Guidance for Generic Terms of Reference
for Epidemiological and Impact Analysis
January 2022

Contents

This document constitutes a generic Terms of Reference (ToRs) that can guide the implementation of an Epidemiological and Impact Analysis, to be completed as part of a Program Review.

Format

This document follows a standard format, outlining:

- **Introduction** to the topic and the purpose of the ToR
- **Background** of the topic in the target country
- **Objectives** of the evaluation or assessment
- **Approach** to the evaluation or assessment
- **Deliverables** expected as a result of the evaluation or assessment
- **Level of Effort and Timeline** needed for the evaluation or assessment
- **Profile Required** of the key expert(s)
- **Place of Performance** of the evaluation or assessment
- **Key Reference Documents** to be considered in shaping the evaluation or assessment

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Tips for Use

These generic ToR document is designed to be used by Country Teams, Strategic Initiative teams, implementers (PRs or SRs) or any other partners planning or commissioning an Epidemiological and Impact Analysis (hereafter referred to as “the user”).

This document should be used as a template, which may be adjusted to individual country circumstances as needed. Text in *blue italics* provides instruction to the user where tailored information is required. In some cases, optional objectives are provided to be considered for inclusion.

Levels of Effort and Timelines should receive special attention for tailoring by the user, as time required and timelines are often dictated by specific country circumstances.

Additional changes may be made to the generic ToR as needed. The user may wish to consult the MECA team for additional support, as needed.

Terms of Reference for Epidemiological and Impact Analysis
Country: _____ *(HIV/TB/Malaria)* Program

Introduction

An epidemiological and impact analysis aims to provide a detailed understanding of the level of, and trends in, *(HIV/TB/malaria)* disease burden and how these have been and can be influenced by the implementation of prevention, treatment and system strengthening interventions. This type of analysis provides a more robust assessment of impact and outcomes than would be obtained from an exclusive focus on output and coverage level program results, and seeks to establish whether changes in outcomes or impact are either plausibly resulting from national program input and interventions, or are likely due to some other factors. It also highlights a short number of priorities to address going forward to keep the program focused on impact.

This information is of considerable importance to national health programs, as well as development partners. It can help to ensure health service planning with the appropriate allocation of funding and ultimately help to save more lives and avert more infections in the future. Epidemiological and outcome/impact analysis should be included systematically as part of national health sector reviews and disease-specific program reviews. The analysis is often completed as an input to these reviews, to ensure they are focused with the end in mind, which is impact.

The initial Global Fund Guidance Note for Epidemiological and Impact Analysis was developed under the guidance of the Technical Evaluation Reference Group (TERG) in 2014, and later incorporated into the respective WHO program review guidelines for HIV, TB and malaria. These Terms of Reference (ToR) serve the purpose of translating the guidance into concrete actionable items for the national disease program, and should be used to define and guide the core set of key tasks, the roles and responsibilities as well as the required technical expertise of the review team members[1].

Background

In this section, please briefly describe (up to one page):

- *The history and evolution of the national (HIV/TB/malaria) program (or equivalent structure), within in the overall health and social development context of the country;*
- *The current epidemiological context;*
- *The current status of program implementation;*
- *The period of and any key observations and conclusions from the previous epidemiological and impact analysis conducted; and*
- *The rationale for the timing of the planned review.*

[1] This TOR is also informed by the "Standards and benchmarks for tuberculosis surveillance and vital registration systems, checklist and user guide", "Framework for conducting reviews of tuberculosis programmes" and "Framework for Evaluating National Malaria Programs in Moderate- and Low-Transmission Settings".

Objectives

1. Describe and assess current national *(HIV/TB/malaria)* surveillance, data management and reporting, and vital registration systems, with particular attention to their capacity and reliability to measure the level of and trends in *(HIV/TB/malaria)* disease burden (incidence, prevalence, and mortality *(user should remove "prevalence" in the case of a TB analysis)*), outcomes (behaviors, treatment success), coverage and gaps in interventions, as well as the geographical disaggregation of these to sub-national levels and by demographic and socio-economic variables.

2. Assess the level of, and trends in, *(HIV/TB/malaria)* disease burden using available surveillance, survey, programmatic and other data.

3. Assess causal pathways leading from outputs and coverage to outcomes and impact on *(HIV/TB/malaria)*, considering confounding and competing explanations for the changes observed and other factors aside from those related to *(HIV/TB/malaria)* programs, e.g. socio-economic, political, health factors, etc.

4. Define any actions and investments needed to generate more and better quality data to directly measure trends in *(HIV/TB/malaria)* disease burden and program data in the future.

5. Build the capacity of the national *(HIV/TB/malaria)* program to analyze and participate in and lead epidemiological and impact analyses.

6. Identify a short list of evidence based gaps and priorities to improve impact to contribute this focus to the overarching *(HIV/TB/malaria)* program review, to inform on recommendations and prioritization for future program investments

Disease-specific tasks by objective are further described in Annexes I-III.

Approach

The Epidemiological and Impact Analysis should be conducted with an emphasis on utilizing existing data in published documents and national programmatic records and published documents, through disaggregated and nuanced analysis. This may be supplemented or verified by limited additional data collection and analysis as needed, focusing on the capacity and reliability of existing data collection systems, and analysis of existing data. Additional data may be collected through mixed methods, which may include but are not limited to interviews, consultative meetings and field visits. These are carried out, as necessary, at national, provincial, district, facility and community levels. The description of phases of work below provides more detail on the expected approach for this analysis.

➔ **Phase I: Planning, Preparation and Initial Data Analysis**

Desk Review: A review of existing documents will be conducted to obtain the current *(HIV/TB/malaria)* epidemiological and program profile. These should be provided by the program as much as possible in advance. This process will:

- Identify the core indicators to be covered in the review process (output/coverage, outcome and impact), including the level of analysis expected (national/sub-national and level of disaggregation)
- Prepare data gathering tool, interview guides and analytical templates; and identify the data sources and partners to be consulted;
- Assess progress against national targets;
- Describe what is known of the overarching policy and program environment, including the current or planned integration of *(HIV/TB/malaria)* services within the health sector;
- Include a brief economic analysis of the provision of *(HIV/TB/malaria)* services;
- Identify issues emerging from recent related program and epidemiological reviews and assessments (if any are available), in order to follow-up during Phase II;
- Develop several plausibility arguments to be investigated, to determine whether the observed changes in disease trends could be explained by programmatic efforts and/ or any other external non-programmatic factors.
- Develop a plan for acquisition or analysis of any additional data needed to conduct plausibility analysis.

Further details to guide initial analysis and mapping of data can be found in Annexes I-III of this ToR.

➔ **Phase II: In-country or Remote Review**

The field visit (or remote review/interview) will include an initial presentation to a broad range of stakeholders to support transparency and country ownership. This presentation will summarize the preliminary findings from Phase I, including progress made since the last review (if relevant), as well as present the objectives, process and expected outcomes of the visit.

The field visit (or remote review) will then be used to collect supplementary, clarifying or validating information. This may be done through:

- Gathering of programmatic data/information along the indicators and sources identified at the planning stage
- Interviews with stakeholders of surveillance and data processes, including but not limited to offices of national statistics or vital registration, health authorities for laboratory, HMIS, health insurance, district and provincial managers, community groups, academic institutions, etc.;
- Review and cross-check of *(HIV/TB/malaria)* records, laboratory registers and electronic surveillance and information systems at TB dispensaries; ANC, commodities and ITN intervention data for malaria;
- Review of electronic databases to assess the level of completeness and quality of reporting and core variables and to carry out data validation and consistency checks over time and between core variables; and
- Analysis of notification/surveillance and program data and survey results, over time and space (at least 5 years of data, and including relevant subnational units), and

population group, to identify trends in disease burden and programmatic efforts. This will include disaggregation of data to assess trends by geography, age, sex, gender, key and vulnerable populations, and other relevant population factors. Where disaggregation is not possible, data gaps should be assessed.

- Site visits to selected health facilities and associated labs, at different levels (primary, secondary, tertiary care centers) in both urban and rural locations; and to selected communities to observe the provision of services with particular emphasis on the key thematic areas identified above, discussion of hypotheses and competing hypotheses, and potentially for triangulation of information.

A presentation of findings will then be shared with national stakeholders at the conclusion of the visit (or remote review), and will include preliminary evidence-based priorities and noted gaps in achievement of impact, to allow incorporation of feedback from stakeholders prior to final analysis and interpretation.

➔ **Phase III: Detailed Analysis and Interpretation of Findings**

All available data, from both Phase I and Phase II, will be analyzed to identify whether the observed changes in disease trends could be explained by programmatic efforts and/ or any other external non-programmatic factors, explain/interpret the outcomes of the analysis observed findings, and explore any alternative explanations. This should be done at the national level, and where relevant and feasible for: 1) person (e.g., by age, sex, wealth quintiles, or vulnerability and key populations); 2) and place (subnational geographic and ecological zones); and 3) time (years or seasonal variations). The findings will be assembled in a narrative to be reviewed and agreed with national stakeholders, and inform a plausibility argument of outcomes and impact, to assess how non-programmatic factors may have had an impact on trends in disease burden.

➔ **Phase IV: Report Development**

Develop draft comprehensive report: Upon completion of data analysis and interpretation, a comprehensive report will be produced in line with the details provided in the Deliverables section, below. This draft should be submitted to the Global Fund and other relevant stakeholders for review and comment.

Final report and presentation: A final report will be developed, addressing all comments, and accompanied by a slide deck summarizing relevant findings and conclusions.

Deliverables

1. Inception report: An initial report which:
    a. Summarizes the available data on the *(HIV/TB/malaria)* situation in *(country)* by data source, describing any apparent gaps which will be addressed during Phase II/in-country review;

b. Outlines the methodology that will be employed to complete data collection and analysis, including a detailed list of stakeholders to be consulted, facilities to be visited, and data sources to be retrieved during any in-country review;
c. Includes the agenda for in-country work;
d. Provides an outline of the final analytical report, making any adjustments needed for context (see further guidance on report format, directly below); and
e. Is accompanied by a slide-deck for initial briefing to stakeholders during Phase II.

2. Draft comprehensive report: An analytical report is produced presenting the *(HIV/TB/malaria)* situation in *(country)* and the prospects for achieving program objectives. This report should be structured around the objectives outlined above, and include:
    a. An Executive Summary
    b. A narrative description of the main features of the current national *(HIV/TB/malaria)* program context, programmatic objectives (as outlined in the NSPs), the national health information management system (HMIS), and other disease surveillance and information systems (if separate), including analysis of quality. This should touch upon on all the review topics under Objective 1 and highlighting which areas are in need of improvement.
        i. This should include a list of core indicators, baseline and targets that were set in the National Strategic Plans; list of data sources used during the review/analysis, including any available data quality assessments for those sources;
        ii. Consideration should be given to summary and analysis of whether all disease-specific surveillance and information systems (including logistics management information systems, laboratory data, community-led monitoring systems, entomological and intervention data (malaria)) are appropriately integrated into the HMIS and any gaps to be addressed in this area
    c. Trend analysis on program results on core coverage indicators (HIV/TB/malaria) by geographic area and disaggregated by important population characteristics (such as age and gender); and analysis of the factors for observed changes
    d. Time series plots of *(HIV/TB/malaria)* prevalence *(user should remove "prevalence" for TB analysis)*, incidence, mortality and any other routinely collected indicators, with specific attention to dates/years of scale-up of key interventions. Note that time of procurement and actual availability for beneficiaries may be very different, and also by regions.
    e. Analysis of the geographic distribution of *(HIV/TB/malaria)* incidence and prevalence (where data are available), whether this has changed over time, and exploration of reasons for observed trends and geographical heterogeneity
    f. Trends in age- and sex-specific *(HIV/TB/malaria)* incidence, prevalence, mortality (where data are available) and any other routinely collected indicators, whether this has changed over time, and exploration of reasons for observed trends
        i. This should be supported by a set of other relevant analytics including tables, charts, and/or graphs and accompanying narrative containing

detailed, evidence-based interpretations and conclusions reached with respect to disease burden and outcomes (behaviors and intervention success, e.g. treatment success, viral suppression, prevention outcomes)

g. A list of plausibility arguments or hypotheses and associated logic models or causal pathway diagrams.
    i. This should include a map or matrix of data and sources for each plausibility to be investigated, across the results chain, and identifying any gaps.
    ii. This should also include a set of analytics including tables, charts, and/or graphs and accompanying narrative containing detailed, evidence-based interpretations and conclusions reached with respect to any alternative hypotheses explored and plausibility argument(s)
h. A list of any hypotheses or plausibility arguments that need to be investigated further in the program review or through operational research
i. A summary of investments recommended to improve programmatic results as well as surveillance and/or information system/evidence about disease trends and burdens in the future
j. A priority set of evidence based gaps (5-6 with evidence and description) and opportunities to improve the impact of the program to guide the comprehensive program review

3. Final comprehensive report: A final analytical report (as described above) which responds to consolidated feedback from the national program, the Global Fund, WHO, and any other relevant stakeholders. This comprehensive report will be annexed to the National *(HIV/TB/malaria)* Program Review Report and be made publicly available online.

4. Presentation to stakeholders: Presentation of a slide deck summarizing key findings and conclusions presented in the final analytical report, presented to and for use by the national *(HIV/TB/malaria)* control program, Global Fund and external stakeholders, and accompanied by a facilitated discussion on any follow-up plans.

Expertise and Partnerships As with other aspects of Program Review, the national *(HIV/TB/malaria)* program should lead and coordinate the epidemiological and impact analysis[2] to be conducted by an independent consultant. As alternative causal pathways are developed as part of the epidemiological and impact analysis, care should be taken to include technical stakeholders who may have insight into these pathways as well. Sub-national level health managers may be involved where feasible and important.

[2] Typical partners in a Program Review include the epidemiologists, evaluation experts and data analysts of a disease program, the data manager of the country's health information system, technical partners with analytical and epidemiological capacities, such as WHO and UNAIDS, and major donors in country, e.g. World Bank, PEPFAR and PMI. Other partners, e.g. other bilateral programs, local universities and technical NGOs, should also be engaged, in particular in consultation meetings at the start and end of the process.

Level of Effort and Timeline

The Level of Effort (LOE) required for conducting an Epidemiological and Impact Analysis depends in part on the scope of the analysis, the methodology employed, availability of & access to data, 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, and their previous experience of conducting such analyses.

An indicative LOE with associated timeline is provided below, but may be adjusted based on context:

Phase	Task	LOE	Week								
			1	2	3	4	5	6	7	8	9
Phase I	Collection and initial analysis of data	Up to 10 days	X	X							
	Development of inception report	Up to 5 days			X						
Phase II	In-country/ remote investigation	Up to 10 days				X	X				
Phase III	Final data analysis and development of draft comprehensive report	Up to 15 days						X	X		
	Finalize comprehensive report based on Global Fund and stakeholder feedback, present findings	Up to 5 days								X	X
Total		Up to 45 days									

Profile Required

- A senior epidemiologist or statistician with extensive quantitative skills and a proven track record of producing analytical results and communicating them well (including in scientific publications in peer reviewed journals);
- Excellent understanding of *(HIV/TB/malaria)* epidemiology, surveillance systems, public health policies and interventions on *(HIV/TB/malaria)*, and health systems;

- Extensive experience in working with national *(HIV/TB/malaria)* health programs and offering technical assistance.
- Strong writing skills and ability to succinctly communicate complex information and analysis.
- Fluency in English and at least one of the primary languages used for conversation and reporting in the country.

Place of Performance

Specific place of performance should be inserted for each individual case. Desk review and initial data analysis may be conducted remotely, while in-country investigation will generally require presence in at least the capital city of the country under investigation (though may be able to be conducted remotely in case of physical or health security concerns).

Annex I: HIV-Specific Tasks

Objective 1. Review and describe current national HIV surveillance and vital statistics, with particular attention to their capacity to measure the level of and trends in HIV disease burden (incidence, prevalence, \and mortality).

Task 1.1. Provide a written description and explanation of the main features of the current national HIV data and information system across the results chain (See Annex 1 for a diagram of the results chain). The sources should include routine program reports on inputs (resource tracking documents; national health accounts; control program budgets, national health and HIV strategies); service delivery outputs (including surveillance and program reports, facility assessments, clinical reporting, community-based service provider reports); and outcome and impact (epidemiological estimates, population-based surveys, HIV surveillance, behavioral surveys, studies of key and vulnerable populations, and vital registration sources). See “Q11. Strategic Information” in WHO Guidelines document. The description should include:

a) Definition of the agencies/individuals responsible for data collection (both quantitative and qualitative data), analysis and reporting;

b) Mechanisms/processes used to assure/assess data quality;

c) Timing and timeliness of reporting including lag times that hamper reporting;

d) The type of data available at the national level and sub-national levels (e.g. aggregated/dis- aggregated reports, case-based data);

e) Approach to analysis and reporting of data;

f) An overview of HIV data systems -- including those from laboratory, logistics management information systems (LMIS), community-based service sites -- are related to/linked with any other health information systems, e.g. the national Health Management Information System (HMIS), health insurance, TB Program Information Systems

Task 1.2. Assess the current capacity of national systems, surveys and the vital registration systems to provide direct measures or estimation/modelling of HIV disease burden.

Task 1.3. Summarize the main strengths of the current surveillance system and the weaknesses/gaps that need to be addressed, based on the findings from 1.1 and 1.2.

Objective 2. Review the level of, and trends in, HIV disease burden (incidence, prevalence, mortality) using available surveillance, survey, programmatic and other data.

Task 2.1. Review, compile and interpret published results or estimates of HIV incidence, prevalence, and mortality that are already available from existing sources to assess the level of,

and trends in, HIV disease burden (at least nationally and when feasible sub-nationally and among sub-populations, including key and vulnerable populations).

Task 2.2. Analysis of the level of, and trends in, HIV mortality.

- This is best done using data from a national or sample civil registration system of vital statistics with age, sex and where possible cause of death data.
- If local data are not available estimates can be obtained from WHO/UNAIDS data or from Global Burden of Diseases data.

Task 2.3. Analysis of trends in the distribution HIV mortality associated with TB, if data are available, and of TB notification and mortality trends.

Task 2.4. Analysis of the level of, and trends in, HIV prevalence and HIV incidence, including the factors associated with these trends, for example outcomes and behaviors.

Task 2.5. Other miscellaneous analyses may be called for in specific settings (to be determined by the epidemiologist(s) undertaking the assessment in consultation with the Review Team and key stakeholders).

Objective 3. Review trends on HIV program results with a focus on core coverage level indicators (prevention, testing, treatment) and analysis of HIV service cascade.

Task 3.1. Review, compile and interpret results on core coverage level indicators and trends over time (at least nationally and when feasible sub-nationally and among sub-populations).

- This is best done using data from a national program (including data available from DHIS2 or other systems at central level)
- The results are analyzed against set targets
- Analyze along the cascade of HIV services.

Task 3.2. Review the main interventions (on prevention, testing, treatment, systems strengthening, etc.), the level of implementation, main successes/achievement as well as challenges during implementation.

Task 3.3. Other miscellaneous analyses may be called for in specific settings (to be determined by the epidemiologist(s) undertaking the assessment in consultation with the Review Team and key stakeholders).

Task 3.4. Analyze and interprets the coverage level results over time against the type and level/scope of implementation and the challenges experienced during implementation, i.e. trying to explain if the interventions are linked to the coverage level results and whether other factors might have contributed to.

Objective 4. Determine the plausibility of whether observed changes in disease trends are explained by programmatic efforts and/or any external, no-programmatic factors

Task 4.1. Plausibility argument formulation

a) State reasonable and epidemiologically sound plausibility statements to be examined, together with any confounding and competing explanations for observed changes. There should be one statement centered on the results chain of the HIV program, and at least one centered on factors external to HIV programs that may have influenced or results in impact on HIV

b) For each plausibility statement developed, consider (i) whether data are likely to be available for a given country, and (ii) whether the non-program factors explain trends in disease burden due to factors not related to disease-specific funding and associated interventions. Each statement should have a simple logic model/causal pathway following the results chain.

Task 4.2. Data Mapping.

a) For both HIV and non-program plausibility statements, indicate likely or preferred sources of data needed to assess these statements, and determine availability and sources of data across the results chain from inputs to outcomes (note that impact measures will have been addressed under Objectives 1 and 2). The data must be informative of any alternative scenarios, and any gaps identified.

b) To test the plausibility of each scenario, consult in-country stakeholders in addition to examining data sources related to:

- Inputs (e.g. funding, policies)
- Service delivery outputs (e.g. routine program and facility reports, cascade analyses) Outcomes (e.g. program reports, population-base surveys)

c) For non-program plausibility arguments, see Annex 1 and consult additional in-country stakeholders as needed. In the case of the non-program plausibility arguments/hypotheses, it is understood that in some instances it will not be possible to locate or obtain data sources for all components of the results chain.

Task 4.3. Data Acquisition. Assemble and assess quality of available data pertaining to each plausibility statement. Obtain data from relevant in-country and online sources, as well as from international partners and donors where relevant.

Task 4.4. Quality Check and Validation. Undertake standard checks on the quality of data. This would include a consideration of any known sources of measurement error and how these were addressed; completeness of the data set; and a consideration of non-measurement sources of error or bias (e.g. selection bias).

Task 4.5. Analysis, Synthesis and interpretation. Analyze and interpret the evidence across the each results chain to relate the interpretation to the appropriate logic model/causal pathway and trends in HIV impact analyzed under Objective 2 of the epidemiological and impact analysis.

Task 4.6. Develop Plausibility Argument, Report writing, Presentation, and Use of Findings.

a) Address the objectives of the epidemiological and impact analysis outlined earlier into a report section, using output of previous tasks. This section should be included with the findings of other components of the review and should contain the following content:

   - The extent to which changes in disease burden plausibly reflect programmatic efforts or appear due, in part or in whole, to other factors. A qualitative judgment about the relative contribution to impact of program and non- program factors should be included;

   - Whether there are specific geographical areas or subpopulations 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;

   - Potential areas of investment needed to improve evidence about impact (trends in disease burden) in future;

   - Priority set of evidence based gaps and opportunities to improve the impact of the program to guide more detailed program reviews

   - Implications and recommendations to improve program management.

b) Work in collaboration with the other members of the review team under the guidance of the national HIV/AIDS program or Ministry of Health to produce a single, complete review report incorporating the epi and impact analysis
c) Participate in data use and dissemination workshops or presentations at the conclusion of the review period to share findings with the key in-country stakeholders.

Objective 5. Define the investments needed to directly measure and analyze trends in HIV disease burden in future.

Task 5.1. Provide analysis on the adequacy of the program design towards impact - including scope/intervention areas covered, the geographic focus, target population, implementation arrangements and the level of investment.

Task 5.2. Provide analysis on the adequacy of the existing routing information/data system and how it can be improved

Task 5.3. Determine whether any baseline or repeat analysis or surveys (e.g. incidence or prevalence survey, cause of death survey, size estimation, etc.) are needed, and if so what timing would be appropriate and when these are expected to be conducted. Describe the data that is required to strengthen the causal analysis, for example evidence of outcomes including behaviors and intervention success, and programmatic data on cascade gaps in services.

Annex II: TB-Specific Tasks

Further guidance on information containing Epidemiological and Impact Analysis for TB is also available in WHO's:

- *Framework for conducting reviews of tuberculosis programmes,*
- *Draft Implementation guidance for national tuberculosis and epidemiological reviews*
- *Standards and benchmarks for tuberculosis surveillance and vital registration systems, checklist and user guide, and*
- *Handbook for understanding and using TB data*

Objective 1. Review and describe current national TB surveillance and vital registration, with particular attention to their capacity to measure the level of and trends in TB disease burden (incidence, prevalence, and mortality).

Task 1.1. Provide a written description and explanation of the main features of the current national TB surveillance and vital registration systems. These should include:

a) the data being captured (e.g. notified cases, treatment outcomes, causes of death);
b) definition of the agencies/individuals responsible for data collection, analysis and reporting and how they interact;
c) 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;
d) 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);
e) approach to analysis and reporting of data;
f) staffing levels, including/with emphasis on staffing of monitoring and evaluation positions;
g) overview of TB data systems -- including those from laboratory, logistics management information systems (LMIS), community-based service sites -- are related to/linked with any other health information systems, e.g. the national Health Management Information System (HMIS), health insurance, hospital reporting system, HIV information system, etc.

To help characterize the TB surveillance system, Part A of the WHO TB surveillance checklist (18 questions) should be completed[3].

Task 1.2. 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 (Part B).

[3] As of February 2021, the WHO standards and benchmarks document is currently being revised and updated.

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. The 13 standards cover the dimensions of TB data quality (B1.1-B1.7), system coverage for TB surveillance (B1.8-B1.9) and vital registration (B1.10), as well as the surveillance of drug-resistant TB (B1.11), TB/HIV (B1.12), and pediatric TB (B1.13).

Task 1.3. Summarize the main strengths of the current surveillance system and the weaknesses/gaps that need to be addressed, based on the findings from Tasks 1.1 and 1.2.

A comprehensive list of data sources is provided in the user guide that accompanies the WHO TB Surveillance Checklist.

Objective 2. Review the level of, and trends in, TB disease burden (incidence, mortality, notifications) using available surveillance, survey, programmatic and other data.

Task 2.1. Analysis of the level of, and trends in, TB incidence. This includes:

a) Analysis of trends in TB incidence among HIV-negative and HIV-positive individuals.
    - Each year, WHO publishes estimates of TB incidence among HIV-negative and -positive people from 2000 onwards for all countries in the annual global TB report. These estimates provide a contextual picture of the epidemiological situation.
b) Analysis of the notification gap, by linking the incidence estimates with the reported notifications (see also task 2.3) and conduct the analysis disaggregated by sex and age where data available,
c) If the country has conducted prevalence surveys, an analysis of how the prevalence survey results link to the incidence and notifications.

Task 2.2. Analysis of the level of, and trends in, TB mortality. This includes:

a) 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).
b) 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.

Task 2.3. Analysis of the level of, and trends in, TB prevalence.

This task only applies to countries where one or more prevalence surveys have been conducted. It includes:

- Analysis of the trend if data are available from a baseline and at least one repeat survey (7-10 years apart). If the country has conducted one prevalence survey

Task 2.3. Analysis and interpretation of the level of, and trends in, TB case notifications for drug susceptible (DS) and drug resistant (DR) TB (e.g. for the last 5-10 years). This should include (where data is available):

a) Plotting time series of case notifications and analysis of 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.
b) 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).
c) Analysis of trends in service provision, i.e. public, private or community settings.
d) Analysis of coverage of WHO approved Rapid Diagnostics and of drug susceptibility testing.
e) Analysis of trends and geographic heterogeneity in the proportions of types cases notified: (a) by type of TB disease – pulmonary bacteriologically confirmed, pulmonary clinically diagnosed, and extra-pulmonary TB; (b) by age group, including the proportion of cases among children (0-4, 5-14); (c) by treatment history (previously treated out of total notified cases).
f) Analysis of trends in age- and sex-specific case notification rates *(where population data is available for the denominator)*, the average age of newly notified cases, and the extent to which these can be explained by demographic or other factors.
g) Analysis of the level of (and ideally trends in) under-reporting from national inventory studies if these are available before the assessment and incorporation of the results from the inventory study into the overall report narrative.
h) 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.
i) Other miscellaneous analyses that may be relevant in specific settings (to be determined by the epidemiologist undertaking the assessment).

Task 2.4. Analysis and interpretation of the level of, and trends in, TB treatment outcomes for both DS- and DR-TB (e.g. for the last 5-10 years). This should include:

a) Analysis of treatment outcomes, including disaggregation by age & gender *(where available),* HIV status, geography, time series and other population factors as relevant.
b) Analysis of DS-TB versus DR-TB treatment success.

c) Analysis of proportion of people treated for TB out of all notified, and the treatment outcomes by category: cure, treatment completed (together treatment success), treatment failure, lost-to-follow-up, died and not evaluated);
d) 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;
e) For a) and b) include in the analysis disaggregation by age, gender, geography and other population factors as relevant.

Objective 3. Determine causal pathways leading to impact on TB due to programmatic explanations and factors aside from those related to TB programs.

Task 3.1. Define and compile available data that are relevant to understanding how the 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:

a) Government and international donor funding for TB care and control;
b) Number of health facilities providing TB diagnostic services per 100,000 population;
c) Number of health facilities providing TB treatment services per 100,000 population;
d) Number of people investigated for presumptive TB (if available data are reliable) and the ratio of presumptive TB to notified TB cases;
e) Performance of community/active case finding (number of cases screened and detected by each mechanism);
f) 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);
g) Any quantitative data on diagnostic delays (due to patient, private sector, or public sector delays);
h) Number of people treated for TB out of all notified (disaggregated by treatment outcomes: successfully treated (cure and treatment completion), treatment failure, lost-to-follow-up and died);
i) 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;

j) Any relevant data from earlier objectives should also be considered here.

Task 3.2. Define and compile available data that are relevant to assessment of 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:

a) Prevalence of HIV among the general population, and ART coverage.
b) Prevalence of diabetes, tobacco use and under-nutrition.
c) GNI per capita and the % of the population under the poverty line, and the impact of economic crises.
d) Coverage of financial protection for health care costs (by government health budget or health insurance etc.) and social protection programs (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
e) Demographic changes; percentage of population who are less than 15, and those more than 65 years
f) Under-5 mortality rate (as an indicator of the overall performance of the health- care system).

Objective 4. Define the investments needed to improve TB program performance and impact; to improve TB information system and to measure impact over time.

Task 4.1. Provide analysis on the adequacy of the program design towards impact - including scope/intervention areas covered, the geographic focus, target population, implementation arrangements and the level of investment.

Provide recommendations to overcome data gaps identified through the review: these may include improvements to the (routine) surveillance system, conduct or repeat surveys or inventory studies or others as deemed relevant.

Task 4.2. Provide analysis on the adequacy of the existing routing information/data system and how it can be improved. 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).

Task 4.3. Determine whether any further analysis or surveys (e.g. prevalence survey, inventory study, cause of death survey) are needed, and if so what timing would be appropriate; and when these are expected to be conducted. An appropriate amount of time should be ensured between repeat surveys (for example, a repeat TB prevalence survey should normally be done 7-10 years after the previous one). Guidance on countries where prevalence surveys are recommended is available from the Global Task Force on TB Impact Measurement.

Annex III: Malaria-specific Tasks

Further guidance on information containing Epidemiological and Impact Analysis for malaria is also available in "The practical manual for malaria programme review (MPR) and malaria strategic plan mid-term review (MTR), Framework for Evaluating National Malaria Programs in Moderate- and Low-Transmission Settings"; and Section 7 of the Malaria surveillance, monitoring & evaluation: a reference manual.

Objective 1. Carry out a rapid malaria surveillance system assessment using the standardized WHO surveillance assessment toolkit which aims to assess the capacity of national malaria surveillance and vital statistics (CRVS) systems to accurately measure the level of and trends in disease burden (incidence and mortality).

The following tasks should be carried out through implementation of the WHO malaria surveillance system toolkit. This Terms of Reference is only suitable for countries that plan to carry out a rapid surveillance system assessment. Countries requiring a comprehensive assessment should implement the assessment separately as per guidelines.

Task 1.1. Using the indicator table from the WHO surveillance assessment toolkit, define the scope of the assessment by selecting surveillance strategies and high priority indicators which will be assessed as part of a rapid malaria surveillance system assessment, and develop a standardized concept note which is part of the toolkit.

Task 1.2. Assess the current capacity of national surveillance systems and the CRVS systems to provide direct measures of malaria disease burden through desk and data quality review of case based surveillance (burden reduction and/or elimination settings) at the national, and service delivery levels, as necessary. As relevant, carry out a high-level assessment of other surveillance strategies (data collected, surveillance systems in use and level of integration with routine malaria surveillance). Desk review and data quality review tools are provided in the WHO surveillance system assessment toolkit to allow standardized data collection and analysis of core indicators.

Task 1.3. Summarize the main strengths of the current malaria surveillance system and the weaknesses/gaps that need to be addressed, based on the findings from 1.1 and 1.2 in a technical briefing presentation and report. This report should include key recommendations for surveillance system strengthening and a prioritized operational activities plan.

Objective 2. Review the level of, and trends in, malaria burden using available surveillance, survey, programmatic and other data.

Task 2.1. Analysis of the level of, and trends in, all-cause under-five and malaria-specific mortality.

a) This is best done using data from a national or sample civil registration and vital statistics system with cause of death data.
b) If local data are not available estimates can be obtained from the UN Inter-agency Group

for Child Mortality Estimation (IGME)[4] and from the Global Burden of Diseases data (for all ages)[5].

c) In the absence of population-level data, analysis of trends in in-patient malaria deaths from routine surveillance should be considered as it would provide valuable insights on temporal and spatial trends of malaria mortality.

Task 2.2. Analysis of the level of, and trends in, malaria morbidity: prevalence and incidence as well as prevalence of severe anemia in children.

Task 2.3. Assess the progress towards entomological impact of the MSP, looking at:

a) inclusion and appropriateness of entomological impact indicators included in the MSP; appropriate phrasing and smartness of indicators;
b) inclusion of baselines and targets for each entomological impact indicator contained in the MSP;
c) progress towards the MSP entomological impact targets;
d) trends of entomological inoculation rate, including any changes in vector behaviors;
e) trends of malaria vector bionomics; and
f) vector map and species distribution.

Task 2.4. Other miscellaneous analyses may be called for in specific settings (to be determined by the epidemiologist(s) undertaking the assessment in consultation with the Program Review team and/or key stakeholders).

Objective 3. Determine causal pathways leading to impact on malaria due to programmatic explanations and factors aside from those related to malaria programs.

Task 3.1. Plausibility argument formulation.

a) State reasonable and epidemiologically sound plausibility statements to be examined. There should be one statement centered on the results chain of the malaria control and elimination program, and at least one centered on factors external to malaria programs that may have influenced or resulted in impact on malaria. (See Global Fund Guidance Note p46-47 for examples.)
b) b) For each plausibility statement developed, consider (i) whether data are likely to be available for a given country, and (ii) whether the non-program factors explain trends in disease burden due to factors not related to disease-specific funding and associated interventions. Each statement should have a simple logic model/causal pathway following the results chain.

[4] IGME. https://childmortality.org/data
[5] WHO, Mortality estimates by cause, age and sex: https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death

Task 3.2. Data Mapping.

a) For both malaria programmatic and non-programmatic plausibility statements, indicate likely or preferred sources of data needed to assess these statements, and determine availability and sources of data across the results chain from inputs to outcomes (note that impact measures will have been addressed under Objectives 1 and 2). The data must be informative of each alternative scenarios, and any gaps identified.
b) For the malaria program plausibility arguments linked to impact, consult in-country stakeholders in addition to examining data sources related to:
    - Inputs (e.g. funding, policies)
    - Service delivery outputs (e.g. routine program and facility reports)
    - Outcomes (e.g. program reports, population-base surveys)
c) For the non-program hypothesis or plausibility arguments, see Annex 1 and consult additional in-country stakeholders as needed. In some of the non-programmatic arguments, it may not be possible to locate or obtain data sources for all components of the results chain.

Task 3.3. Data Acquisition. Assemble and assess the quality of available data pertaining to each plausibility statement. Obtain data from relevant in-country and online sources, as well as from international partners and donors where relevant.

Task 3.4. Quality Check and Validation. Undertake standard checks on the quality of data. This includes a consideration of any known sources of measurement error and how these were addressed; completeness of the data set; and a consideration of non-measurement sources of error or bias (e.g. selection bias). This should be carried out as part of the surveillance assessment and toolkit described under objective 1 above.

Task 3.5. Analysis, Synthesis and interpretation. Analyze and interpret the evidence across the results chain to relate the interpretation to the appropriate logic model/causal pathway and trends in malaria impact analyzed under Objective 2 above.

Task 3.6. Develop Plausibility Argument, Report writing, Presentation, and Use of Findings. Address the objectives of the epidemiology and impact analysis outlined earlier into a comprehensive report section, using output of previous tasks. This section should be included with the findings of other components of the review and should contain the following content:

a) The extent to which changes in disease burden plausibly reflect programmatic efforts or appear due, in part or in whole, to other factors
b) A qualitative, expert judgment about the relative contribution to impact of program and non-program factors should be included
c) Whether there are specific geographical areas or subpopulations in which the burden of disease is especially high – or not changing over time – 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) Potential areas of investment needed to improve evidence about impact (trends in disease

burden) in future

e) Implications and recommendations to improve program management
f) Work in collaboration with the other members of the review team under the guidance of the national malaria control program or Ministry of Health to incorporate the epidemiology and impact analysis into the bigger program review report.
g) Participate in data use and dissemination workshops or presentations at the conclusion of the review period to share findings with the key in-country stakeholders.

Objective 4. Define the investments needed to directly measure trends in malaria disease burden in future.

Task 4.1. Determine the nature and extent of investments required to address the gaps in malaria surveillance (routine reporting, sentinel surveillance, community and private sector reporting, etc.) and CRVS systems.

Task 4.2. Determine areas of investment needed to improve the quality and completeness of malaria data.

Task 4.3. Determine whether any baseline or repeat population-based surveys (such as malaria indicator survey – MIS) are needed, and if so what timing would be appropriate. An appropriate amount of time should be ensured between repeat surveys.