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 incidence[1] 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 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			2009		
	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. Layer 6: Patients that have no access to health care									
.1.2. Layer 5: Access to health care facilities, but do not present themselves									
.1.3. Layer 4: Presenting to health care facilities, but not diagnosed									
.1.4. Layer 3: Diagnosed by public non-NTP or private providers, but not notified									
.1.5. Layer 2: Diagnosed by NTP or collaborating providers, but not notified									
.1.6. Sum of % of missing cases: layers 2 to 6									
.1.7. Participants estimates of case detection rate (CDR) (= 100 minus the sum of % of missing cases: layers 2 to 6)									
.1.8. WHO estimates of CDR (all cases - 2007)*									
.1.9. Difference (participants - WHO estimates)									

* Global TB report 2009

You might have found it difficult to estimate the percentage of cases missed by the notifications system. With data beyond routine TB surveillance it might be possible to learn more about where cases are being missed. Think about this as you answer the questions below.

.2 What sources of data or other evidences did you use to complete the table in exercise 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.

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

.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.

- ☐ Inventory studies (i.e. cross-checking various registers) using existing sources of data (layers 2 and 3)
- ☐ Inventory studies using newly collected sources (e.g. introducing a TB registry in a private hospital) of data (layers 2 and 3)
- ☐ Studies of diagnostic procedures performed on TB suspects attending samples of health care facilities (layer 4)
- ☐ Yield of patients found as a result of advocacy, communication and social mobilization activities (layers 2 and 3)
- ☐ Yield of patients found while contact tracing (layers 4 and 5)
- ☐ Yield of patients found because of improvements in diagnostic quality or tools (layer 4)
- ☐ Yield of patients found as a result of PPM (layer 3)
- ☐ TB disease prevalence studies (all layers)

☐ Yield of patients found following training staff on Practical Approach to Lung Health (layers 4 and 5)

☐ Yield of patients found while screening high risk populations (layers 4 and 5)

☐ Capture recapture studies (all layers)

☐ Studies of post-mortem registration of TB (layers 4, 5 and 6?)

☐ 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.

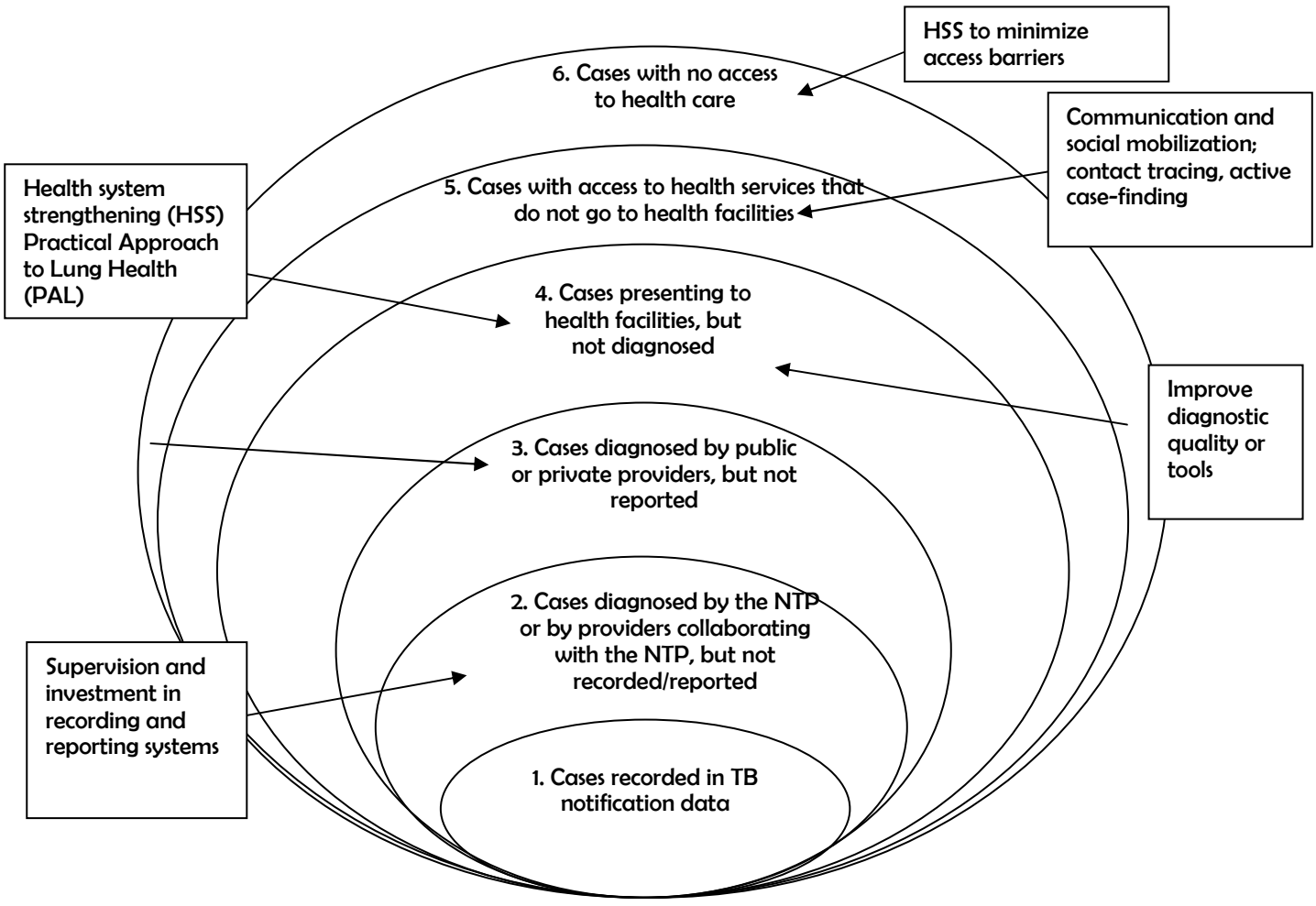


Table 1. Examples of data and methods that could be used to assess how many TB cases are missing from TB notification data

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 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[17-20] 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). 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.	Botha E et al (S. Africa)[5]	
Cases diagnosed by non-NTP providers that are not notified (Ring 3)		Miglioiri et al (Italy), Maung et al, (Myanmar), Lonnroth 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)			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)		Gasana et al (Rwanda), Espinal et al (Dom. Rep.), 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)		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.

References

1) Suarez PG, Watt CJ, Alarcon E, et al. The dynamics of tuberculosis in response to 10 years of intensive control effort in Peru. Journal of Infectious Diseases 2001;184:473-8.
2) Dye C, Ottmani S, Laasri L, Bencheikh N. The decline of tuberculosis epidemics under chemotherapy: a case study in Morocco. International Journal of Tuberculosis and Lung Disease 2007;11:1225-31.
3) Vree M, Duong BD, Sy DN, Co NV, Borgdorff MW, Cobelens FGJ. Tuberculosis trends, Vietnam. Emerging infectious diseases 2007;13:332-3.
4) Mansoer J, Scheele S, Floyd K, Dye C, Williams B. New methods for estimating the tuberculosis case detection in Kenya. submitted to publication.
5) Botha E, Den Boon S, Verver S, et al. Initial default from tuberculosis treatment: how often does it happen and what are the reasons? International Journal of Tuberculosis and Lung Disease 2008;12(7):820-3.
6) Migliori GB, Spanevello A, Ballardini L, et al. Validation of the surveillance system for new cases of tuberculosis in a province of northern Italy. Varese Tuberculosis Study Group. European Respiratory Journal 1995;8:1252-8.
7) Maung M, Kluge H, Aye T, et al. Private GPs contribute to TB control in Myanmar: evaluation of a PPM initiative in Mandalay Division. Int J Tuberc Lung Dis 2006;10(9):982-7.
8) Lonnroth K, Thuong LM, Lambregts K, Quy HT, Diwan VK. Private tuberculosis care provision associated with poor treatment outcome: comparative study of a semi-private lung clinic and the NTP in two urban districts in Ho Chi Minh City, Vietnam. National Tuberculosis Programme. International Journal of Tuberculosis and Lung Disease 2003;7:165-71.
9) Lonnroth K, Lambregts K, Nhien DTT, Quy HT, Diwan VK. Private pharmacies and tuberculosis control: a survey of case detection skills and reported anti-tuberculosis drug dispensing in private pharamcies in Ho Chi Minh City, Vietnam. IntJTubercLung Dis 2000;4:1052-9.
10) World Health Organization. Public-Private Mix for DOTS: Global Progress. Geneva: World Health Organization; 2004. Report No.: WHO/HTM/TB/2004.338.
11) Ambe G, Lonnroth K, Dholakia Y, et al. Every provider counts: effect of a comprehensive public-private mix approach for TB control in a large metropolitan area in India. International Journal of Tuberculosis and Lung Disease 2005;9:562-8.
12) Arora VK, Lonnroth K, Sarin R. Improved case detection of tuberculosis through a public-private partnership. Indian J Chest Dis Allied Sci 2004;46(2):133-6.
13) Dewan PK, Lal SS, Lonnroth K, et al. Improving tuberculosis control through public-private collaboration in India: literature review. British Medical Journal 2006;332:574-8.
14) Gasana M, Vandebriel G, Kabanda G, et al. Integrating tuberculosis and HIV care in rural Rwanda. Int J Tuberc Lung Dis 2008;12(3 Suppl 1):39-43.
15) Espinal MA, Reingold AL, Koenig E, Lavandera M, Sanchez S. Screening for active tuberculosis in HIV testing centre. Lancet 1995;345:890-3.
16) Lee MS, Leung CC, Kam KM, et al. Early and late tuberculosis risks among close contacts in Hong Kong. Int J Tuberc Lung Dis 2008;12(3):281-7.
17) van Hest NA, Smit F, Baars HW, et al. Completeness of notification of tuberculosis in The Netherlands: how reliable is record-linkage and capture-recapture analysis? Epidemiol Infect 2007;135(6):1021-9.
18) van Hest NA, Smit F, Baars HW, et al. Completeness of notification of tuberculosis in The Netherlands: how reliable is record-linkage and capture-recapture analysis? Epidemiology and infection 2006;135:1021-9.
19) Baussano I, Bugiani M, Gregori D, et al. Undetected burden of tuberculosis in a low-prevalence area. International Journal of Tuberculosis and Lung Disease 2006;10:415-21.
20) Crofts JP, Pebody R, Grant A, Watson JM, Abubakar I. Estimating tuberculosis case mortality in England and Wales, 2001-2002. Int J Tuberc Lung Dis 2008;12(3):308-13.

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?

Objective
The goal of part 2 is to gain an understanding of how complete and reliable the data collected at the national level is. In order to determine this, we will look at whether or not units, districts, provinces and/or states consistently report their TB cases. We will also look at unusual variations over time and across geography in order to see if we can understand why reported rates may vary. In order to assess reliability, we will try to understand to what extent cases are classified correctly.

Rationale
For data to be considered complete at the national level, all administrative levels must report their TB cases (or that they have none) consistently over time. There should not be gaps in reporting over time or geography. And you should be able to explain differences over time and across sub-national geography in the notification rates. For data to be considered reliable, the cases that are reported should be classified correctly by smear and treatment status, etc. Also, data on TB/HIV and MDR-TB is very helpful in assessing the epidemiology in a country.

.5 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	
.5.1. 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	Yes / No / Don't know
.5.2. If yes, since when? Select as appropriate.	Year _____
.5.3. 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
.5.4. If yes, since when? Select as appropriate.	Year _____
.5.5. 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
.5.6. If yes, since when)? Select as appropriate.	Year _____
.5.7. **Summary question**: Based on your answers above, do you think that the completeness of your country's TB notifications has been consistent over time?	Yes / No / Don't know
Identification of unusual fluctuations	
Trend in notification of new TB cases **See graphs A2, C1**	
.5.8. Were there unusual fluctuations in the time series? e.g. notifications	Yes / No / Don't know

that differ significantly from one year to the next.	
.5.9. If yes, can you list the reasons for these unusual fluctuations in time? You can select more than one.	☐ 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.) ☐ Inclusion of data from new reporting units (e.g. inclusion of data from the penitentiary sector, military hospitals) ☐ 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.) ☐ 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.) ☐ Don't know ☐ Other. Please specify.
.5.10. Were the fluctuations driven by a certain case type?	☐ Yes, it was mainly driven by fluctuations in the number of SS+ pulmonary TB cases ☐ Yes, it was mainly driven by fluctuations in the number of SS- pulmonary TB cases ☐ Yes, it was mainly driven by fluctuations in the number of extra-pulmonary TB cases ☐ No, I don't believe the fluctuations were driven by a certain case type. ☐ Don't know ☐ Other. Please specify.
.5.11. **Summary question**: Based on your answers above, do you think that your country's TB notifications are equally complete across states or provinces?	Yes / No / Don't know
Variation in notification rates of new TB cases across admin1 **See graphs B1, B2**	
.5.12. Is there a lot of variation between notification rates of new (all and by smear) TB cases across admin1?	Yes / No / Don't know
.5.13. If yes, what are the main reasons to explain this variation? You can select more than one.	☐ True differences in TB epidemic sub-nationally (TB determinants such as HIV prevalence, urbanization and socio-economic situation etc.) ☐ Differences in TB diagnostic capacity (staff or laboratory capacity, access to health care, etc.) ☐ Differences in the recording and reporting system (structure, coverage or performance of the notification system) ☐ Don't know ☐ Other. Please specify.

.5.14. Were the fluctuations found for the national data driven by certain admin 1 areas?	Yes / No / Not applicable (e.g. sub-national data not provided) Comments:
.5.15. **Summary question**: Based on your answers above, do you think that your country's TB notifications are equally complete across states or provinces?	Yes / No / Don't know
Comparison notifications workshop template versus reported in WHO TB database	
.5.16. Was there a difference between the number of notifications reported in the workshop template and those reported in the WHO Global TB database? **See graph A5**	Yes / No
.5.17. If yes, can you list the reasons for this difference? You can select more than one.	☐ Case definition understood as different in each database ☐ Inclusion of reports that arrived late ☐ Don't know ☐ Other. Please specify.
.5.18. **Summary question**: Based on your answers above, how would you characterize the completeness of your national TB notifications?	Largely complete / Somewhat complete / Incomplete

.6 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 A6** *(Compare with the global and regional averages)*	
.6.1. In the last year, how does the proportion of TB cases that are new compare with the global and regional average?	Regional: Similar / Higher / Lower Global: Similar / Higher / Lower
.6.2. If the proportion is considerably different from the regional and/or global average, how do you explain this? You can select more than one.	☐ Factors that affect the number of retreatment cases, including differences in risk factors, TB control efforts, proportion of drug-resistant TB ☐ Misclassification problems (i.e. retreatment cases classified as new cases) ☐ Don't know ☐ Other causes - please specify
.6.3. Are there significant variations over time?	Yes / No / Don't know
.6.4. If yes, how do you explain these variations over time?	☐ Variations in the factors that interfere with the number of retreatment cases, including TB control efforts, proportion of drug-resistant TB ☐ Reduction of misclassification problems (i.e. retreatment cases no longer classified as new cases) ☐ Don't know ☐ Other causes - please specify
B - Proportion of new cases that are pulmonary **See graph: A7** *(Compare with the global and regional averages)*	
.6.5. In the last year, how does the proportion compare with the global and regional average?	Regional: Similar / Higher / Lower Global: Similar / Higher / Lower
.6.6. If the proportion is higher or lower than the global average, how do you explain this? You can select more than one.	☐ Differences in extra-pulmonary TB diagnostic capacity **See graph: A4** ☐ Differences in the age structure of TB cases (higher % of extra-pulmonary TB in children) **See graph: A10** ☐ Differences in HIV prevalence (higher % extra-pulmonary TB in HIV-positive cases) **See graph: A11** ☐ Differences in notification policy or practice (regulation or lack of knowledge about need to notify EP cases)

	☐ Misclassification problems (i.e. mixed cases are classified as pulmonary or extra-pulmonary) **$ee graph$ A4** ☐ Don't know ☐ Other causes - please specify
.6.7. Are there significant variations over time?	Yes / No / Don't know
.6.8. If yes, how do you explain these variations over time? You can select more than one.	☐ Variations in extra-pulmonary TB diagnostic capacity **$ee graph$ A4** ☐ Variations in the age structure of TB cases **$ee graph$ A10** ☐ Variations in HIV prevalence **$ee graph$ A11** ☐ Variations in notification policy/practice ☐ Variations in misclassification problems (introduction of measures to correct the misclassification problem) **$ee graph$ A4** ☐ Don't know ☐ Other causes - please specify
C - Proportion of all pulmonary cases that are smear positive *(Compare with the global and regional averages)*	
.6.9. In the last year, how does the proportion compare with the global and regional average? **$ee graph$ A8**	Regional: Similar / Higher / Lower Global: Similar / Higher / Lower
.6.10. If the proportion is higher or lower than the global average, how do you explain this? You can select more than one.	☐ Differences in capacity to perform smear examination (number of quality assured labs, poor efficiency of labs, referral practices, ...) **$ee graph$ A3** ☐ Differences in the age structure of TB cases (lower smear positivity in children) **$ee graph$ A10** ☐ Differences in HIV prevalence (lower smear positivity in HIV+ patients) **$ee graph$ A11** ☐ Differences in notification policy or practice (regulation or lack of knowledge about need to notify SS- cases) ☐ Misclassification problems (smear negative / culture positive cases notified as smear positive, because there is no other case category to notify a bacteriologically positive case) **$ee graph$ A4** ☐ Don't know ☐ Other causes - please specify
.6.11. Are there significant variations over time?	Yes / No / Don't know
.6.12. If yes, how do you explain these variations over time? You can select more than one.	☐ Variations in diagnostic capacity for smear positive cases **$ee graph$ A4** ☐ Variations in the age structure of TB cases **$ee graph$ A10** ☐ Variations in HIV prevalence **$ee graph$ A11** ☐ Variations in notification policy/practice

	☐ Variations in misclassification problems (introduction of measures to correct the misclassification problem) **See graphs A4** ☐ Don't know ☐ Other causes - please specify
D - Proportion of all TB cases that are male **See graphs A9**	
.6.13. In the last year, how does the proportion compare with the global and regional average?	Regional: Similar / Higher / Lower Global: Similar / Higher / Lower
.6.14. If the proportion is considerably different from the regional and/or global average, which of the following might explain this?	☐ Factors that affect health care access, such as barriers women face when accessing TB care ☐ Reporting practices differ among providers who have an unbalanced number of patients of one gender. For example, in your country males may have preferential access to military health care institutions that do not report their TB cases to the NTP registry, or women may use the public sector more often than men and private sector underreports. ☐ Influence of the HIV-TB co-epidemic ☐ Other causes - please specify
.6.15. Are there significant variations in the proportion over time in your country?	Yes / No / Don't know
.6.16. If yes, how do you explain these variations over time?	☐ Changes in health care access barrier over time, such as barriers women face when accessing TB care ☐ Changes in recording practices of different providers ☐ Changes in HIV-TB co-epidemic male/female patterns ☐ Other causes - please specify
E - Proportion of all re-treatment cases that are 1) relapse, 2) treatment-after-failure, 3) treatment-after-default 4) other re-treatment **See graphs B3**	
.6.17. In the last year, which of the categories contributed most to the total number of retreatment cases?	☐ Relapse ☐ Treatment-after-failure ☐ Treatment-after-default ☐ Other re-treatment
.6.18. 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
.6.19. If yes, how do you explain these changes over time? You can select more than one.	☐ Variations in the factors that drive the TB epidemic, including TB control efforts and TB treatment regiments ☐ Variations in the prevalence of drug-resistant TB

	☐ Variations in notification policy/practice in these categories over time ☐ Variations in the amount of misclassification between the categories over time ☐ Don't know ☐ Other causes - please specify
.6.20. **Summary question**: Based on the information above, how consistent would you say your data are with regional and global averages?	Largely consistent / Somewhat consistent / Inconsistent
.6.21. **Summary question**: Based on the information above, how consistent would you say your data are over time?	Largely consistent / Somewhat consistent / Inconsistent

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

Specific questions:

<table>
<tr><td colspan="5">TB-HIV See graphs A10</td></tr>
<tr><td>.7.1. Is there a national TB-HIV surveillance system?</td><td colspan="4">☐ Yes, data on the results of HIV testing of TB patients is collected as part of the main TB surveillance system
☐ Yes, data on the results of HIV testing of TB patients is collected in a parallel system (e.g. HIV sentinel surveillance system)
☐ No, there is no system to record results of HIV testing of TB patients
☐ Don't know</td></tr>
<tr><td>.7.2. If you have a TB/HIV surveillance system, since when? Select as appropriate</td><td>Since before 1995</td><td>1995 to 2000</td><td>2000 to 2005</td><td>From 2005 onwards</td></tr>
<tr><td>.7.3. If you have a TB/HIV surveillance system, have there been variations in the proportion of registered TB patients with known HIV+ status over the last 5 years?</td><td colspan="4">☐ Yes, and they are mainly due to real changes in the proportion of co-infected patients
☐ Yes, and they are mainly due to changes in the proportion of TB patients that are tested for HIV
☐ Yes, and they are mainly due to changes in the recording of this information in the system
☐ Yes, and they are due to a combination of the above mentioned causes
☐ No, the proportion has not varied much
☐ Don't know</td></tr>
<tr><td>.7.4. Have you ever done a national survey for the prevalence of HIV positive patients among a representative sample of your registered TB patients?</td><td colspan="4">☐ Yes, one survey
☐ Yes, more than one survey
☐ No
☐ Don't know</td></tr>
<tr><td rowspan="2">.7.5. What was the result of your last national survey?</td><td>Year</td><td colspan="2">% of all new TB cases tested for HIV</td><td>Prevalence among new TB cases (%)</td></tr>
<tr><td></td><td colspan="2"></td><td></td></tr>
</table>

.8 Do you have data on MDR-TB cases?

Specific questions:

MDR-TB					
.8.1. Is there a national MDR-TB surveillance system?	☐ Yes, data on MDR-TB patients is collected as part of the main TB surveillance system ☐ Yes, data on MDR-TB patients is collected in a parallel or sentinel system ☐ No, there is no system to record MDR-TB patients data ☐ Don't know				
.8.2. If you have a MDR-TB surveillance system, since when? Select as appropriate	Since before 1995	1995 to 2000	2000 to 2005	From 2005 onwards	
.8.3. If you have a MDR-TB surveillance system, have there been variations in the proportion of registered TB patients that have MDR-TB over the last 5 years?	☐ Yes, and they are mainly due to real changes in the proportion of MDR-TB patients ☐ Yes, and they are mainly due to changes in the proportion of TB patients that have access to culture and/or drug sensitivity testing ☐ Yes, and they are mainly due to changes in the recording of this information in the system ☐ Yes, and they are due to a combination of the above mentioned causes ☐ No, the proportion has not varied much ☐ Don't know				
.8.4. Have you ever done a national survey for the prevalence of MDR-TB patients among a representative sample of your registered TB patients?	☐ Yes, one survey ☐ Yes, more than one survey ☐ No ☐ Don't know				
.8.5. 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?

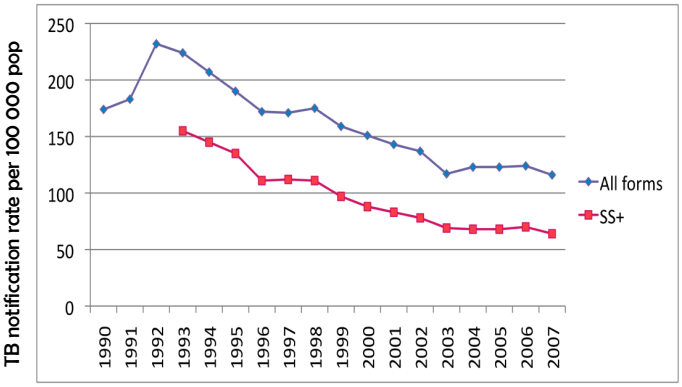
3.4 Based on the information discussed in questions 3.1 through 3.3, how do you think true underlying incidence has changed over time?

Objectives

The goal of Part 3 is to assess the trends over time in notifications in your country, and to understand what is driving these trends. Notifications can change due to changes in incidence, but they can just as easily change due to case-finding efforts and variations in recording and reporting. In this section, we will ask you several questions to help us determine how and why your notifications are changing.

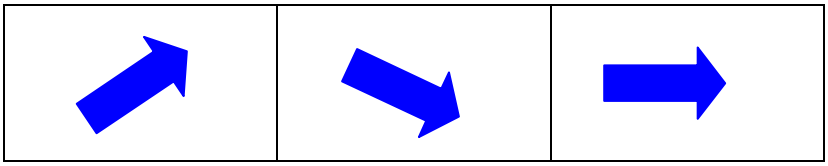
.9 Have TB notifications been increasing, decreasing or stable over time?

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.



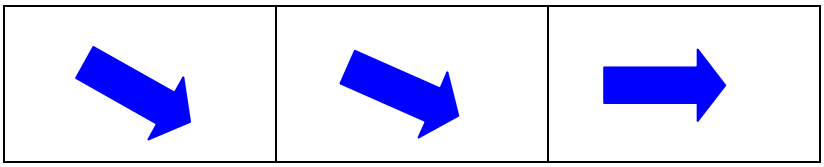
New all forms notifications

1990 1992 2003 2007



New SS+ notifications

1993 1996 2003 2007



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.

.9.1. New pulmonary notifications **See graph: A1, A2**

Year ___(Start) Year ___ Year ___ Year ___ (End)

.9.2. New extra-pulmonary notifications **See graph: A4**

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?

.9.3. New pulmonary SS+ notifications **See graph: A4**

Year ___(Start) Year ___ Year ___ Year ___ (End)

.9.4. New pulmonary SS- notifications **See graph: A4**

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.

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

a) Case-finding effort

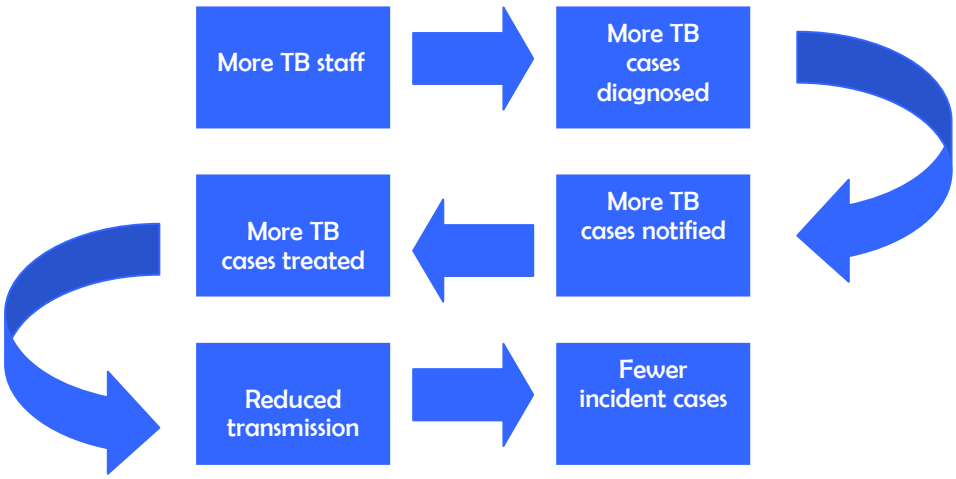
As with notifications, case-finding efforts may have been increasing, decreasing or stable over time. Below are some of the indicators of case-finding effort. Please indicate how these indicators have changed over time, if at all, in the same way that you did for notifications. You will also be asked to describe the impact, if any, you think these case-finding efforts had on notifications. Generally, as case-finding efforts increase, notifications increase and vice versa.

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.

.10.1. Number of labs doing smear and/or culture **See graph: A3**

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?

.10.2. Number of NTP staff **See graph A3**

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?

.10.3. Expenditure on TB control **See graph A10**

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?

.10.4. Suspect rate **See graph A3**

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?

.10.5. Number of slides per patient to diagnose one TB patient **See graph A3**

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?

_____

_____

_____

.10.6. Proportion of all pulmonary TB cases diagnosed through active case finding

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?

_____

_____

_____

.10.7. Proportion of population screened through active case finding

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?

_____

_____

_____

.10.8. Proportion of notified cases reported by non-NTP **See graph A3**

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?

_____

_____

_____

.10.9. **Summary question:** Overall, do you think case-finding efforts have affected notifications?

Yes / No / Don't know

.10.10. **Summary question:** If you don't know, is there more data that you could look at to be able to answer this question in the future?

Yes / No / Don't know

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. Therefore, it is important to look at changes in reporting practices over time to understand if this might have led to changes in notifications. Please indicate below if and when the changes below occurred.

.10.11. 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.

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

.10.13. **Summary question:** Overall, do you think changes in recording and reporting have affected notifications?

Yes / No / Don't know

.10.14. **Summary question:** If you don't know, is there more data that you could look at to be able to answer this question in the future?

Yes / No / Don't know

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

Up until now we have been looking at factors that affect notifications, not underlying incidence. Now we will look at factors that could explain how incidence may be changing in your country. Programme performance can impact incidence, but it takes many years to see the change; however, there are external (non-programme) factors that can also influence TB incidence. For example, as HIV prevalence increases, we expect to see TB incidence increase and vice versa. As general socio-economic conditions improve, we expect to see TB incidence decline and vice versa. Other risk factors for TB such as malnutrition, smoking, alcoholism, diabetes, indoor air pollution can also impact TB incidence. Below we will ask about these and other indicators in your country and how you think these might be impacting incidence, if at all. **(see graphs A1, A10)**

Has the indicator had an affect on incidence?	**If yes, during what time period?**	**If yes, please explain.**
.11.1. HIV prevalence **See graph** € Yes, increased incidence € Yes, decreased incidence € No impact € Don't know	From _____(yr) to ____(yr)	
.11.2. GDP **See graph** € Yes, increased incidence € Yes, decreased incidence € No impact € Don't know	From _____(yr) to ____(yr)	
.11.3. Use of anti-retroviral therapy (ARV) among HIV patients in need € Yes, increased incidence € Yes, decreased incidence € No impact € Don't know	From _____(yr) to ____(yr)	
.11.4. Other risk factors (please specify)_____ € Yes, increased incidence € Yes, decreased incidence € No impact € Don't know	From _____(yr) to ____(yr)	

.11.5. **Summary question:** Overall, do you think these external factors have affected incidence?

Yes / No / Don't know

.11.6. **Summary question:** If you don't know, is there more data that you could look at to be able to answer this question in the future?

Yes / No / Don't know

.12 Exercise with the onion model Excel tool

Based on your questions to the sections above, please have another look at the estimates for the percentage of TB cases that might be missed in each layer of the onion model for the three reference years.

In the onion model Excel tool, we show you the trends in notification of new TB cases of your country. You will be able to see how your estimates for the three reference years would affect the overall TB incidence.

4. Planning

Objectives

The goal of this exercise is to help you plan activities to improve TB surveillance and programme monitoring and evaluation systems in your country.

Rationale

Through the exercises in Parts 1 to 4, you may now have a better sense of where data are lacking and how the data, if obtained, could be used to improve your TB programme and to document the impact those improvements have on the TB situation in your country. We hope that the suggestions below will give you some ideas about what you can do to improve data collection and analysis.

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
1.13 Improve recording and reporting capacity:				
1.13.1. Improve coverage of recording and reporting	Yes No		Yes No	
1.13.2. Improve supervision of recording and reporting activities, from data collection to data validation to data analysis and reporting of findings	Yes No		Yes No	
1.13.3. Introduce a new or improve the existing electronic recording and reporting system, with the following features:				
Type of data				
• Aggregated data	Yes No		Yes No	
• Case-based data	Yes No		Yes No	
Administrative level in which data will be entered into the electronic system				
• Health care facility (mostly)	Yes No		Yes No	
• District / Municipality (mostly)	Yes No		Yes No	
• State / Province	Yes No		Yes No	
Mode of data transmission				
• Off-line (via email or memory-disk)	Yes No		Yes No	
• Web-based	Yes No		Yes No	
1.14 Improve capacity to analyse TB notification and other supporting data at				
• National level	Yes No		Yes No	
• Sub-national level	Yes No		Yes No	

1.15 Improve feedback of data analysis and interpretation to TB staff and other health care staff working at the peripheral level	Yes No		Yes No		
1.16 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		
1.17 Perform data quality assessment in a sample of selected units (e.g. using available tools for assessment of data quality. E.g. RDQA for TB)	Yes No		Yes No		
1.18 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.	Yes No		Yes No		
1.19 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.	Yes No		Yes No		
1.20 Perform cross-validation of TB notification data with other sources of TB data: • 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) These cross-validation studies, which are also called inventory studies, can be used to find cases which are not in the NTP notification registry.	Yes No Yes No		Yes No Yes No		
1.21 Capture-recapture studies. By comparing several sources of TB cases, the capture-	Yes No		Yes No		

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)				
1.22 Perform a national survey to estimate the prevalence of drug-resistant TB	Yes No		Yes No	
1.23 Perform a national survey of the prevalence of HIV prevalence among registered TB patients	Yes No		Yes No	
1.24 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	
1.25 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	
1.26 Perform a national survey of the prevalence of TB disease	Yes No		Yes No	
1.27 Perform studies to assess TB burden in high risk populations (e.g. prisons)	Yes No		Yes No	
1.28 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	
1.29 Other Please specify	Yes No		Yes No	
1.30 Other Please specify	Yes No		Yes No	