Draft implementation guidance for national tuberculosis epidemiological reviews

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# Table of contents

1. Background ................................................................................................................................. 4

2. Part I. Preparation .......................................................................................................................... 4
   2.1 Optimal timing of the review ................................................................................................. 4
   2.2 Review team composition ...................................................................................................... 5
   2.3 Setting the review agenda ...................................................................................................... 7
   2.4 Preparing the data .................................................................................................................. 7

3. Part II. In-country mission .......................................................................................................... 9
   3.1 Briefing meeting with key stakeholders ................................................................................ 9
   3.2 Finalising the agenda for the in-country mission ................................................................. 10
   3.3 Interviews with NTPs and key stakeholders ......................................................................... 10
   3.4 Desk review of all relevant national documents ................................................................. 10
   3.5 Field visits ............................................................................................................................ 11
   3.6 Analysis of surveillance data ............................................................................................... 12
   3.7 De-briefing meeting .............................................................................................................. 12

4. Part III. Follow-up ...................................................................................................................... 13
   4.1 Report compilation and submission ..................................................................................... 13
   4.2 Ownership, publication and sharing policy of review content and report ......................... 13
   4.3 From recommendation to funding allocation and finally implementation ............................ 14

5. Part IV. Common findings from TB epidemiological reviews .................................................... 17
   Objective 1. Results from TB surveillance checklist of standards and benchmarks .................... 17
   Objective 2. Results from TB surveillance data (national and sub-national) .............................. 23
   Objective 3. Results from external, but related to, TB factors .................................................... 26
   Objective 4. Investment framework of activities to strengthen surveillance and directly measure disease burden .................................................................................................................. 27

6. Part V. Summary of feedback and suggested changes to ToR’s .................................................. 30
   6.1 Stakeholder feedback .......................................................................................................... 30
   6.2 Stakeholder online survey .................................................................................................... 30
   6.3 Major proposed updates to standardised ToR’s ................................................................. 32

Appendix I. Standardised terms of reference ................................................................................. 35

1. BACKGROUND .......................................................................................................................... 35

2. OBJECTIVES ............................................................................................................................ 35

3. TASKS BY OBJECTIVE ............................................................................................................ 35

   Objective 1: Assessment of current national TB surveillance and vital registration systems with particular attention to their capacity to measure the level of and trends in TB disease burden .... 35
   Objective 2: Assessment of the level of, and trends in, TB disease burden ............................. 36
Objective 3: Are recent trends in TB disease burden plausibly related to changes in TB-specific interventions accounting for other external factors? ................................................................. 37

Objective 4: Assessment of investments needed to directly measure trends in disease burden in the future .................................................................................................................. 39

4. DELIVERABLES ............................................................................................................. 39

5. PROFILE REQUIRED ..................................................................................................... 39

6. TIME REQUIRED ......................................................................................................... 40

Appendix II. Example of an agenda for an in-country mission ........................................... 41
Appendix III. Example of a briefing presentation (Liberia) .................................................. 44
Appendix IV. Example of Epidemiological Review Report: Detailed Outline ...................... 48
1. Background

An excellent understanding of the level of, and trends in, disease burden and how these have been (and can be) influenced by the implementation of prevention and treatment interventions is of critical importance to national health programmes, as well as international donor agencies; it can help to ensure the appropriate allocation of funding and ultimately reduce disease burden and save more lives. The need for such epidemiological and impact analyses to be included systematically and in a standardised way as part of National Health Sector Reviews and disease-specific programme reviews was recognised in early 2013.\(^1\) Such analyses were also introduced as part of the development of “concept notes” that provide the basis for funding applications to the Global Fund in the New Funding Model (NFM) introduced in 2013; in this context, the analyses were called the “epidemiological stage” and preceded the development of the concept note (also see paragraph 4.3). In 2013 the WHO Global Task Force on TB Impact Measurement developed standardised terms of reference for TB epidemiological and impact analyses, covering four objectives, associated tasks and expected deliverables (Appendix I).

The purpose of this document is to synthesize experience, share common findings and lessons learnt, and present practical examples from TB epidemiological reviews conducted in 48 countries during the period 2013-2016. The document has five parts. The first part covers all required activities during the period of the planning and preparation in advance of the in-country mission. The second part outlines the typical activities carried out during the in-country mission. The third part covers everything that follows the in-country mission and particularly the finalisation of the report and the need for follow-up to ensure that agreed recommendations and associated activities do in fact get funded and are implemented. The fourth part shares common findings for each of the four objectives of the standardised ToRs. The fifth and final part provides a summary from elicited stakeholder feedback on what worked, what did not work and what should we be doing differently in the future with TB epidemiological reviews.

This document is a collaborative effort of key partners of the WHO Global Task Force on TB Impact Measurement\(^2\), subgroup on strengthening TB surveillance.

2. Part I. Preparation

2.1 Optimal timing of the review

The epidemiological review provides necessary background information to help understand the burden of TB disease and the characteristics of the TB epidemic in the country. It also provides an overview of the TB surveillance system and Monitoring and Evaluation (M & E) activities that are necessary to strengthen surveillance and measurement of TB burden. This evidence based information should be used by the National TB Programme (NTP) to develop a National Strategic Plan (NSP) and an investment plan related to the M & E system. Associated activities should be incorporated into the concept note to ensure they are adequately resourced. The TB epidemiological review should therefore preferably be scheduled before the development or revision of a NSP and the concept note (e.g. during a Joint Annual TB Program Review). NSPs are generally revised every 5 years but concept notes may be updated every 2 years if relevant information becomes available that affect the prioritisation of activities or resource allocation, for example, results of a prevalence survey which

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\(^1\) http://www.who.int/tb/publications/framework-tb-programme-reviews/en/

\(^2\) http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/en/
lead to the revision of TB estimates in the country. An assessment of the TB surveillance system is recommended every 5 years.

If the epi-review is carried out prior to the Joint Annual TB Program Review, ideally the debrief of the epi-review should coincide with the brief of the program review. This will allow the program review teams to collect additional information during their visits to regions, districts and facilities to provide important missing information for interpretation of the epi-review. For example, doing a rapid data quality assessment of routine surveillance data during facility visits, verifying availability of latest recording and reporting tools at each level, or assessment of use of surveillance data to inform policy and planning at each level.

Most importantly, it is essential to ensure that the epidemiological review results are anticipated, taken seriously, and used in surveillance system strengthening. This requires consultation with the NTP prior to the review.

**Examples of case studies with optimal timing to be added**

### 2.2 Review team composition

The national epidemiological review team should ideally involve key decision-makers, TB program managers and M&E staff. As a TB epidemiological review is undertaken as part of the national strategic planning and implementation cycle, it should be coordinated by the NTP. A key member of the NTP should be appointed for the duration of the mission who should be technically skilled in epidemiology and also familiar with TB program management. It is important to include TB program managers as well as staff with specific responsibilities for TB M&E at different levels of the system so as to ensure optimal data interpretation.

Staff from bi-lateral and multi-lateral agencies providing technical support in-country can play an important role in the assessment process, including support for follow-up of implementation of recommendations and capacity building. Academics from Universities, national epidemiologists from the Ministry of Health Statistics Department, country offices of development and other technical partners such as NGOs can also participate in the review as they can provide relevant complementary information and data as well as assist in improving the performance of the surveillance system. The number and composition of the epidemiological review team is determined by the size and organisation of the NTP team, the size of the country and the involvement of technical partners in the surveillance system.

The national review team could include some of the following people:

- **NTP staff:**
  - NTP manager
  - NTP program officer
  - NTP monitoring and evaluation team
  - NTP statistician/epidemiologist
  - NTP data manager

- **MOH staff other than NTP:**
  - HIV department: program officer, M&E team members
- Staff responsible for the Health Information System (HIS) and the National Statistics Office

- Non MOH staff:
  - Agencies/individuals (technical partners of NTP) involved in data analysis at national level

- Minimum requirement:
  - NTP manager
  - NTP program officer
  - NTP data manager/epidemiologist/M & E staff member

The national review team will be involved in key aspects of leading the preparation and conducting the review. Each member of the team will participate in specific activities of the review according to his/her expertise. Specific benchmarks of the Standards and Benchmarks Checklist (the Checklist)\(^3\) can be assessed by separate team members (eg. audit of Basic Management Unit (BMU) data, calculation of indicators, analysis of trends). The involvement of each team member in the following activities should be defined prior to the review:

- Finalisation of the agenda
- Desk review of documents and characterisation of the TB surveillance system (Part A of the Checklist)
- Assessment of each of the 13 Standards, including field visit with/without BMU audit (Part B of the Checklist)
- Participation in work session on characteristics of the TB surveillance system
- Organization and participation in meetings with partners of NTP and with other departments of MOH (HIV/AIDS, Statistics department, vital registration system focal person)
- Preparation of TB notification data
- Participation in a work session to discuss preliminary results of the surveillance assessment and recommendations for strengthening surveillance
- Organization of debriefings (NTP and higher level)
- Conducting epidemiological analysis

Two external (international) experts should complete the internal (national) review team. In addition to bringing new experience and an objective perspective, external experts can devote significant time to data review and analysis. This is essential as some indicators required to assess specific benchmarks as part of the Checklist are not routinely calculated and often data have not been previously analysed in detail. The assessment of the level of, and trends in, TB disease burden requires extensive in-depth analysis and the data quality assessments require field work which is why it is recommended that two external experts participate to share the workload.

In terms of local capacity building, the data review and analysis can be performed jointly with the NTP statistician/epidemiologist or data manager. Bringing together the TB program officer and TB statistician/epidemiologist/data manager will allow for optimal data use (defining indicators, interpreting results) and help the country to establish a “national analysis team for TB data”.

\(^3\) [http://apps.who.int/iris/bitstream/10665/112674/1/WHO_HTM_TB_2014.06_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/112674/1/WHO_HTM_TB_2014.06_eng.pdf?ua=1)
2.3 Setting the review agenda

The epi-review will be based on the standardized ToRs developed by WHO and technical partners (see Appendix I). This is a standardized ToR covering all key aspects of an epi-review as part of a national program review. The ToRs outline four key objectives and describe analysis to be carried out in detail with suggested data sources.

Countries could expand the standardized ToRs based on their needs, by adding specific key questions, for example as to why a certain downward or upward trend in case notification is being observed or why certain regional patterns are occurring. The feasibility to address all objectives outlined in the ToRs depends on the availability and quality of TB surveillance data and other data sources. As many countries still face challenges in ensuring completeness and quality of TB surveillance data and most countries do not yet have an electronic patient-based surveillance system this limits the scope of questions that can be answered with the data.

It is important that the agenda is developed in close consultation with members of the epi-review team to ensure optimal use of the epi-review results for country planning. The agenda is based on a two-week assessment period. The duration of a TB epidemiological review will depend on the following main determinants: 1) the type of system used by NTP (paper-based or electronic) and the type of datasets available from NTP (one or multiple electronic datasets of aggregated data), 2) the access to key TB facilities, 3) the need to do a full/incomplete audit of BMU’s (for paper-based system), 4) the extent of data analysis at national and sub-national level.

Establishing the quality of the TB surveillance data is part of the Standards and Benchmarks tool and reference is made to the Service Availability and Readiness Assessment (SARA) tool\(^4\) or other routine data quality assessments. During the development of the agenda it should be discussed whether or not a recent formal assessment of data quality has been done and if not whether this should be done as part of the ToRs or whether a SARA assessment is planned in the near future that can assist to determine data quality. A full data quality assessment is substantial work and is not within the scope of the epi-review unless specifically requested during development of the agenda. The review can provide indications of potential data quality issues by performing a rapid assessment that can help to identify the need for a formal SARA assessment.

An example of an agenda is shown in Appendix II.

2.4 Preparing the data

In preparation for the actual epi-review, the available data should be compiled in advance. Ideally the data would be sent to the external consultants prior to the in-country visit to check for completeness and perform initial analyses. To facilitate analysis a standardized template, adapted to reflect the administrative levels in the country, could be used.

Key data to be collected are:

- **All available historical national and sub-national TB surveillance data.** This is the routine national TB surveillance data available in the country. It is best to collect all historically available data to assess national trends on the burden of TB, TB/HIV and drug-resistant TB. Data should be collected for each of the administrative levels available disaggregated by age, sex, site of disease and previous history of treatment. The national level data compiled should be compared against WHO annual report data, and reasons for inconsistencies should be clarified. Data from the

subnational level can be used to assess geographical patterns. Countries will have data stratified by the first subnational level (province or region) and many may also have data stratified by lower levels, i.e. district or even health facility level. Geographical Information System (GIS) mapping can be used to visualize geographical patterns of subnational data. For this shapefiles of the administrative levels of the country often are freely available online (for example via http://www.diva-gis.org/gdata). TB mortality data are mostly not routinely available due to a paucity of vital registration systems. In this case WHO estimates can be used. The same holds true for TB prevalence. Although about 20 countries have conducted a TB prevalence survey, only few of them conducted a second survey allowing for TB prevalence trend estimations and only on national level usually. A note of caution to be made is that nearly all national TB prevalence surveys conducted have been powered for national analysis and do not provide accurate subnational results in most cases.

An accurate timeline of key TB events can help to explain observed patterns in the notification data. Therefore, information should be assembled on the occurrence and timing of implementation of new guidelines, introduction of new regimens, roll out of key interventions like community TB care, active case finding initiatives but also changes in the routine reporting system. This information can be obtained from TB control guidelines, annual reports and interviews with expert TB control staff in country.

- **Census data and updates projections per sub region and per age group.** The latest available census information and projections should be collected for the same period that TB surveillance data are available. If new census data are available, provided notification rates should be verified with latest census data or updated projection as this might change the actual figures.

- **All available known TB determinant data (e.g. World Bank indicators, Global Health Observatory indicators).** Besides factors directly related to the TB control program there are also external factors that can influence the TB epidemic like implementation of the HIV program (i.e. HIV prevalence, ART coverage), prevalence of diabetes and other co-morbidities general trends in health care and population health indicators (e.g. under five mortality, availability of health insurance, out of pocket expenditure on health) and economic developments (e.g. GDP, proportion living below the poverty line) that can help explain the observed trends in the TB surveillance data. For most countries such data is compiled on a regular basis (annual, five or ten year interval) and can be found at the World Bank (http://data.worldbank.org/country) or WHO website (http://www.who.int/gho/en/). Diabetes data are available from periodically conducted STEPwise approach to surveillance (STEPS) surveys and can be found for example in the IDF diabetes Atlas (http://www.idf.org/atlasmap/atlasmap). These data are not complete for all countries. These data should be obtained for the same time period as TB surveillance data are available in country to optimally link and assess trends. It is best to obtain this data also before travelling to the country as internet access might not be optimal in all countries.

Add a table of possible data sources and links rather than in text

- **Literature review of research data available for the country.** To gain more insight into the local TB epidemiology and local trends a literature review should be part of the Epi-review. However a full-fledged literature review is a substantial amount of work especially for countries with many

5 More details via: http://www.who.int/chp/steps/en/
publications. During development of the agenda the need for a separate literature review should be discussed and the main objectives of such literature clearly defined and incorporated into the ToR as per the needs of the country. For some countries literature reviews have been done and the results thereof can be updated as part of the epi-review. As a minimum effort a search in Pubmed and other online databases such as Medline, for example, should be done to gain insight into key publications for the country with regards to TB, TB/HIV and drug-resistant TB epidemiology. The following key search terms could be used: TB (or tuberculosis) AND country name with limits on human only and e.g. last 5-10 years. Provide the total number of abstracts found. Subsequently a quick title and abstract scan should be done to exclude fundamental research and select those most relevant for epidemiological assessment. Indicate how many papers are fulfilling these criteria. Papers could be grouped by risk factors, such as age, HIV infection, diabetes, malnutrition, People Who Inject Drugs (PWID), living conditions (i.e. prisoners, contacts, refugees) and occupation, or alternatively grouped by e.g. diagnostics, health service delivery, MDR.

- In summary, the preparatory work that can be done prior to country visit / review is as follows:
  - Send the Checklist of Standards & Benchmarks to NTP for information and preliminary discussion
  - Inquire about NTP TB data notification system (paper or electronic-based system, organisation and format of files)
  - Inquire about the NTP central databases; sometimes the NTP uses excel sheets containing multiple data tables within the same sheets. You will need to identify and isolate the data tables needed for the review and create separate sheets with a single raw data table
  - Inquire about the existence of previous data audits (specific to TB or SARA’s)
  - Download databases (e.g. WHO website, World Bank)
  - Literature review (e.g. published articles on PubMed, reports with national data on TB and non-TB)
  - Ask the NTP for a list of BMUs in the country (to prepare for audit)
  - Ask the NTP for results of surveys (DST, prevalence)
  - Send the NTP a list of documents needed for the review (e.g reports, protocols, guidelines); these can be sent if available in electronic version or prepared ahead of time

3. Part II. In-country mission

3.1 Briefing meeting with key stakeholders
At the start of the mission it is important to meet with the WHO Representative (WR) and the National Profession Officer (NPO) from the WHO country office to brief them on the key objectives of the mission. This is important because these individuals can help to facilitate field visits as well as ensure essential data are obtained in a timely manner. They will also provide relevant information on the current situation on TB surveillance and control activities in the country in terms of challenges and priorities.

A briefing meeting should then be held, usually hosted by the NTP. The NTP should send out invitations in advance to all stakeholders who will participate in the review and perhaps more importantly, uptake the recommendations. The NTP and stakeholders should be briefed by the reviewers on the purpose of the epidemiological review, the activities that will be carried out and the key deliverables. An example of a briefing presentation is shown in Appendix III. During the
briefing presentation the NTP and stakeholders should have the opportunity to raise questions of interest relating to TB surveillance and epidemiological analysis that they would like the reviewers to investigate during the mission if this was not done when finalising the agenda. As previously discussed it may not always be possible to address all requests in the given time frame or with the existing data. If this is the case reviewers should work with the NTP to provide solutions on how to answer these questions in the future, which could be incorporated into the recommendations.

3.2 Finalising the agenda for the in-country mission
An agenda should be developed in advance of the mission but usually it has not been finalised at the start of the mission and should be discussed during the briefing meeting. This discussion is important as it provides an opportunity to ensure that appointments are made with all key stakeholders and reviewers can add or remove activities if necessary. A degree of flexibility is required and reviewers should be prepared that they may have to regularly revise the agenda throughout the mission often due to competing priorities of those who will be interviewed. Furthermore, it often becomes apparent during the mission that some key stakeholders were not included in the original agenda or results from the data analysis sometimes indicate that a specific region may benefit from being included in the review; for example, if inconsistent or unusual trends are observed. If particular stakeholders refuse to participate or there are problems with the general organisation of activities the WR or the NPO should be contacted to help to resolve this. One or more members of the NTP should be assigned to accompany the reviewers on all of the planned visits. This is important for logistics and so that the NTP members can be actively involved in the review process.

3.3 Interviews with NTPs and key stakeholders
Many of the individuals that will be interviewed during the mission will not have been present at the initial briefing meeting. It is therefore important at the beginning of the interview to introduce yourself and explain clearly what the purpose of the mission is, provide an overview of the information you would like from the individual being interviewed and how this information will be used, for example, to make recommendations that will be incorporated into the NSP. The names and job roles of all individuals met should be noted with contact details if available and listed in the report.

It is recommended to begin the interview by leading with an open question on what the interviewee’s role is in TB surveillance and control and to ask them to describe specific processes or activities that they are involved in. Allowing the staff to talk with limited interruptions will usually reveal many interesting aspects of the TB programme that can then be followed up with further questions for clarification. Depending on the individual you are interviewing it is also important to have specific questions in mind that you aim to answer by the end of the interview. This is to ensure that you obtain all the necessary information to carry out an adequate assessment but also helps to keep the interview focused on the topic at hand. At the end of the interview the interviewee should be given the opportunity to raise any other issues that they feel are important to discuss. The interviewee should also be informed that they may be contacted again for further information if necessary and will be given feedback if requested.

3.4 Desk review of all relevant national documents
Ideally the desk review should be carried out on the first day of the mission with key NTP staff in the national team. It is not common to have a dedicated block of time for this activity and it may be necessary to gather the information in stages. It is recommended however to try and complete this at the beginning of the mission as it provides an overview of the entire TB surveillance system,
associated M&E activities and the chronological order of key TB control (and other health control and related) events in the country. A list of all documents required for the desk review should have been sent to the NTP in advance and should have been subsequently prepared. In reality these documents are rarely readily available or pre-prepared but are necessary to complete Part A of the Checklist. Staff should not feel that it is a major criticism if they cannot provide the required documents. It should be made clear to staff that part of this assessment is to identify documents that are missing or are out of date to ensure technical assistance can be provided in the future, if required. Some of the items that are discussed during the desk review, such as frequency of training, frequency of supervision, data quality checks carried out and whether all forms used in the field are standardised, should be verified during the field visits. If this is not feasible in full during the epi-review mission some of this can be taken up by the program review team (if this is following the epi-review).

3.5 Field visits
Field visits to clinics, laboratories and sub-national M&E staff are important in order to understand the flow of data from the facility to the national level, to observe M&E activities in the field, to examine the recording and reporting forms and surveillance systems in use, to interview staff diagnosing and treating childhood TB, TB-HIV, MDR-TB, to carry out an assessment on data quality as part of the Standards and Benchmarks assessment and to gain an understanding of the vital registration system and the work carried out by NGOs working in collaboration with the NTP. The field visits should be organised by the NTP and usually more than one site can be reached in a day. Most interviews take around 1-2 hours. The following field visits relating to the Standards and Benchmarks assessments are recommended:

- Clinics and associated source laboratories in a rural low TB burden and an urban high TB burden clinic
- TB-HIV clinic
- Paediatric TB clinic or hospital
- MDR-TB clinic
- National Reference Laboratory
- Key NGOs and partners
- Vital statistics and/or population statics division or equivalent

The purpose of the clinic visits is not to carry out a comprehensive assessment that is nationally representative but more to get an understanding of the issues in TB surveillance, data flow and data quality. A comprehensive assessment can be added to the recommendations if the reviewer feels that it is necessary based on findings. The clinic visits usually take 3-4 hours. The reviewers should factor in travel time and road conditions including traffic, road blocks and weather when planning the agenda. It is common that due to unforeseen circumstances not all appointments will be kept and may have to be rescheduled.

The rural clinic should be selected based on somewhere that can be reached and returned from in one day before it gets dark. For UN staff and consultants employed by WHO formal clearance is usually required prior to embarking on the rural visit. If with another organisation there may be other clearance procedures that should be followed before visiting some areas and this should be checked in advance. The rural visit usually takes longer than expected and reviewers may often return in the dark as a consequence. It is up to the reviewer to decide whether it is safer to make the return journey or stay overnight.
Due to the large number of visits required in a short time frame it is best, if possible, to get an assigned vehicle for the duration of the mission, otherwise logistically it is difficult to keep to the schedule. For UN staff and consultants employed by WHO a request should be submitted by the reviewers to the NPO on the first day. Again, depending on the organisation, a request may be submitted to other parties to secure a vehicle. Although it may be tempting, due to time constraints, for the reviewers to split up to cover more sites, both reviewers are required for the clinic and lab visits in particular due to the extensive work load. It is recommended that the assigned member of the NTP should be actively engaged in the data quality assessment and should prepare the reports received at national level prior to the clinic visits so that numbers reported can be compared against the TB registers.

If visiting a hospital it is common that you will be asked to meet with the hospital director to explain the purpose of your mission and you will be expected to provide feedback at the end of the assessment. Often you may be asked to look at other aspects of TB treatment within the clinic such as infection control. It is therefore important to clearly and firmly outline the activities that will be carried out during the visit and remain focused on the immediate tasks.

### 3.6 Analysis of surveillance data

It is crucial that a sufficient amount of time is allocated for data analysis. At least four days is required to complete data analysis. Ideally data should be obtained ahead of the mission. If this has not been done then the earlier that the data is obtained in the mission the better as usually substantial amounts of data validation and cleaning is necessary. The NTP should be asked to prepare the TB surveillance data and population data from the earliest year available in advance. In low income countries is it rare that data are already available in a single database required for time trends analysis and the reviewers may be presented with multiple excel sheets of data which they will be required to combine in a standardized format. Please note: it may also be the case that (especially) in earlier years data will have to be entered from hard copies of annual reports if available. Other data on TB-HIV, MDR-TB, mortality data and any results from active case finding or surveys are usually obtained during the mission. Analysis should be split between the two reviewers and if possible, the local team, and should cover all key indicators outlined in the ToRs (Appendix I).

### 3.7 De-briefing meeting

Prior to the final de-briefing meeting a de-brief should be held first with the NTP to ensure all data has been correctly interpreted and to get input for explaining some trends observed for which there is no obvious explanation.

A debrief should then be held separately with the WR and the NPO. This is to inform them of the main findings from the Standards and Benchmarks assessment and the epidemiological analysis and to discuss the associated recommendations and whether they are happy to support the related activities. They may also wish to add some recommendations. This feedback is usually given verbally in a 30 minute meeting.

Half a day at the end of the mission should be put aside to formally de-brief the NTP along with the key stakeholders. This feedback is best delivered as a presentation (Appendix IV). At this meeting recommendations and related activities that will be incorporated into the investment framework should be discussed. It is therefore crucial that all key stakeholders that are anticipated to uptake these recommendations attend the meeting. During this meeting the NTP and key stakeholders are given the opportunity to discuss the recommendations in detail, express whether they agree with them or not and suggest changes. The reviewers should be open minded to discussing and changing the
recommendations. At the same time reviewers should not feel pressured to recommend something that cannot be realistically achieved in the current environment, is not following the evidence provided or that is contrary to practices recommended in international guidelines. The reviewers should be aware that some recommendations suggested in this meeting may be political rather than being based on scientific evidence. The reviewers should diplomatically discuss these sensitive issues but should also stress that without scientific evidence these recommendations will not be included in the epidemiological review.

4. Part III. Follow-up

4.1 Report compilation and submission

The main deliverable from the epi assessment is a comprehensive, written report to be shared with the NTP, WHO country office, WHO Geneva, and other stakeholders, as authorized by the NTP. As this report will be used to inform Joint Monitoring Missions, program reviews, and Global Fund concept notes, the report should follow a prescribed template for epi-reviews. The outline that should be followed is found in Appendix IV. You may wish to review reports from past epi assessments to ensure comparability of your report. Due to the standardization of epi assessments, portions of the report, such as purpose and methods, may be identical, or almost identical, for each country.

It is advisable to complete a first draft of this report during the mission as it is expected that you will share your findings in an oral debrief with the NTP and local partners, and/or program review team, at the conclusion of your trip. To expedite the process of completing the report, you may wish to complete some components prior to arriving in country for the epi assessment (e.g., introduction, purpose, methods). It is particularly advisable to see if you can complete portions of the Standards and Benchmarks tool and epidemiological assessment as part of a desk-review prior to your visit in country.

A draft report should be shared with the NTP no later than two weeks following the epi assessment. The final draft, which should incorporate feedback from the NTP, should be sent to all designated partners no later than three weeks after the conclusion of the epi assessment.

4.2 Ownership, publication and sharing policy of review content and report

Epidemiological assessments provide critical information used by multiple stakeholders for a variety of purposes at national and global level. Each stakeholder has a vested interest in the outcomes and use of the report. For example, National TB Programs and Ministries of Health may use the assessments for internal evaluation and planning purposes and to prioritize interventions to improve epidemiological data, while donors and technical partners may use them to direct investments and allocate technical assistance resources. The technical assistance providers who support NTPs to conduct epidemiological assessments also have a long term interest in the recommendations, since they may be well placed to provide follow up support. These interests are often complimentary, but may be occasionally be in conflict with each other.

Ultimately, National TB Programs and Ministries of Health own the epidemiological assessments conducted in their countries. Expectations about the finalization of and the distribution of the report should be made clear during the planning process to avoid conflict after the exercise is complete. A process for resolving differing opinions on the final results and recommendations should be proposed and agreed upon during the planning process. Additionally, stakeholders should describe how they...
intend to use the results of the report early in the process to avoid surprises and conflict as the epidemiological assessment is concluding.

For example, if the assessment is undertaken under the auspices of the WHO TB Global Programme’s technical support to countries, the final report is likely a key deliverable to the donor (e.g., USAID) who financially supports this unit at WHO. Thus, it should be understood that copies of the report will be maintained in Geneva headquarters and made available to the donor on request. Additionally, when the results of an epidemiological assessment are developed into a manuscript for publication in a peer review journal, discussions about authorship and expectations about in-country review should be made clear. Likewise, technical assistance partners undertaking the assessment should communicate directly with the NTP regarding any concerns about sharing the final draft.

The following list includes potential internal and external stakeholders who should be included in the sharing policy for an epidemiological assessment. This list is not meant to be comprehensive and should be adapted according to each country’s unique circumstance.

**List below to be made more generic**

**Key internal audiences**

- National TB Program
- Ministry of Health
  - Department of Epidemiological Surveillance
  - Infectious Diseases Program
- TB focal points at US Government agency country offices
  - Centers for Disease Control and Prevention
  - United States Agency for International Development
- TB focal point at WHO country office
- Key technical partners operating in the country

**Key external audiences**

- Global Fund Portfolio Manager
- TB focal points at US Government agencies
  - Centers for Disease Control and Prevention
  - United States Agency for International Development
- WHO Tuberculosis Monitoring and Evaluation Unit

### 4.3 From recommendation to funding allocation and finally implementation

TB epi-reviews have a very important place in the development of concept notes for the NFM of the Global Fund, for guiding key programmatic decisions and strategic investment, by serving a vital purpose of informing the following areas;

- **Input for NSP**
  A key principle of the NFM is the support on disease-specific NSPs that are robust, evidence based, prioritized and costed, which are country-owned and provide the overall strategic direction for a country over a period of time (usually five years). A robust NSP should be derived from clear and
relevant priorities and strategies, and based on a sound situation analysis and should also have gone through a well-defined and inclusive development and endorsement process. As part of these processes, applicants need to conduct an epidemiological review using standard tools and methodology. It should happen according to country timeframes, with the support from relevant technical partners. The potential benefits of epi-reviews are: improved quality and consistency of national strategies; improved strategy development and implementation processes, including stakeholder involvement, and renewed focus on national strategies as a basis for alignment and harmonization. From a Global Fund perspective, it may also lead to increased confidence in the priorities reflected in a funding request and their potential impact.

- Input for different components of the concept note:
  - For programmatic gap analysis
    - Epi-reviews serve as important tool for a gap analysis of existing programs in prioritizing interventions. This is a key step to ensure that prioritized interventions are fully costed. This process has made the concept note development process much smoother and tailor made. The programmatic gap analysis provides the underlying rationale why priority modules are being requested from the Global Fund, as it provides information on the overall need, the proportion of need already being covered, and the proportion of the need that is proposed to be covered by Global Fund funds. Focused on program coverage, it allows the applicant to position all of the Global Fund financing (including existing funding, the allocated amount, and the request above the allocated amount) within the national coverage gaps identified.
  
  - Input for country context section
    - Epidemiologic information is discussed in detail in this section with emphasis on the programmatic progress, success and major gaps. The findings from epi-analysis are vital to summarize the current and evolving epidemiological situation and profile of the disease, and if and how the response has changed recently due to changes in epidemiological evidence (including changing incidence or prevalence). It tries to analyse the link between the epidemiology of the disease and drivers of the epidemic, the type of epidemic, and what population groups are most affected. An important set of information also includes explaining any changes in disease mortality, morbidity, disease risk, incidence or prevalence which may explain the trends in TB burden. It emphasizes the focus on key geographic settings and populations where rates of transmission and unmet need services are high in the country. A description of how the epidemic affects these populations, in particular populations that have disproportionately low access to services, why these populations are affected, and any improvement or deterioration in disease outcomes is included. Epi-reviews also help to explain the relevant data sources and any weaknesses in the surveillance system and how to address them.

- As input for funding allocation
  - Impact was one of the qualitative factors for allocation in NFM. The impact qualitative factor is defined as progress made by a Global Fund supported program in reducing mortality and morbidity of the disease to meet the 2015 MDGs /international targets. It leads to an adjustment of 0-15% of the formula-based allocated amount for each disease component. Epidemiologic reviews were used as key source of data for measuring impact, providing estimates of disease burden as well as key coverage and outcomes indicators.

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6 The Global Fund; Resource book for Applicants, February 2015
Significance of epi-review in the new funding model

Experience of GF country teams on using recommendations for action

According to the experience from GF supported country teams, TB epi-reviews have been highly informative about epidemiologic situation providing clear analysis of the context on service coverage, treatment outcome and highlighting gaps in the surveillance system. In most cases, it pursues a well-coordinated process involving high level technical assistance (TA) whilst ensuring a participatory process that engages all key partners. It has been demand driven by NTPs which guarantees ownership from the outset. The fact that it covers TB and HIV issues makes it a perfect fit for informing joint TB/HIV concept notes. The analysis is done in a robust way which is an important step to produce SMART recommendations which many concept notes benefited from.

Some of the challenges, based on the experience of the countries that went through an epi-review, is that the findings were not optimally utilized as much input, resource and technical expertise is invested in them. Besides, most of the time the reports were not made available in time, with considerable delay in submitting the final report. This creates a scenario where the delayed reports end up in shelf, without proper utility. Some countries have made use of results of epi-reviews for planning purposes, especially for NSPs and concept notes, however there are not many success stories in terms of its use for implementation and monitoring.

Specific Country examples

GF country teams joined the TB epi-review team in Sierra Leone in October 2015 and also in Liberia in September 2015. The implementation of the TB epi-review was extremely valuable to both countries at a time when they were emerging from the Ebola Virus Disease (EVD) outbreak which had a substantial negative impact on the implementation of TB interventions and on reporting.
In both countries, the epi-review has highlighted key needs to the TB Program in terms of implementation and opportunities for TA. To mention specific examples of the findings and follow up in Liberia: the findings of the epi-review have resulted in the identification of TA needs which WHO is helping the Program to fill in with the financial support of the GF (for example on epidemiology and also the programmatic management of MDR-TB), it has also resulted in the support to the DHIS 2 team to develop a case-based reporting for MDR-TB patients and the implementation of a TB situational analysis that we are co-financing with the support of WHO.

The follow up of WHO with Programs and the GF after the epi-review to ensure that the recommendations are implemented is commendable, and have allowed the GF to direct funding to key necessary activities to improve data and Program implementation.

The only recommendation for improvement for future reviews is related to the timing. In both countries the main donor to the TB Program is the GF. Thus, it would be great to plan the epi-reviews taking into account the timelines for the country to apply for GF funding. In both countries the reviews were undertaken after the submission of the proposal to the Global Fund which made it difficult for the country to integrate the findings identified into the GF proposal. In the case of Liberia, the PowerPoint debrief shared by Epi-review team with the country was available for grant negotiations and we used it as the basis for the negotiations. In the case of Sierra Leone the epi-review took place the same week that the CT was in Sierra Leone for negotiations of the TB grant which meant that findings were not included in the new grant and are currently being incorporated as part of the negotiations of the above allocation portion. For future epi-reviews, WHO should contact the GF in advance in order to align the timelines of the epi-review with the timelines for application submission.

Experience on data use in NSP development

Since an updated disease program NSP was a prerequisite for concept note submission, all high TB burden countries have updated strategic plans based on program reviews. All funding applications are required to include analysis of the current and evolving epidemiology of the disease any significant variations among geographic areas and population groups in disease risk, prevalence or mortality.

Examples:

- Nigeria TB program review revealed serious limitations in TB case detection, while treatment success among detected cases was very high.
  - The primary focus of the current TB strategic plan is therefore, improving access - expanding TB diagnostic services in primary health care facilities.

- On the contrary, the Uganda TB program review revealed a high rate of loss to follow up among cases on TB treatment, highlighting the need to improve quality of care.

5. Part IV. Common findings from TB epidemiological reviews

Objective 1. Results from TB surveillance checklist of standards and benchmarks

Between January 2013-June 2015 the Standards and Benchmarks checklist was completed in 41 countries; 18 high and 23 low TB burden countries (Figure 1). Two countries (South Africa and Saudi Arabia) only carried out a Standards & Benchmarks assessment and did not carry out the full epi review. The results from Part A are shown in Table 1. The majority of countries assessed have
paper based surveillance systems collecting aggregate data through standardised forms on a quarterly basis. Most countries had guidelines on recording and reporting but in many countries some care providers did not report to the NTP. Although most countries verified data for accuracy, timeliness and completeness from the service level upwards, mainly through supervisory monitoring missions, there appeared to be little systematic feedback on data quality from upper to lower levels. Many countries did not have a training plan in place and did not carry out routine training. More than half of countries did not have an epidemiologist and almost 40% did not have a database manager in the national team.

**Figure 1. Countries where the Standards and Benchmarks checklist has been used (n=41)**

![Map showing countries](image)

**Table 1. Characteristics of TB surveillance systems for 41 countries that undertook the Checklist**

*Categories are not mutually exclusive

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How are data recorded for individual TB cases at the service delivery level, e.g. in TB diagnostic units, health centres, clinics? *</td>
<td></td>
</tr>
<tr>
<td>Data are recorded electronically on a national internet-based system</td>
<td>17</td>
</tr>
<tr>
<td>Data are recorded electronically on a state/provincial/regional internet-based system</td>
<td>17</td>
</tr>
<tr>
<td>Data are recorded electronically on a local system</td>
<td>27</td>
</tr>
<tr>
<td>Data are recorded on paper</td>
<td>90</td>
</tr>
<tr>
<td>Data are not recorded</td>
<td>0</td>
</tr>
<tr>
<td>Do all service delivery points systematically use standardised TB data collection forms and tools?</td>
<td></td>
</tr>
<tr>
<td>Yes, completely</td>
<td>83</td>
</tr>
<tr>
<td>Mostly</td>
<td>15</td>
</tr>
<tr>
<td>Partially</td>
<td>0</td>
</tr>
<tr>
<td>No, not at all</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Which TB cases are included in the national TB surveillance data? *</td>
<td></td>
</tr>
<tr>
<td>All TB cases from all parts of the country</td>
<td>46</td>
</tr>
<tr>
<td>Some TB cases are excluded</td>
<td>54</td>
</tr>
<tr>
<td>Some part(s) of the country are excluded</td>
<td>7</td>
</tr>
<tr>
<td>Some case types are excluded</td>
<td>7</td>
</tr>
<tr>
<td>Some care providers, e.g. non-NTP providers, prisons, private practitioners, are excluded.</td>
<td>41</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
</tr>
<tr>
<td>Unknown</td>
<td>7</td>
</tr>
<tr>
<td>What types of TB data are available at the national level? *</td>
<td></td>
</tr>
<tr>
<td>Patient level data that allow multiple episodes of TB in the same person to be identified are available</td>
<td>12</td>
</tr>
<tr>
<td>Case level data are available for all of the country</td>
<td>17</td>
</tr>
<tr>
<td>Case level data are available for parts of the country</td>
<td>12</td>
</tr>
<tr>
<td>Aggregated data are available, i.e. summaries for groups of cases.</td>
<td>78</td>
</tr>
<tr>
<td>What is the expected frequency of data transmission from the first sub-national administrative level to the national level? *</td>
<td></td>
</tr>
<tr>
<td>Real-time</td>
<td>17</td>
</tr>
<tr>
<td>More often than monthly</td>
<td>2</td>
</tr>
<tr>
<td>Monthly</td>
<td>27</td>
</tr>
<tr>
<td>Quarterly</td>
<td>78</td>
</tr>
<tr>
<td>Less often than quarterly</td>
<td>5</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
<tr>
<td>At what levels of the system are TB data systematically verified for accuracy, timeliness and completeness? *</td>
<td></td>
</tr>
<tr>
<td>From the service unit upwards</td>
<td>61</td>
</tr>
<tr>
<td>From the 1st administrative level upwards</td>
<td>12</td>
</tr>
<tr>
<td>From the 2nd administrative level upwards</td>
<td>5</td>
</tr>
<tr>
<td>Only at the national level</td>
<td>5</td>
</tr>
<tr>
<td>Not at any level</td>
<td>0</td>
</tr>
<tr>
<td>What types of quality assurance procedures are systematically undertaken for TB data? *</td>
<td></td>
</tr>
<tr>
<td>Quality controls are in place for the electronic surveillance system (automated checks at data entry and batch checking, plus SOPs)</td>
<td>34</td>
</tr>
<tr>
<td>Data are reviewed during supervisory monitoring visits to service units and sub-national levels</td>
<td>93</td>
</tr>
<tr>
<td>Data are reviewed during meetings with TB staff</td>
<td>66</td>
</tr>
<tr>
<td>Other</td>
<td>15</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
</tr>
<tr>
<td>Is feedback on TB data quality systematically provided to all lower reporting levels?</td>
<td></td>
</tr>
<tr>
<td>Yes, completely</td>
<td>37</td>
</tr>
<tr>
<td>Mostly</td>
<td>20</td>
</tr>
<tr>
<td>------------------------</td>
<td>----</td>
</tr>
<tr>
<td>Partially</td>
<td>29</td>
</tr>
<tr>
<td>No, not at all</td>
<td>7</td>
</tr>
<tr>
<td>Unknown</td>
<td>8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When are national TB case data for a given calendar year considered ready for national analyses and reporting?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before April the following calendar year</td>
</tr>
<tr>
<td>Before May the following calendar year</td>
</tr>
<tr>
<td>Before June the following calendar year</td>
</tr>
<tr>
<td>On or after beginning of June the following calendar year</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Are there national guidelines for recording and reporting of TB data, e.g. documentation or instructions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes. They are posted on the internet.</td>
</tr>
<tr>
<td>Yes. They are available in a manual or other reference document, e.g. training materials</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does the national TB programme have a training plan which includes staff involved in data collection and reporting at all levels of the reporting process?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How often do TB programme staff receive training specifically on TB surveillance, i.e. recoding and reporting of TB data?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training is routinely received at national and sub-national levels</td>
</tr>
<tr>
<td>Training is received on an ad hoc basis</td>
</tr>
<tr>
<td>Staff receive training when they are hired</td>
</tr>
<tr>
<td>No routine training is received</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How many staff work on TB surveillance at the national level?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
</tr>
<tr>
<td>3-4</td>
</tr>
<tr>
<td>≥5</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is there an epidemiologist at the NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is there a database manager at the NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Question</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Is a national TB surveillance report routinely produced and disseminated on an annual basis?</td>
</tr>
<tr>
<td>Are there written goals of the surveillance system?</td>
</tr>
<tr>
<td>Policies and procedures are in place to protect the confidentiality of all surveillance data e.g. records, registers.</td>
</tr>
<tr>
<td>Is there a long term financial plan and budget in place to support TB surveillance activities?</td>
</tr>
<tr>
<td>When was the last time the TB surveillance system was evaluated?</td>
</tr>
</tbody>
</table>

The results from Part B of the Standards and Benchmarks assessment is shown in Figure 2. The majority of countries had case definitions which were consistent with WHO guidelines (34 met) and had surveillance systems that captured a minimum set of variables (26 met). Some countries were still reporting to the 2006 WHO case definitions\(^7\) and had not updated their recording and reporting tools to be in line with 2013 WHO case definitions\(^8\). Most countries also met or partially met benchmarks which assessed whether all scheduled periodic data submissions had been received and processed at national level, whether data was externally consistent and if surveillance data directly measured drug-resistant TB in new cases and prevalence of HIV infection in TB cases. Where these benchmarks were not met common problems included a lack of tools to easily record whether quarterly reports had been received and delayed reports had no active follow up, under-diagnosis or under-reporting of childhood TB, no routine diagnosis of drug-resistant TB or adequate surveillance system where data were not

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\(^7\) [http://www.who.int/tb/dots/r_and_r_forms/en/](http://www.who.int/tb/dots/r_and_r_forms/en/)

\(^8\) [http://apps.who.int/iris/bitstream/10665/79199/1/9789241505345_eng.pdf](http://apps.who.int/iris/bitstream/10665/79199/1/9789241505345_eng.pdf)
shared between the lab and the treatment centre, low levels of HIV testing and poor integration of TB and HIV programmes for diagnosis and treatment.

Many countries did not meet the benchmarks which assessed data quality, internal consistency and under-reporting usually due to a lack of systematic supervision at the sub-national level, no validation checks at the national level, no routine meetings where data are reviewed, a lack of capacity for data analysis and no inventory study, all of which have led to poor quality data. A common finding was that cases who died or were lost to follow up before starting on treatment were not notified. Bacteriologically confirmed cases were also not always notified e.g cases diagnosed by the lab but did not appear in the TB register if they did not start on treatment, and there was no cross referencing between laboratory and clinical registers. Patients from the private sector were also often missed and the NTP were often unaware of the number of private clinics treating TB in the country and which were integrated into the TB programme. Only one country met the benchmark which assesses whether data are reliable and accurate for childhood TB. The majority of countries did not disaggregate data by age to capture 0-4 years olds and 5-14 year olds separately which is required to assess this benchmark. Small data audits in several countries also suggested substantial under-reporting of children due to poor recording and reporting and weak referral systems which means that patients cannot be easily followed up. Often guidelines for diagnosis and treatment of paediatric TB did not exist and there was no focal person in the country to lead on paediatric TB. Other benchmarks that were not met in most countries were outside the direct control of the TB programme; access to health care and the existence of a vital registration (VR) system. Where vital registration systems did exist often the NTP had never had any contact with staff responsible for VR and were unaware of the data that was being collected.
Objective 2. Results from TB surveillance data (national and sub-national)

Epidemiological reviews were carried out in 48 countries. In 9 countries the Standards and Benchmarks assessment was not included. In several francophone African countries an epidemiological review had been attempted but the standard ToRs were not used because documents had not been translated into French.

The majority of epi-reviews have been carried out by WHO and in particular by those in TB Monitoring and Evaluation at HQ, Geneva (Table 2). To date, several other partners have been involved such as technical agencies KNCV, CDC and RIT, NGOs, funding bodies and Public Health
Institutions. The majority of reviews were carried out by more than one individual. Only 3 NTPs have been involved so far in the analysis and report writing or in leading the review but we would like to encourage more involvement because it give NTP an opportunity to gain experience and build capacity in this sort of assessments. Where the capacity is not available in the NTP it is good to engage with Universities or other research partners to strengthen collaborations between the NTP and Universities for future operational research to better understand the TB epidemic.

There are ToRs which clearly outline variables and indicators to be used in the epidemiological analysis of routine TB data (Appendix I) as well as the guide on Understanding and Using TB data which provides guidance and practical examples of analysis that can be carried using routine TB surveillance data. 21/46 epidemiological reviews were assessed for whether the ToRs had been followed (Table 3). In more than 70% of reviews examined analysis was carried out on the following: time trends (100%), age including childhood TB, site of disease, sputum smear status, treatment history, sub-national level analysis including rates using population data, HIV testing and prevalence of HIV in TB patients and treatment outcomes. It is unclear whether the data were not available for the countries where this analysis was not carried out or whether the ToRs were not followed by the reviewer. Analysis of rifampicin resistant data was less common than for MDR-TB (28%). Only 19% of reviews made use of laboratory data and presented data by bacteriologically confirmed cases in line with 2013 WHO case definitions. Only one review made use of active case finding data in high risk groups and no reviews reported the use of a unique ID which could be used to link clinical and laboratory data.

Analysis of trends at sub-national level commonly showed inconsistencies in data suggesting issues with recording and reporting. Data had not been examined routinely by the NTPs in the past in most instances and so it was the first time they were made aware of such issues which then required further investigation in order to interpret the data. Treatment outcome was also extremely variable at sub-national level for most countries and the reasons for this had not been investigated. In some instances there were inaccuracies in reporting where proportions of treatment success had been calculated out of those with a reported treatment outcome rather than out of the total notifications for that year, thus inflating the treatment success rate. In other cases there were more treatment outcomes than notifications due to lack of data validation.

---

Table 2: Organisations involved in epidemiological reviews and the number of reviews they have been involved in

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO</strong></td>
<td></td>
</tr>
<tr>
<td>HQ</td>
<td>14</td>
</tr>
<tr>
<td>EURO</td>
<td>8</td>
</tr>
<tr>
<td>EMRO</td>
<td>2</td>
</tr>
<tr>
<td>WPRO</td>
<td>1</td>
</tr>
<tr>
<td>AFRO</td>
<td>1</td>
</tr>
<tr>
<td>PAHO</td>
<td>1</td>
</tr>
<tr>
<td>Liberia</td>
<td>1</td>
</tr>
<tr>
<td>Kenya</td>
<td>1</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>1</td>
</tr>
<tr>
<td>Uganda</td>
<td>1</td>
</tr>
<tr>
<td>TDR</td>
<td>1</td>
</tr>
<tr>
<td>Consultant</td>
<td>4</td>
</tr>
<tr>
<td><strong>Public Health Institutions/Funding agencies</strong></td>
<td></td>
</tr>
<tr>
<td>KNCV</td>
<td>7</td>
</tr>
<tr>
<td>CDC</td>
<td>4</td>
</tr>
<tr>
<td>RIT, Japan</td>
<td>4</td>
</tr>
<tr>
<td>PHE, UK</td>
<td>2</td>
</tr>
<tr>
<td>NICD, South Africa</td>
<td>2</td>
</tr>
<tr>
<td>MSH</td>
<td>2</td>
</tr>
<tr>
<td>USAID</td>
<td>1</td>
</tr>
<tr>
<td>IUTALD</td>
<td>1</td>
</tr>
<tr>
<td><strong>National TB Programmes</strong></td>
<td></td>
</tr>
<tr>
<td>Mongolia</td>
<td>1</td>
</tr>
<tr>
<td>Swaziland</td>
<td>1</td>
</tr>
<tr>
<td>South Sudan</td>
<td>1</td>
</tr>
<tr>
<td><strong>Universities</strong></td>
<td></td>
</tr>
<tr>
<td>University of Philippines</td>
<td>1</td>
</tr>
<tr>
<td>Ghana College of Physicians and Surgeons</td>
<td>1</td>
</tr>
<tr>
<td><strong>MoH</strong></td>
<td></td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>1</td>
</tr>
<tr>
<td>Swaziland</td>
<td>1</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>THINK South Africa</td>
<td>2</td>
</tr>
<tr>
<td>Independent consultant</td>
<td>4</td>
</tr>
</tbody>
</table>
This will be completed for all 48 reviews at a later stage

Table 3: Analysis carried out as part of epidemiological reviews (n=21)

<table>
<thead>
<tr>
<th>&gt;70% of reviews</th>
<th>50-70%</th>
<th>30-50%</th>
<th>&lt; 30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time trends</td>
<td>Sex</td>
<td>Presumptive TB</td>
<td>Rifampcin resistance</td>
</tr>
<tr>
<td>Age, including childhood TB</td>
<td>Treatment of TB-HIV co-infected patients with ART and CPT</td>
<td>Laboratory confirmed MDR-TB</td>
<td>Laboratory data</td>
</tr>
<tr>
<td>Site of disease</td>
<td>Treatment of TB-HIV co-infected patients with CPT</td>
<td>Proportion of confirmed MDR-TB started on treatment</td>
<td>Bacteriologically confirmed</td>
</tr>
<tr>
<td>Sputum smear status</td>
<td>Treatment outcomes of drug resistant TB</td>
<td>Treatment delay</td>
<td>Symptoms and duration</td>
</tr>
<tr>
<td>Treatment history</td>
<td></td>
<td></td>
<td>Treatment given and side effects</td>
</tr>
<tr>
<td>Sub-national level analysis including rates using population data</td>
<td></td>
<td></td>
<td>Number of contacts screened (total and in children)</td>
</tr>
<tr>
<td>HIV testing</td>
<td></td>
<td></td>
<td>Number of contacts positive for TB</td>
</tr>
<tr>
<td>Prevalence of HIV in TB patients</td>
<td></td>
<td></td>
<td>Number of contacts placed on isoniazid preventative therapy</td>
</tr>
<tr>
<td>Treatment outcome</td>
<td></td>
<td></td>
<td>Risk factors such as prison, diabetes, health care workers, migrants, smoking, alcohol and occupation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>BCG</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Culture conversion at the end of treatment,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Source of referral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Demographic and clinical details for MDR-TB patients</td>
</tr>
</tbody>
</table>

Objective 3. Results from external, but related to, TB factors
While establishing direct causality for determinants of TB is not something that can be accomplished within the context of TB epidemiological reviews, hypothesizing the plausibility of an association, or not, is a desirable outcome of the process (Appendix I, Objective 3). Chapter 4 of the WHO handbook for understanding and using tuberculosis data provides advice on how to set up a conceptual framework of an ecological analysis of determinants of TB and how these affect disease burden. An example of such a framework is shown in Figure 2 with many more examples in the handbook.
Figure 2: Conceptual framework on which direction factors associated with TB are expected to drive disease burden

A table will be added summarising the data that has been used in epi reviews to meet this objective

Objective 4. Investment framework of activities to strengthen surveillance and directly measure disease burden

Examples of activities from investment frameworks of completed TB epidemiological reviews, grouped in broad themes defined in the surveillance checklist of standards and benchmarks, are presented in this section.

Data quality
- National guidelines for recording and reporting of TB data should be available.
- All data reporting tools should be in line with WHO 2013 definitions and reviewed to ensure consistency.
- An assessment of training needs for TB recording and reporting should be carried out at local levels. Conduct necessary trainings to ensure successful uptake and implementation of new data collection tools.
- Standardised quantitative supervisory checklist for supervisors can be developed and used to carry out data quality checks at the facility level. This should include completeness and accuracy checks on key variables and cross-checking of laboratory, TB suspect and TB registers to ensure all cases are notified and followed up. Findings should be fed back to the national level at quarterly meetings.
- Standard templates for quarterly reporting and data presentation which should be developed and used to include key epidemiological and data quality indicators that can be monitored over time.
- Templates can be used by local TB supervisors to assist in feedback to facilities on data quality. Comparative analysis between health facilities may be beneficial.
- A tool can be developed using Excel and used to monitor timeliness of reports received at the national level should be implemented.
- Conduct a national-level data quality audit to systematically assess data quality and identify sources of under reporting (if any). This would preferably be done as a TB component of a Service Availability and Readiness Assessment (SARA).

Use and analysis of TB surveillance data
- A descriptive epidemiology annual report should be produced on a yearly basis using data from the previous year.
• TB staff should prepare presentations in advance for routine meetings (e.g. quarterly meetings) using a standard template developed by the national team.
• TB staff should carry out routine analysis by facility and provide feedback.
• TB staff should undertake training on updated recording and reporting tools, data quality and supervisory checklist, data analysis and computing skills.
• Staff should use handbook on understanding and using TB surveillance data and send one representative to participate in WHO regional workshops for analysis of TB data.

**Human resources**

• Ensure sufficient staff at national level, to include at least 1) epidemiologist(s) 2) database manager(s), 3) M&E officer(s), 4) IT staff, to support strengthening and updating of the surveillance system and to increase analysis and use of national data.

**National TB surveillance system**

• Case-based electronic recording and reporting system should be implemented\(^\text{10}\) and in line with WHO 2013 definitions and any paper forms used by the programme.
• Use a national identification number as unique number in electronic TB registers and databases.
• Ensure appropriate patient confidentiality and data protection standards.

**Improve direct measurement of TB disease burden**

• TB should be a notifiable disease. All private providers should report to the TB programme.
• All bacteriologically and clinically confirmed TB cases should be notified, including initial defaulters and cases that die prior to starting on treatment.
• Implement a standard referral register in all facilities and establish a system to ensure that all referred cases are followed up and receive TB treatment. All referred cases lost to follow up should be notified in the TB register of the referral centre.
• Make an initial assessment of the number of cases diagnosed and treated in the private sector by producing a list of all private clinics by district (already completed by the private sector) and carry out an audit on the number of TB cases seen at each clinic within a given time period.
• Monitor the level of under-reporting over time through inventory studies to directly assess under-reporting of cases, assess unmet needs for PPM and to improve the estimation of TB incidence.
  - The mapping of health providers necessary in an inventory study will facilitate linkage with and expansion of PPM activities.
  - Monitor and address under-reporting of TB in children through inventory studies by linking with pediatric and private hospitals and clinics and and evaluate the quality of diagnostic practices.
• In high TB burden settings and where recommended\(^\text{11}\) and feasible, consider conducting a national TB prevalence survey, which provides data that directly measure TB prevalence and inform estimates of TB incidence. The prevalence survey can also be used to:
  - Identify and map high risk groups for TB (“know your epidemic”) and assess the barriers to health care these groups face. Subsequently, work to improve access to health care, specifically for TB, among those identified to be high risk groups for TB.
  - Understand the extent of unknown or undiagnosed cases and the characteristics of these cases. Alternatively, a delay in diagnosis survey may be undertaken to understand the length of time persons with TB remain undiagnosed and untreated.


TB mortality
- TB mortality should be monitored through routine causes of death registration in a vital registration system and/or by conducting a TB mortality survey to provide estimates for deaths due to TB.
- Improve the accuracy and completeness of mortality data to better estimate TB mortality by strengthening reporting of causes of death in hospitals through training and assessing accuracy of coding (ICD-10).

Childhood TB
- Develop national guidelines for the diagnosis and management of childhood TB, including M and E activities, and roll out with appropriate training.
- Identify a clinical focal person for childhood TB to work closely with the NTLP for the development of guidelines and to provide expertise in this area.
- Introduce a robust referral and feedback system to allow active follow up children to ensure continuity of treatment and care and recording of treatment outcome.
- Ensure close monitoring of childhood TB surveillance activities through dedicated M and E supervision, including TB-HIV co-infection rates by geography.
- Introduce routine household source contact tracing and contact tracing of adults focusing on potentially exposed children.

Drug resistant TB
- Routine testing for drug resistant TB should be carried out on high-risk groups. Consider using GeneXpert. The number of GeneXpert machines required should be based on the expected number of cases.
- Supply chain should be established to ensure all antibiotics are available.
- Sufficient number of clinicians should be trained in the treatment of MDR-TB at national level.
- An expert in MDR-TB programme management should be recruited to co-ordinate all activities in the country ranging from clinical and laboratory training, diagnostics, treatment, contact tracing and active case finding.
- An electronic case-based MDR-TB surveillance system should be established. A unique patient identifier should be used to link patients in the system.
- Routine data analysis should be carried out to closely monitor the MDR-TB situation.
- Conduct a national drug resistance survey using standard methodology such that surveillance data can provide a direct measure of drug resistant TB in new cases.

TB-HIV
- The TB programme should collaborate closely with the National AIDS Control Programme in the ministry and the National AIDS Secretariat to strengthen coordination of TB-HIV activities.
- Recording and reporting tools should be aligned between the 2 programmes e.g TB variables collected in HIV registers and HIV variables collected in TB registers.
- Validation of data across registers should be undertaken by district supervisors.
- To ensure surveillance data provide a direct measure of the prevalence of HIV in TB cases, expand routine testing and document results to reach high (>80%) coverage nationally.
- TB screening should be carried out in HIV positive partners of those who are TB-HIV co-infected. WHO policy on collaborative TB/HIV activities: Guidelines for national programmes

and other stakeholders\textsuperscript{13} should be followed to ensure patients start on treatment with ART within the first 8 weeks

- TB and HIV should be collected in the same electronic recording and reporting system
- TB-HIV services should be integrated within the same clinic to facilitate treatment in co-infected patients and a robust referral system between TB and HIV clinics should be established.

6. Part V. Summary of feedback and suggested changes to ToR’s

6.1 Stakeholder feedback
A meeting was held in Cape Town on the 30\textsuperscript{th} of November 2015 to discuss the current ToRs for carrying out an epidemiological review. The participants consisted of WHO staff for HQ and regional country offices and representatives from technical agencies and funding bodies who have been heavily involved in carrying out epidemiological reviews. The experience of carrying out an epidemiological review was presented with lessons learned. An in depth discussion was then held on how to improve on the current ToRs based on these lessons.

6.2 Stakeholder online survey
An online survey was distributed to staff who had participated in epidemiological reviews via WHO regional offices. Responses were received from 19 countries; Afghanistan, Bangladesh, Belarus, Brazil, Cote d’Ivoire, Chile, Georgia, Indonesia, Mongolia, Rwanda, Sierra Leone, Solomon Islands, South Africa, Sri Lanka, Swaziland, Turkmenistan, Ukraine, Viet Nam and Zimbabwe. In total 40 staff responded, of which the majority were National TB Programme (NTP) staff (17) followed by WHO staff (15), the Global Fund (4), NGOs (1), Universities (2) and other organisations (1). Afghanistan, Brazil and Ukraine conducted epidemiological reviews but not prior to concept note submission and did not complete the rest of the survey. In South Africa only a Standards and Benchmarks assessment was completed.

For countries that did complete the survey, consultants led the epidemiological reviews with the exception of Chile and Sri Lanka where the NTPs carried out the review. In countries where consultants carried out reviews the role of the NTP and level of involvement varied (Table 4). All NTPs provided the data and most participated in the preparation of the review and the interpretation of the results. Very few participated in the analysis of the data and the report writing.

Chile and the Solomon Islands were the only countries that did not use standardized terms of reference and did not implement the standards and benchmarks check list. Some of the staff in Vietnam were not aware that the checklist had been used. The majority of epidemiological reviews included an HIV component (Table 4). A full epidemiological review was submitted to the NTP in all countries by the consultants. Some staff in Rwanda, Cote d’Ivoire, Turkmenistan and Viet Nam were unaware of the final report suggesting that it had not been shared with all staff. Chile, Vietnam and the Solomon Islands felt that clear recommendations for improving TB surveillance or the direct measurement of disease burden were not included in the final report. Less than half of reports included an investment plan but all countries, with the exception of Sierra Leone, used the epidemiological review to identify activities for concept note development. All countries with the exception of Chile, Solomon Islands, Sierra Leone and Georgia had M & E activities funded following grant making.

\textsuperscript{13} \url{http://apps.who.int/iris/bitstream/10665/44789/1/9789241503006_eng.pdf?ua=1}
Table 4: Results from survey on the experience of epidemiological reviews

<table>
<thead>
<tr>
<th>Country</th>
<th>HIV component</th>
<th>NTF involvement in review</th>
<th>Investment plan</th>
<th>Activities funded after grant making</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preparation</td>
<td>Field visits</td>
<td>Provide data</td>
<td>Presentation of results</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Belarus</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Cote d'Ivoire</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Chile</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Georgia</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Indonesia</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Mongolia</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Rwanda</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Solomon island</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Swaziland</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Turkmenistan</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>y</td>
<td>y</td>
<td>y</td>
<td>x</td>
</tr>
</tbody>
</table>

Tables 5 and 6 show the best and aspects of epidemiological reviews reported by countries and proposed changes, respectively.

Table 5: Best and worst aspects of TB epidemiological reviews reported by countries

<table>
<thead>
<tr>
<th>Best aspects</th>
<th>Worst aspects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data analysis</td>
<td>Not linked with activities and funding</td>
</tr>
<tr>
<td>In depth understanding of situation</td>
<td>Short time</td>
</tr>
<tr>
<td>Support to NTP to interpret data</td>
<td>No access to VR data</td>
</tr>
<tr>
<td>Support in obtaining data</td>
<td>Mismatch between data available and indicators to be analysed</td>
</tr>
<tr>
<td>Assessment of data impact</td>
<td>Small team</td>
</tr>
<tr>
<td>Analysis of programme performance based on benchmarks</td>
<td>Data not in correct format for analysis</td>
</tr>
<tr>
<td>Opportunity for the field to report to boards/training and adjust the recommendations</td>
<td>Time consuming and costly</td>
</tr>
<tr>
<td>Enable the program to identify high burden provinces despite the fact that notifications did not reflect real incidence</td>
<td>Personnel capacity not build on data analysis and interpretation</td>
</tr>
<tr>
<td>Use of ecological analysis</td>
<td>Need more time to have a good orientation of epidemiology tools</td>
</tr>
<tr>
<td>Knowledge was increased not only in the epidemiologists but also in the public</td>
<td></td>
</tr>
<tr>
<td>Enable the program to identify high burden provinces despite the fact that notifications did not reflect real incidence</td>
<td>At least draft report writing and interpretation should be done in country</td>
</tr>
<tr>
<td>Communication</td>
<td>Over dependence on external support on technical issues</td>
</tr>
<tr>
<td>To authorities</td>
<td>No local capacity building to allow future analysis to be done locally</td>
</tr>
<tr>
<td>Between the epidemiologist and NTP</td>
<td></td>
</tr>
<tr>
<td>Cooperation of service providers</td>
<td></td>
</tr>
<tr>
<td>Public-private partnerships</td>
<td></td>
</tr>
</tbody>
</table>

Good planning, well organized and completion on time |
High level involvement |
Informed the concept rate and strategic plan |
NTF staff involved in the process |
Information used to improve TB services |
Funding was available and adequate for the review process
Table 6: Proposed changes associated with epidemiological reviews

**Proposed changes**
- Clearer definitions of epidemiological reviews and the purpose.
- Better guidelines on the TB epidemiological review process and its background.
- Duration of the review should be extended if necessary.
- The Checklist should be implemented prior to the review.
- Presentation of epidemiological analysis (including tables and diagrams) should be standardized.
- Visits should be carried out to many parts of the country required.
- All key epidemiological indicators should be assessed.
- Ensure M&E NTP staff are involved in the review process.
- The national team should be involved in data analysis to build capacity.
- Draft report writing and interpretation should be carried out with the national team.
- The review should be carried out on a routine basis.

6.3 Major proposed updates to standardised ToR’s

6.3.1. The dimension of the End TB Strategy and SDG era

The previous ToRs for epidemiological reviews were developed by the Task Force during the era of the Millennium Development Goals (MDGs) and the Stop TB Strategy. These have now been replaced by the Sustainable Development Goals (SDGs) and the End TB Strategy which have implications for the Task Force’s mandate and strategic areas of work post-2015 (see background document 1). In relation to the ToRs for epidemiological reviews, the analyses carried out must include the three high-level global indicators (GI) (Table 7) and the top 10 priority operational indicators (OI) (Table 8) for the End TB strategy.

The current ToRs include the analysis of mortality (GI 1), incidence based on TB notifications (GI 2), financial protection for health costs, social protection and the percentage of health-care expenditures accounted for by out-of-pocket payments (part of GI 3), MDR-TB treatment coverage (part of OI 1), number of people successfully treated for TB out of all notified and treatment outcomes among MDR-TB patients (part of OI 2) and HIV testing (OI 9). GI 3 and the remaining of the ten OIs are not included in the current ToRs for epidemiological reviews. Proposed updates to ToRs need to address these indicators, both in terms of data availability or, if available, data quality. The specifics of changes to the ToRs will be developed by a small technical group and shared for comments.

Table 7. The End TB Strategy’s three high-level global indicators (GI) and associated targets and milestones. The targets are for 2030, marking the end of the Sustainable Development Goals (SDGs), and for 2035, marking the end of the period covered by the Strategy. The milestones are for 2020 and 2025.

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Milestones</th>
<th>Targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Percentage reduction in the absolute number of TB deaths (compared with 2015 baseline estimated at 1.3 million)</td>
<td>35%</td>
<td>75%</td>
</tr>
<tr>
<td>2. Percentage reduction in the TB incidence rate (compared with 2015 baseline, estimated at around 120 cases per 100,000 population)</td>
<td>20% (&lt;85 per 100,000 population)</td>
<td>50% (&lt;55 per 100,000 population)</td>
</tr>
<tr>
<td>3. Percentage of TB patients and their households experiencing catastrophic costs due to TB (level in 2015 unknown)</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Table 8. Top-ten priority operational indicators (OI) (not ranked) for monitoring implementation of the End TB Strategy at global and national levels, with recommended target levels that apply to all countries

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Recommended target level*</th>
<th>Main rationale for inclusion in top-ten</th>
</tr>
</thead>
</table>
| 1  TB treatment coverage  
   Number of new and relapse cases that were notified and treated, divided by the estimated number of incident TB cases in the same year, expressed as a percentage. | ≥90%                      | High-quality TB care is essential to prevent suffering and death from TB and to cut transmission. High coverage of appropriate treatment is a fundamental requirement for achieving the milestones and targets of the End TB Strategy. In combination, it is likely that these 2 indicators will be used as tracer indicators for monitoring progress towards universal health coverage (UHC) within the post-2015 Sustainable Development Goals (SDGs). |
| 2  TB treatment success rate  
   Percentage of notified TB patients who were successfully treated. The target is for drug-susceptible and drug-resistant TB combined, although outcomes should also be reported separately. | ≥90%                      |                                                           |
| 3  Percentage of TB-affected households that experience catastrophic costs due to TB**  
   Number of people treated for TB (and their households) who incur catastrophic costs (direct and indirect combined), divided by the total number of people treated for TB. | 0%                        | One of the End TB Strategy’s three high-level indicators; a key marker of financial risk protection (one of the two key elements of UHC) and social protection for TB-affected households. |
| 4  Percentage of newly notified TB patients tested using WHO-recommended rapid tests  
   Number of newly notified TB patients diagnosed with WHO-recommended rapid tests, divided by the total number of newly notified TB patients. | ≥90%                      | Accurate diagnosis is a fundamental component of TB care. Rapid molecular diagnostic tests help to ensure early detection and prompt treatment. |
| 5  LTBI treatment coverage  
   Number of people living with HIV newly enrolled in HIV care and the number of children who are contacts of cases started on LTBI treatment, divided by the number eligible for treatment, expressed as a percentage (separately for each of the two groups). | ≥90%                      | LTBI is the main treatment intervention available to prevent development of active TB disease in those already infected with *M. tuberculosis*. |
| 6  Contact investigation coverage  
   Number of contacts of people with bacteriologically-confirmed TB cases who were evaluated for TB divided by the number eligible, expressed as a percentage. | ≥90%                      | Contact tracing is a key component of TB prevention, especially in children. |
| 7  DST coverage for TB patients  
   Number of TB patients with DST results divided by the number of notified bacteriologically confirmed cases in the same year, expressed as a percentage.  
   DST coverage includes results from molecular (e.g. Xpert MTB/RIF) as well as conventional phenotypic DST results. | 100%                      | Testing for drug susceptibility for WHO recommended drugs is essential to provide the right treatment for every person diagnosed with TB. |
| 8  Treatment coverage, new TB drugs  
   Number of TB patients treated with regimens that include new (endorsed after 2010) TB drugs, divided by the number of notified patients eligible for treatment with new TB drugs, expressed as a percentage. | ≥90%                      | An indicator that is relevant to monitoring the adoption of innovations in all countries. Indicators related to the development of new tools are needed at global level but are not appropriate for monitoring progress in all countries. The definition of which patients are eligible patients for treatment with new drugs may differ among countries. |
| 9  Documentation of HIV status among TB patients  
   Number of new and relapse TB patients with documented HIV status divided by the number of new and relapse TB patients notified in the same year, expressed as a percentage. | 100%                      | One of the core global indicators used to monitor collaborative TB/HIV activities. Documentation of HIV status is essential to provide the best care for HIV-positive TB patients, including ART. |
| 10 Case fatality ratio (CFR)  
   Number of TB deaths (from a national VR system) divided by estimated number of incident cases in the same years, expressed as a percentage. | ≤5%                       | This is a key indicator for monitoring progress towards 2020 and 2025 milestones. A CFR of 6% is required to achieve the 2025 global milestone. |
The SDGs also call for dis-aggregation of national data, specifically under SDG3, which aims to assess within-country equity in access to resources, opportunities, services and basic human rights. This analysis is also emphasised in the End TB Strategy in the context of “know your epidemic”. The current ToRs include:

- Analysis and interpretation of the level of, and trends in, TB case notifications (e.g. for the last 5-10 years) by geography, age, sex, site of disease, treatment history, bacteriologically confirmed and in high risk groups such as people living with HIV, the elderly, people with diabetes, people with compromised immune systems, prisoners, miners.

To promote the availability of data for these dis-aggregations of key indicators WHO is developing a TB module in DHIS2 for aggregate and another one for case based surveillance data (see background document 2a). Countries will be asked to enter historical sub-national data into the standardised platform if a single database does not exist. This will be recommended as part of the ToRs and additional disaggregated analysis will be added which also reflects the analysis recommended in the WHO guidelines for “Understanding and Using TB Data”.

6.3.2 The dimension of projections of notifications and disease burden

There has also been growing demand for projections of TB notifications and TB disease burden to inform the development of National Strategic Plans and particularly the allocation of resources. A tool investigating the impact of interventions and projections on TB disease burden, the TIME model, has been developed by Avenir Health and the London School of Hygiene and Tropical Medicine (see background documents 5f). Another tool, developed by TME WHO, has been developed to make projections for TB notifications and proportions of MDR-TB cases based on national and sub-national data, adjusting for interventions such as strengthening surveillance to decrease under-reporting and active case finding (see background documents 5g). The dimension of projections will also be addressed in the updated ToRs of epidemiological reviews according to specific country needs and priorities.
Appendix I. Standardised terms of reference

1. BACKGROUND
An excellent understanding of the level of, and trends in, disease burden and how these have been influenced by the implementation of prevention and treatment interventions is of considerable importance to national health programmes, as well as international donor agencies. It can help to ensure the appropriate allocation of funding and ultimately help to save more lives in the future. Epidemiological and impact analysis should be included systematically as part of National Health Sector Reviews and disease-specific programme reviews. Such analyses are also now required as part of the development of “concept notes” that provide the basis for funding applications to the Global Fund in the new funding model introduced in 2013; in this context, the analyses are called the “Epidemiological stage”, and should precede the development of the concept note. These terms of reference cover the objectives and associated tasks and expected deliverables for TB epidemiological and impact analyses conducted as part of national TB programme reviews, as inputs to health sector reviews and for the “epidemiological stage” of the Global Fund’s new funding model.

2. OBJECTIVES
1. Describe and assess current national TB surveillance and vital registration systems, with particular attention to their capacity to measure the level of and trends in TB disease burden (incidence and mortality).
2. Assess the level of, and trends in, TB disease burden (incidence, prevalence, mortality) using available surveillance, survey, programmatic and other data.
3. Assess whether recent trends in TB disease burden indicators are plausibly related to changes in TB-specific interventions taking into account external factors including economic or demographic trends.
4. Define the investments needed to directly measure trends in TB disease burden in future.

3. TASKS BY OBJECTIVE

Objective 1: Assessment of current national TB surveillance and vital registration systems with particular attention to their capacity to measure the level of and trends in TB disease burden

a) Provide a written description and explanation of the main features of the current national TB surveillance and vital registration systems. These should include the data being captured (e.g. notified cases, treatment outcomes, causes of death); definition of the agencies/individuals responsible for data collection, analysis and reporting and how they interact; mechanisms/processes used to capture and transmit data between different administrative levels and agencies (e.g. standardized forms; paper-based and/or electronic systems) and to assure data quality; timing and timeliness of reporting including lag times that hamper capacity to detect, investigate and contain events such as local epidemics (including events related to the emergence of drug resistance); the type of data available at the national level (e.g. aggregated reports, case-based data); approach to analysis and reporting of data; staffing levels; how systems for capturing TB data are related to/linked with other health information systems (e.g. health insurance, hospital reporting systems, district health information systems). To help characterize the TB surveillance system, Part A of the WHO TB surveillance checklist (18 questions) should be completed. 15

b) Assess the current capacity of national TB notification and vital registration systems to provide a direct measure of TB disease burden using the WHO TB surveillance checklist

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14 Analyses of time trends should be attempted as far back in time as possible before the health sector or programme review.
15 http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/meetings/en/
(Part B). The ultimate goal is to measure TB incidence and mortality directly from notification and vital registration data, respectively; Part B of the checklist consists of a set of 13 standards and associated benchmarks that allow assessment of the extent to which existing surveillance systems (notification and vital registration) meet these standards. (NB the first standard in the checklist relates to case definitions. In this context, there should be an assessment of whether the 2013 WHO revised case definitions and reporting framework have been adopted and implemented, and at what scale, and any actions needed to introduce or fully implement them).

c) Summarize the main strengths of the current surveillance system and the weaknesses/gaps that need to be addressed, based on the findings from a) and b).

(Suggested data sources 16: Interviews with relevant staff; national and sub-national case-based or aggregated TB notification data, national or sample vital registration data, results from facility audits (e.g. Service Availability and Readiness Assessment, SARA) or reviews of the quality of recorded data, results from drug resistance surveillance including drug resistance surveys, research literature). A comprehensive list of data sources is provided in the user guide that accompanies the checklist).

Objective 2: Assessment of the level of, and trends in, TB disease burden
This assessment includes review and compilation of published estimates of TB morbidity and mortality that are already available to assess the level of, and trends in, TB disease burden (at least nationally and when feasible sub-nationally and among sub-populations); analysis of TB notification data; and interpretation of available data.

a) Analysis of the level of, and trends in, TB mortality.
   i. Analysis of trends in TB mortality among HIV-negative individuals. This is best done using data from a national or sample civil registration system of vital statistics with cause of death data that meet the standards defined in the WHO TB surveillance checklist. Each year, WHO publishes estimates of TB mortality among HIV-negative people from 1990 onwards for all countries in the annual global TB report (the global TB report also identifies the countries for which mortality among HIV-negative individuals has been estimated from vital registration data and mortality surveys, and the countries for which estimates rely on other methods).
   ii. Analysis of trends in the distribution of contributory causes of AIDS deaths (with particular emphasis on TB), if data are available. From 2012, estimates of TB mortality among HIV-positive people are being produced using the TB component of Spectrum, and published on an annual basis by WHO and UNAIDS.

(Suggested data sources: WHO TB database, AIDSinfo database, records from national or sample civil registration of vital statistics with cause of death data from NTP/MoH databases, results from mortality surveys, research literature).

b) Analysis of the level of, and trends in, TB prevalence. If data are available from a baseline and at least one repeat survey, then there is strong evidence about trends in disease burden. If results from two surveys conducted about 10 years apart are not available, estimates of trends are

16 It is likely that some of the suggested data are not yet available. The identification of these data gaps is important and they should be identified in a specific section of the final report, along with clearly defined next steps for addressing these gaps.
available from WHO but uncertainty intervals are wide. The results from a recent survey can be used to assess the current level of TB disease burden and may also provide important evidence about the effectiveness of current TB programmatic efforts and actions needed to improve TB care and control.

(Suggested data sources: results from surveys of the prevalence of TB disease, WHO TB database, research literature)

c) Analysis and interpretation of the level of, and trends in, TB case notifications (e.g. for the last 5-10 years).

i. Plot time series of case notifications and analyse results, including to assess trends and to identify if there is any evidence of reporting problems (e.g. missing data or sudden changes in time-series of reported new episodes of TB at national and first subnational level e.g. state or province). Analysis of results should take into consideration any changes in reporting policies and practices, and case definitions.

ii. Analysis of the geographic distribution of case notification rates among subnational areas and how this has changed over time, and exploration of reasons for observed trends and geographical heterogeneity. These include, but are not limited to, the availability of TB diagnostic services, case finding activities, changes in the ratio of TB cases to the number of people investigated for “presumptive” TB (note that data on the number of people investigated for TB are often not quality-assured and duplicate entries from multiple visits by the same person may exist), health systems characteristics, determinants of/risk factors for TB (e.g. overall levels of income and poverty, HIV prevalence).

iii. Analysis of trends in the proportions of notified cases: (a) by type of TB disease - bacteriologically confirmed and extra-pulmonary TB; (b) by age group, including the proportion of cases among children (0-4, 5-14); (c) by category (retreatment out of the sum of new and retreatment cases).

iv. Trends in age- and sex-specific case notification rates, the average age of newly notified cases, and the extent to which these can be explained by demographic or other factors.

v. Analysis of the level of (and ideally trends in) under-reporting from national inventory studies if these are available before the assessment.

vi. Any data available on TB in high risk groups such as people living with HIV, the elderly, people with diabetes, people with compromised immune systems, prisoners, miners, etc.; numbers, denominators; and if available proportions and trends.

vii. Other miscellaneous analyses that may be relevant in specific settings (to be determined by the epidemiologist(s) undertaking the assessment).

(Suggested data sources: National and sub-national case-based or aggregated TB notifications, laboratory data, results from inventory studies to measure TB under-reporting (and under certain circumstances estimate incidence), laboratory data, research literature, national databases with information about overall health system characteristics and determinants/risk factors related to TB)

Objective 3: Are recent trends in TB disease burden plausibly related to changes in TB-specific interventions accounting for other external factors?

Funding for and implementation of high-quality TB-specific interventions should result in detection of people with TB and curative treatment; in turn, this should have a direct impact on TB mortality.
(cutting case fatality rates compared with no treatment or substandard treatment). Shortening the duration of disease through detection and treatment of cases will also reduce the prevalence of TB disease, and therefore, transmission. There will be an impact on TB incidence if transmission can be reduced sufficiently and/or if preventive treatment of people with latent TB infection is effectively implemented on a large scale. At the same time, a range of factors besides TB-specific interventions influence levels of TB disease burden, by affecting population susceptibility to both TB infection and the risk of developing TB disease once infected. These include overall levels of wealth and the distribution of wealth (measured e.g. as GNI per capita, the proportion of people living in poverty), the overall coverage and quality of health services and the prevalence of HIV and other risk factors for TB. Having considered trends in disease burden in Objective 2, it is important to assess whether these trends can partly be related to changes in TB-specific interventions (and associated funding).

a) Define and compile data that are relevant to assess the extent to which changes in TB disease burden in recent years (e.g. for the last 5–10 years) can be explained by TB-specific interventions/programmatic efforts. This should include, at a minimum:

   i. Government and international donor funding for TB care and control;
   ii. Number of health facilities providing TB diagnostic services per 100,000 population;
   iii. Number of health facilities providing TB treatment services per 100,000 population;
   iv. Number of people investigated for presumptive TB (if available data are reliable) and the ratio of presumptive TB to notified TB cases;
   v. Performance of community/active case finding (number of cases screened and detected by each mechanism);
   vi. Performance and coverage of public-private mix activities in the country. Coverage should be expressed where possible both as % of the country (geographic) and type, the % of providers covered (e.g., 30% of estimated pharmacies and 50% of estimated private pulmonologists);
   vii. Any quantitative data on diagnostic delays (due to patient, private sector, or public sector delays);
   viii. Number of people successfully treated for TB out of all notified;
   ix. MDR-TB treatment coverage (comparing numbers detected and treated with the estimated number of cases among notified TB patients and describing the size of waiting lists), and treatment outcomes among MDR-TB patients. This is especially relevant in countries in which MDR-TB cases account for a relatively large share of the total number of TB cases;
   x. HIV testing, ART and CPT coverage of TB patients, treatment outcomes among PLHIV. This is especially relevant in countries with a high TB/HIV burden.

(Suggested data sources: WHO TB database, NTP database and reports, Service Availability and Readiness Assessments (SARAs), results from inventory studies that show the level of TB under-reporting, research literature, grey literature, national TB prevalence surveys, WHO HIV/AIDS data and statistics, AIDSinfo database, MOH and NGO databases, http://www.foreignassistance.gov for USAID funding data).

b) Define and compile data that are relevant to assess the extent to which changes in TB disease burden in recent years can be explained by factors that are not specifically related to TB-specific funding and associated interventions. This should include, at a minimum:

   i. Prevalence of HIV among the general population, and ART coverage. (Suggested data sources: WHO HIV/AIDS data and statistics, AIDSinfo database);

iii. GNI per capita and the % of the population under the poverty line, and the impact of economic crises. (*Suggested data sources: World Bank Indicators*)

iv. Coverage of financial protection for health care costs (by government health budget or health insurance etc.) and social protection programmes (overall, and for DS-TB and MDR-TB specifically where available) and the percentage of health-care expenditures accounted for by out-of-pocket payments (*Suggested data sources: Research literature, national health accounts, social protection/welfare programme information on coverage of target groups, as relevant and available from WHO at www.who.int/nha; research literature*)

v. Demographic changes; percentage of population who are less than 15, and those more than 65, years (*Suggested data sources: UNPD database*)

vi. Under-5 mortality rate (as an indicator of the overall performance of the health-care system). (*Suggested data sources: WHO Global Health Observatory*)

Objective 4: Assessment of investments needed to directly measure trends in disease burden in the future

a) From the implementation of the WHO TB surveillance checklist: for standards defined in the checklist that are not yet met due to data gaps or data quality problems, identification of the investments required to improve surveillance (including estimated budget). (*Suggested data sources: same as in 1.b, NTP reports*)

b) Assessment of whether a baseline or repeat survey (e.g. prevalence survey, inventory study, cause of death survey) is needed and if so what timing would be appropriate. An appropriate amount of time should be ensured between repeat surveys (for example, a repeat TB prevalence survey should normally be done about 10 years after the previous one). Guidance on countries where prevalence surveys are recommended is available from the Global Task Force on TB Impact Measurement.

4. DELIVERABLES

A comprehensive report addressing all tasks under the three objectives of the epidemiological and impact analysis outlined in this document with a conclusion section on:

a) The robustness of estimates of TB incidence, prevalence and mortality and their sources of uncertainty.

b) Whether it is plausible that TB control interventions have contributed to changing the course of the TB epidemic, accounting for other external factors.

c) Whether there are specific geographical areas or subpopulations (vulnerable/those with poor access) or sectors (e.g. mining, prisons/detention, etc.) in which the burden of disease is especially high and that warrant increased attention including greater investment of financial resources and/or reallocation of resources to focus on more effective, higher impact interventions.

d) Investments needed to improve evidence about trends in disease burden in future.

5. PROFILE REQUIRED

- A senior epidemiologist or statistician with extensive quantitative skills and a proven track record of producing results and communicating them well (including in scientific publications in peer reviewed journals);
● Excellent understanding of TB epidemiology, TB policies and interventions, and health systems;
● Extensive experience in working with national TB health programmes and offering technical assistance.

6. TIME REQUIRED
This depends in part on the extent to which the person(s) conducting the analysis are already familiar with the country where the assessment is being done and the associated data, their previous experience of conducting such analyses, but also the availability and expertise of national M&E counterparts who will participate in this exercise. For someone familiar with the country and the data and with previous experience of such work, it is estimated that 2 weeks of in-country work are required. An additional 2 weeks of preparatory work might be necessary depending on the country context.

Guidance on and related examples of schedules for previous missions that covered the Terms of Reference described are available from WHO and KNCV on request.
Appendix II. Example of an agenda for an in-country mission

WORKPLAN FOR MISSION OF EPIDEMIOLOGICAL TB REVIEW

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
<th>Responsible person</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015.04.04</td>
<td>Monday</td>
<td>Arrival at Chingis Khaan international airport</td>
<td>Technical officer on HIV, STIs and TB, WHO</td>
</tr>
<tr>
<td>2015.04.07</td>
<td>Tuesday</td>
<td>09.00-09.30 Meeting with WHO Representative (WR)</td>
<td>Technical officer on HIV, STIs and TB, WHO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>09.30-10.00 Meeting with Director of Public Health division, Ministry of Health</td>
<td>Officer In Charge of TB and HIV, STIs, MOHS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.15-10.45 Meeting with project coordinator of the Project Co-ordination Unit (PCU), Global Fund</td>
<td>TB project officer, PCU Global Fund</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11.00-11.30 Meeting with General Director of National Centre for Communicable Disease (NCCD)</td>
<td>National TB Program manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11.30-12.30 Meeting with National TB Program (NTP) team and introduction to epidemiological reviews (presentation)</td>
<td>Epidemiologist NTP, NCCD Epi-review consultant</td>
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<tr>
<td></td>
<td></td>
<td>12.30-13.30 Lunch</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>13.30-14.00 Introduction to TB burden in Mongolia (presentation)</td>
<td>Epidemiologist NTP, NCCD</td>
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<tr>
<td></td>
<td></td>
<td>14.00-17.00 Introduction to TB surveillance system in Mongolia including MDR-TB and TB-HIV (National team)-Desk Review</td>
<td>Statistician, TB surveillance and research department, NCCD Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td>2015.04.08</td>
<td>Wed</td>
<td>09.00-09.30 Preliminary results of TB prevalence survey in urban stratum (presentation)</td>
<td>Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>09.30-10.00 Contact investigation study results (presentation-high risk groups)</td>
<td>Epidemiologist NTP, NCCD</td>
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<tr>
<td></td>
<td></td>
<td>10.00-11.00 Visit to National TB Reference</td>
<td>Head of NTRL</td>
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<tr>
<td>Time</td>
<td>Activity</td>
<td>Location</td>
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</tr>
<tr>
<td>11:00-12:00</td>
<td>Meeting with focal points on programmatic management of drug-resistant TB and HIV-TB co-infection.</td>
<td>PMDT focal person HIV doctor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Visit to MDR-TB ward-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:00-13:00</td>
<td>Lunch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13:30-14:30</td>
<td>Visit to Mongolian Anti-Tuberculosis Association (NGO)</td>
<td>Epidemiologist NTP, NCCD</td>
<td></td>
</tr>
<tr>
<td>15:00-15:30</td>
<td>Meeting with National TB Coalition (NGO)</td>
<td>Epidemiologist NTP, NCCD</td>
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<tr>
<td>16:00-17:00</td>
<td>Introduction to internet-based TB information system tubis</td>
<td>Epidemiologist NTP, NCCD</td>
<td></td>
</tr>
<tr>
<td>2015.04.09</td>
<td>Departure to Tuv province (Rural low TB burden area)</td>
<td>Epidemiologist NTP, NCCD</td>
<td></td>
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<tr>
<td>Thursday</td>
<td>08:00-11:30</td>
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<tr>
<td></td>
<td>Meeting with Tuv province Health department Director</td>
<td>Epidemiologist NTP, NCCD</td>
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<tr>
<td></td>
<td>12:30-13:30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13:30-16:00</td>
<td>Visit to Tuv aimag (province) TB dispensary, laboratory, recording and reporting</td>
<td>Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td></td>
<td>16:00</td>
<td>Departure to UlaanBaatar</td>
<td></td>
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<tr>
<td>2015.04.10</td>
<td>09:00-10:00</td>
<td>Visit to National Statistical office (Vital registration data)</td>
<td>NTP manager</td>
</tr>
<tr>
<td>Friday</td>
<td>10:15-11:15</td>
<td>Visit to Research, planning and statistical department of the Center for Health Development</td>
<td>NTP manager</td>
</tr>
<tr>
<td></td>
<td>11:30-12:30</td>
<td>Visit to Bayanzurkh district (Urban high TB incidence area) TB dispensary and laboratory</td>
<td>Epidemiologist NTP, NCCD</td>
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<tr>
<td></td>
<td>12:30-13:30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14:00-15:00</td>
<td>Visit to Paediatric hospital</td>
<td>Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Activity</td>
<td>Organizer</td>
</tr>
<tr>
<td>------------</td>
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<td>---------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>2015.04.13</td>
<td>09.00-17.00</td>
<td>Analysis at the TB surveillance and research department</td>
<td>Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td>2015.04.14</td>
<td>09.00-10.30</td>
<td>Sharing experience of UK working with high risk and vulnerable populations (presentation)</td>
<td>Consultant</td>
</tr>
<tr>
<td></td>
<td>10.30-17.00</td>
<td>Analysis at the TB surveillance and research department</td>
<td>Epidemiologist NTP, NCCD</td>
</tr>
<tr>
<td>2015.04.15</td>
<td>09.00-17.00</td>
<td>Analysis at the hotel</td>
<td></td>
</tr>
<tr>
<td>2015.04.16</td>
<td>09.00-17.00</td>
<td>Analysis at the hotel</td>
<td></td>
</tr>
<tr>
<td>2015.04.17</td>
<td>09.00-12.00</td>
<td>Analysis at the hotel/de-brief presentation</td>
<td></td>
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<tr>
<td></td>
<td>12.00-13.00</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>13.00-15.00</td>
<td>Debrief with Ministry of Health, NTP, WHO and other stakeholders</td>
<td>OIC of TB and HIV, STIs, MOHS Technical officer on HIV, STIs and TB, WHO</td>
</tr>
<tr>
<td></td>
<td>15.00-16.00</td>
<td>De-brief with WR</td>
<td>Technical officer on HIV, STIs and TB, WHO</td>
</tr>
<tr>
<td>2015.04.18</td>
<td></td>
<td>Departure</td>
<td>WHO</td>
</tr>
</tbody>
</table>
Appendix III. Example of a briefing presentation (Liberia)

Epidemiological reviews
Dr Laura Anderson
WHO HQ

What is an epidemiological review?

- Country-level, systematic, and standardized baseline assessment of:
  - The strengths and gaps of the TB surveillance system and direct measurement of disease burden
  - The best estimates of the level of and trends in TB disease burden
  - A plausible interpretation of how TB disease burden is influenced by prevention and treatment interventions implemented by NTP and partners
- To inform programme reviews, "epidemiological stage" of Concept Note submission to the Global Fund

- Standardized terms of reference:
  - Available since early 2013
  - Subjective, with suggested analytical tools per objective
  - Used in about 37 countries so far

Why is it important?

- Helps us to identify weaknesses in TB care and control: has the national TB strategy been implemented? Which strategies worked and which didn’t work and why?
- Allows us to work together to find solutions for the problems we find
- Helps us to make recommendations and new objectives that should be adopted by the strategy for improved TB control
- Helps us to identify resources required to meet the new objectives

TB surveillance data are used for:

- "Know your epidemic"
  - Age, sex, site of disease, geography, ethnic group
  - Case notification and trend analysis
  - Targeting communities affected with active case finding and awareness raising
  - Rapid diagnosis and patients on treatment

The purpose of TB surveillance

- Detecting changes in data which may indicate:
  - Issues with recording and reporting
  - Public health action is required
  - e.g., sudden increase in cases = outbreak, sudden decrease in cases = lack of notification
  - Increases in drug use = increased testing OR transmission-OFF treatment failure
Garbage In, Garbage out!

Your analysis is only as good as your data!

Objective 1: assessing quality and coverage of surveillance
Describe and assess current national TB surveillance and vital registration systems, with particular attention to their capacity to measure the level of and trends in TB disease burdens (incidence and mortality).


What's the point?
- Identify strengths = reliable data
- Identify weaknesses and gaps
  - How can we improve?
  - Develop a framework which can be used to support improvements
  - Develop M and E investment plan

Standards and Benchmarks (S& Bs): Definitions
- Standards: General statements about the characteristics of a high-performance TB surveillance system
- Benchmarks: Define in quantitative terms wherever possible the level of performance that is considered good enough to meet the standard

What is in the Checklist?
13 standards and associated benchmarks:
- Data quality
- System coverage
- TB mortality
- Drug-resistant TB
- TB/HIV
- TB in children

How do we know if our TB surveillance is good enough?
- Data quality
  - Are all the TB cases notified?
  - Is notification timely?
  - Is reporting consistent throughout the country?
  - Are data accurate?
  - Are data complete?
How do we know if our TB surveillance is good enough?

Data validation
- Are data validated routinely at national and sub-national level?
- Are there feedback mechanisms in place?
- Are data which look strange investigated and corrected?

Checklist implementation
- Desk review of available policy documents and guidelines
- Discuss checklist items with TB surveillance team e.g. system and data flow
- Examination of lab and TB register at sub-national level
- Quarterly reports received
- Data received at national level match registers
- Data analysis on key indicators for internal and external consistency
- HIV and death data

Checklist

- Identified gaps in surveillance
- Monitoring and Evaluation investment plan
- Strengthening impact measurement

The Global Fund
To fight AIDS, Tuberculosis and Malaria

Which countries have undertaken the Checklist?

Practical outcomes: Uganda
- Hiring epidemiologist/data manager to assist data analysis and compiling the annual report
- Developed SOPs, data quality training materials and data audit tools
- Conducted data quality assessment - SQA tool
- Strengthened the TB module in DHS

Summary results: 24 countries (Jan 13-Jul 14)

- Systematically assess quality of paper-based TB data
  - Service Availability & Readiness Assessment
  - Move from paper to electronic case-based system
  - Immunology study to measure under-reporting, monitor drug resistance
  - Advanced for use of VBA system
  - Improve surveillance data for burden in MDR-TB, TB/HIV, division
**Objective 2**
understanding the level of, & trends in, TB burden
Assess the level of, and trends in, TB disease burden (incidence, prevalence, mortality) using available surveillance, survey, programmatic, and other data.


**Objective 3**
How do determinants influence TB burden?
Assess whether recent trends in TB disease burden indicators are plausibly related to changes in TB-specific interventions taking into account external factors including economic or demographic trends.

**Objective 4**
Investment plan: the example of Indonesia
Define the investments needed and define associated targets to (i) strengthening surveillance and (ii) directly measuring trends to TB disease burden.

**Methods**
- Analysis of available data
- Breakdowns by geography, age, sex and other relevant variables available.

**Methods**
- Review of data on
  - Age and sex structure of population
  - HIV
  - Diabetes
  - Economic growth
  - Inequalities in health service provision
  - Underlying mortality rates
  - Ebola

**Next steps**
- Appoint staff to assist in each part of the review
- Collate ideas from staff on how to conduct the review and finalize the agenda
- Agree on the objectives of the visit with the Liberia/TB team!
Appendix IV. Example of Epidemiological Review Report: Detailed Outline

Executive Summary
- Summarize each main component of the report and present content under sub-headers with the appropriate titles (e.g., Introduction, purpose, methods).
- Summary should be 1-2 pages, maximum.

1. Introduction
   Key components of the introduction include:
   - Briefly describe TB situation in country: TB burden, TB program, recent achievements of the NTP
   - Briefly introduce country-specific context that could affect TB epidemiology and programmatic response
   - State the need for accurate epidemiological information about the burden of TB in country to effectively plan, monitor, and assess the impact of interventions and progress towards targets.

2. Purpose
   2.1. Objectives
      ▪ Describe and assess the current national TB surveillance and VR systems, with particular attention to their capacity to measure the level of and trends in TB disease burden (incidence and mortality), through the implementation of a checklist of TB surveillance.
      ▪ Assess the level of, and trends in, TB disease burden (incidence, prevalence, mortality) using available surveillance, survey, programmatic and other data.
      ▪ Define the investments needed to directly measure trends in TB disease burden in the future.
      ▪ Define key populations that should be targeted with interventions to improve TB diagnosis and treatment success.
      Additional objectives may be proposed based on the country context (e.g., impact of a natural or manmade disaster or other national emergency on the TB surveillance system).

   2.2. Proposed Outcomes
      ▪ A formal performance assessment of TB surveillance based on WHO standards and benchmarks, with strengths and weaknesses (including data gaps and data quality problems) identified, and any unmet monitoring and evaluation needs described.
      ▪ A formal assessment of the level of, and trends in, TB disease burden.
      ▪ An M&E investment plan with specific recommendations for investment of funds for the improvement of measurement of TB trends in Sierra Leone.
      ▪ Identification of key populations that should be targeted with TB control interventions.
      Additional outcomes may be proposed based on the country context.

3. Methods
   3.1. TB surveillance checklist
      Describe:
      - Meetings held, stakeholders involved in the work, methods used to collect, collate, and analyse data (e.g. desk review of documents and a review of all datasets either held at or made available to the national programme)

   3.2. Epidemiological review of TB disease
      Describe:
      - Data sources used
      - Analyses conducted

   3.3. Dissemination of information
      Describe the debrief presentation
      - When and where held
      - Who were data shared with (e.g., NTP, MoH, WHO country office)
4. **Assessment of Surveillance of TB Cases and Deaths in [Country Name]**

4.1. Rationale--Checklist of TB Surveillance Standards and Benchmarks

4.2. Characteristics of the TB Surveillance and Vital Registration Systems
   - Summarize “Part A” of the checklist

4.3. Results: Checklist for TB surveillance and Vital Registration Systems
   - Summarize “Part B” of the checklist (including supplementary checklist)
   - Include table summarizing results.

5. **TB Epidemiology**

   *For each section below, include the relevant analyses (e.g., graphs and tables) and a written description of epidemiological trends and findings.*

5.1. **TB Case Notifications**
   - Time trends, national level
   - Time trends, subnational level
   - Internal consistency of data
   - Treatment outcomes
   - Childhood TB
   - Anti-TB drug resistance
   - High risk groups and private sector
   - Private sector
   - Other categories of interest to the country

5.2. **TB Prevalence**

5.3. **TB Mortality**

5.4. **TB Incidence**

5.5. **Determinants of TB**
   - *Introduction:* Prevalence of risk factors for TB (e.g., HIV, under-weight, diabetes, problem alcohol use, smoking)
   - Socioeconomic status for country (e.g., GNI per capita)
   - Demographic characteristics of population (e.g., population pyramids)
   - Under-5 mortality
   - HIV burden
   - Malnutrition
   - Smoking
   - Problem Alcohol Use
   - Diabetes Mellitus
   - Rural-urban Disparity
   - Other categories of interest to the country (e.g. impact of a natural or manmade disaster or other national emergency)

6. **Discussion**

6.1. **Synthesis**
   - Summarize findings
   - Highlight similarities, differences in analyses

6.2. **Strengths**
   - Explicitly state the current strengths of TB surveillance and the programmatic approach

6.3. **Gaps, Challenges, and Weaknesses**
   - Epidemiology of TB in country
   - TB surveillance system
   - TB programmatic response
6.4. Limitations
The limitations section should specifically address:
- Availability and quality of data (internal and external to NTP) used for analysis, sections of the assessment that were not able to be completed

7. Recommendations
Organize recommendations by topic (e.g., pediatric TB, MDR TB, surveillance strengthening) within the “short term” or “longer term” categories. Refer to Appendix IV in this manual for widely used recommendations that may be useful in your review.
  o Short term, high impact
  o Longer term, high impact

8. References

9. Appendices

Appendix 1: Persons met
- Include the name, title, and affiliation of key persons met.

Appendix 2: Data sources and other information required for the review
Consider organization of sources into the following sections:
- Description of the TB surveillance system
- Internal to TB Programme
- External to TB Programme
- Analysis and interpretation of TB surveillance data

Appendix 3: Completed checklist of standards and benchmarks
- Attach completed checklist (Parts A and B)

Appendix 4: Debriefing presentation
- Embed or link the PowerPoint presentation used for debrief (example below)