes, please explain.
3.3.1. HIV prevalence See graph 36 <input type="checkbox"/> Yes, increased incidence <input type="checkbox"/> Yes, decreased incidence <input type="checkbox"/> No impact <input type="checkbox"/> Don't know	From ____ (yr) to ____ (yr)	
3.3.2. GDP See graph 36 <input type="checkbox"/> Yes, increased incidence <input type="checkbox"/> Yes, decreased incidence <input type="checkbox"/> No impact <input type="checkbox"/> Don't know	From ____ (yr) to ____ (yr)	
3.3.3. Use of anti-retroviral therapy (ARV) among HIV patients in need <input type="checkbox"/> Yes, increased incidence <input type="checkbox"/> Yes, decreased incidence <input type="checkbox"/> No impact <input type="checkbox"/> Don't know	From ____ (yr) to ____ (yr)	
3.3.4. Other risk factors (please specify) _____ <input type="checkbox"/> Yes, increased incidence <input type="checkbox"/> Yes, decreased incidence <input type="checkbox"/> No impact <input type="checkbox"/> Don't know	From ____ (yr) to ____ (yr)	

See graphs 37–38

3.3.5. Has the age distribution of cases changed over time in your country?

Yes/No/Don't know

3.3.6. Has the mean age of cases gotten older or younger?

Older/Younger/No change

3.3.7. What age range has the highest rate of TB notifications?

0 - 14	
15 - 44	
45 - 60	
>60	

3.4 Based on the information we have discussed in questions 3.1 through 3.3, how do you think true underlying incidence has changed over time?

Draw a line on the notifications chart below indicating how you think **incidence** has changed over time relative to notifications? Think about how in some years notifications might have been closer to true incidence than in other years. How different (or similar) do you feel the true underlying incidence is from the notifications? Feel free to write in new numbers for the incidence rate on the Y axis if you have an idea of what it might be.

4. Planning

Country plan to improve TB Surveillance and programme monitoring and evaluation system

List of activities	Do you plan to implement this activity?		Timeline (Quarter, Year)	Do you need technical assistance from WHO or other technical partners?		Funding source
4.1 Improve recording and reporting capacity:						
4.1.1. Improve coverage of recording and reporting	Yes	No		Yes	No	
4.1.2. Improve supervision of recording and reporting activities, from data collection to data validation to data analysis and reporting of findings	Yes	No		Yes	No	
4.1.3. Introduce a new or improve the existing electronic recording and reporting system, with the following features: Type of data <ul style="list-style-type: none"> • Aggregated data • Case-based data Administrative level in which data will be entered into the electronic system <ul style="list-style-type: none"> • Health care facility (mostly) • District / Municipality (mostly) • State / Province Mode of data transmission <ul style="list-style-type: none"> • Off-line (via email or memory-disk) • Web-based 	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
	Yes	No		Yes	No	
4.2 Improve capacity to analyse TB notification and other supporting data at <ul style="list-style-type: none"> • National level • Sub-national level 	Yes	No		Yes	No	
	Yes	No		Yes	No	
4.3 Improve feedback of data analysis and interpretation to TB staff and other health care staff working at the peripheral level	Yes	No		Yes	No	
4.4 Implement a study to identify and eliminate duplicate and misclassified records at national level so that such records do not artificially inflate the number of new TB cases that are recorded and reported	Yes	No		Yes	No	
4.5 Perform data quality assessment (e.g. using available tools for assessment of data quality)	Yes	No		Yes	No	

<p>4.6 Perform studies of: a) the number of TB cases as a proportion of the number of suspects examined and/or b) the number of suspects examined as a proportion of the number of chronic respiratory cases attending health care facilities. These studies can help to identify the extent to which TB cases are being missed in some health care facilities as compared with others, and the reasons for this.</p>	<p>Yes No</p>		<p>Yes No</p>	
<p>4.7 Perform contact investigation studies in a sample of health care facilities. The aim here would be to estimate the total number of cases that could be found among contacts of TB cases. For example, suppose that a contact investigation study was conducted in 1% of all health care facilities, and that for every 100 index patients who had their close contacts examined 1 new TB case was found. By comparing the characteristics of the index patients and of the general population in the sampled and non-sampled health care facilities, it would then be possible to estimate the total number of new TB cases that could be found among contacts of TB cases diagnosed in the remaining 99% of health care facilities.</p>	<p>Yes No</p>		<p>Yes No</p>	
<p>4.8 Perform cross-validation of TB notification data with other sources of TB data:</p> <ul style="list-style-type: none"> • Other pre-existing sources (such as vital registration data, TB laboratory registers, HIV notification register, hospital registers, electronic versus paper-based TB notification registers) • Prospectively collected TB data (for example, introduce new registries to be completed by a sample of non-NTP providers) <p>These cross-validation studies, which are also called inventory studies, can be used to find cases which are not in the NTP notification registry.</p>	<p>Yes No Yes No</p>		<p>Yes No Yes No</p>	
<p>4.9 Capture-recapture studies. By comparing several sources of TB cases, the capture-recapture methodology can be used to estimate the total number of TB 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 sources, i.e. cases that are not in contact with health facilities at all)</p>	<p>Yes No</p>		<p>Yes No</p>	
<p>4.10 Perform a national survey to estimate the prevalence of drug-resistant TB</p>	<p>Yes No</p>		<p>Yes No</p>	
<p>4.11 Perform a national survey of the prevalence of HIV prevalence among registered TB patients</p>	<p>Yes No</p>		<p>Yes No</p>	

4.12 Implement routine culture and drug susceptibility testing for all new reported cases and link them to the national TB notification system	Yes	No		Yes	No	
4.13 Implement routine culture and drug susceptibility testing for all reported retreatment cases and link them to the national TB notification system	Yes	No		Yes	No	
4.14 Perform a national survey of the prevalence of TB disease	Yes	No		Yes	No	
4.15 Perform studies to assess TB burden in high risk populations (e.g. prisons)	Yes	No		Yes	No	
4.16 Perform studies to quantify the effect of risk factors for TB and their population attributable fraction in your country (for example, HIV, diabetes, and smoking)	Yes	No		Yes	No	
4.17 Other Please specify	Yes	No		Yes	No	
4.18 Other Please specify	Yes	No		Yes	No	