A Practical Handbook for National TB Laboratory Strategic Plan Development

TB CARE I

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A Practical Handbook for National TB Laboratory Strategic Plan Development

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KNCV
To eliminate TB

TUBERCULOSISFOUNDATION

International Union Against
Tuberculosis and Lung Disease
Health solutions for the poor

CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION

msh
Management Sciences for Health

gli
global laboratory initiative
advancing TB diagnosis

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Contents

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Terms and Abbreviations

AFB	Acid Fast Bacilli
AIDS	Acquired Immunodeficiency Syndrome
ATT	Anti-TB Treatment
CDC	Centers for Disease Control and Prevention
CMS	Central Medical Stores
Cx	Culture
CXR	Chest X-ray
DRS	Drug Resistance Survey
DST	Drugs Susceptibility Testing
EQA	External Quality Assessment
FM	Fluorescent Microscopy
GLI	Global Laboratory Initiative
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HRD	Human Resource Development
IC	Infection Control
KNCV	KNCV Tuberculosis Foundation
LED	Light Emitting Diode
LPA	Line Probe Assay
M&E	Monitoring and Evaluation
MDR	Multi Drug Resistant
MoH	Ministry of Health
NHL	National Health Laboratories
NRL	National Reference Laboratory
NTP	National Tuberculosis Program
NTRL	National Tuberculosis Reference Laboratory
PLWHA	People Living with HIV/AIDS
QM	Quality Management
RIF	Rifampicin
SCMS	Supply and commodities management system
SM	Smear
SOP	Standard Operating Procedure
SNRL	Supra-National Reference Laboratory
SS+	Sputum Smear Positive
SS-	Sputum Smear Negative
SWOT	Strength Weakness Opportunity Threat (analysis)
TAT	Turn-around time
TB	Tuberculosis
ToR	Terms of Reference
WHO	World Health Organization
WHO AFRO	World Health Organization Africa
XDR	Extensively Drug Resistant

Glossary

National TB program (NTP) Strategic Plans:	These plans are now common to most TB programs and delineate how countries will achieve their overall TB control strategy over a 5-year period, usually based on addressing the Global Stop TB strategy objectives. These plans include both laboratory and non-laboratory interventions. In this handbook such a strategic plan is abbreviated as **NTP plans.**
National Medical Laboratory Plans:	These plans are sector-wide, health-system strengthening laboratory strategic plans. These strategic plans are becoming more common. As all diseases are included, the portion dedicated specifically to TB is typically minimal. If a national medical laboratory plan exists, such strategy should be incorporated into the TB-specific laboratory strategic plan development. On the other hand, once written, the TB-specific laboratory strategic plan should be utilized for the development of any national medical laboratory plan.
TB-specific Laboratory Strategic Plans:	These plans are new to most countries and are the basis for this handbook. They are similar to the NTP plans, in that they are also 5-year plans but focus only on laboratory interventions to achieve the goals of the NTP plans. In this handbook such strategic plans are abbreviated as **TB laboratory plans.**
Objectives:	For the purposes of the TB- laboratory plan described by this handbook, an **objective** is pre-defined (per Global Plan Stop TB 2011-2015 laboratory strengthening Objectives 1-4) as a broad goal broken down by technical area, of where you want the national TB laboratory network to be in 5 years: **Objective 1:** Increase access to quality-assured AFB microscopy with effective External Quality Assessment (EQA) **Objective 2:** Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV **Objective 3:** Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB **Objective 4:** Establish Laboratory Quality Management Systems.
Strategies:	For the purposes of the TB laboratory plan described by this handbook, a **strategy** is a sub-objective to achieve the objective. The strategies in this handbook are pre-defined per the seven WHO AFRO-GLI strategic priorities and include an eighth one on operational research: 1. Strengthen laboratory infrastructure and maintenance contracts 2. Improve laboratory human resource development 3. Develop and maintain laboratory quality management systems 4. Enhance management of laboratory commodities and supplies including equipment validation and maintenance 5. Fortify specimen transport and referral mechanisms 6. Improve laboratory information and data management systems 7. Establish a TB laboratory regulatory framework 8. Develop OR capacity regarding TB laboratories.

Chapter 1:

Purpose of the Handbook and Getting Started

This handbook is designed to guide simplified steps for national TB control programs to develop a TB-specific national laboratory strategic plan, abbreviated here forward as the TB laboratory plan. This handbook draws upon a broader, non-TB specific guidance document for national laboratory strategic plans namely, *Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infected with and affected by HIV/AIDS, TB and Malaria*. This handbook further draws from the Global Laboratory Initiative's (GLI) *Roadmap for ensuring quality tuberculosis diagnostics services within national laboratory strategic plans*.

Key References:

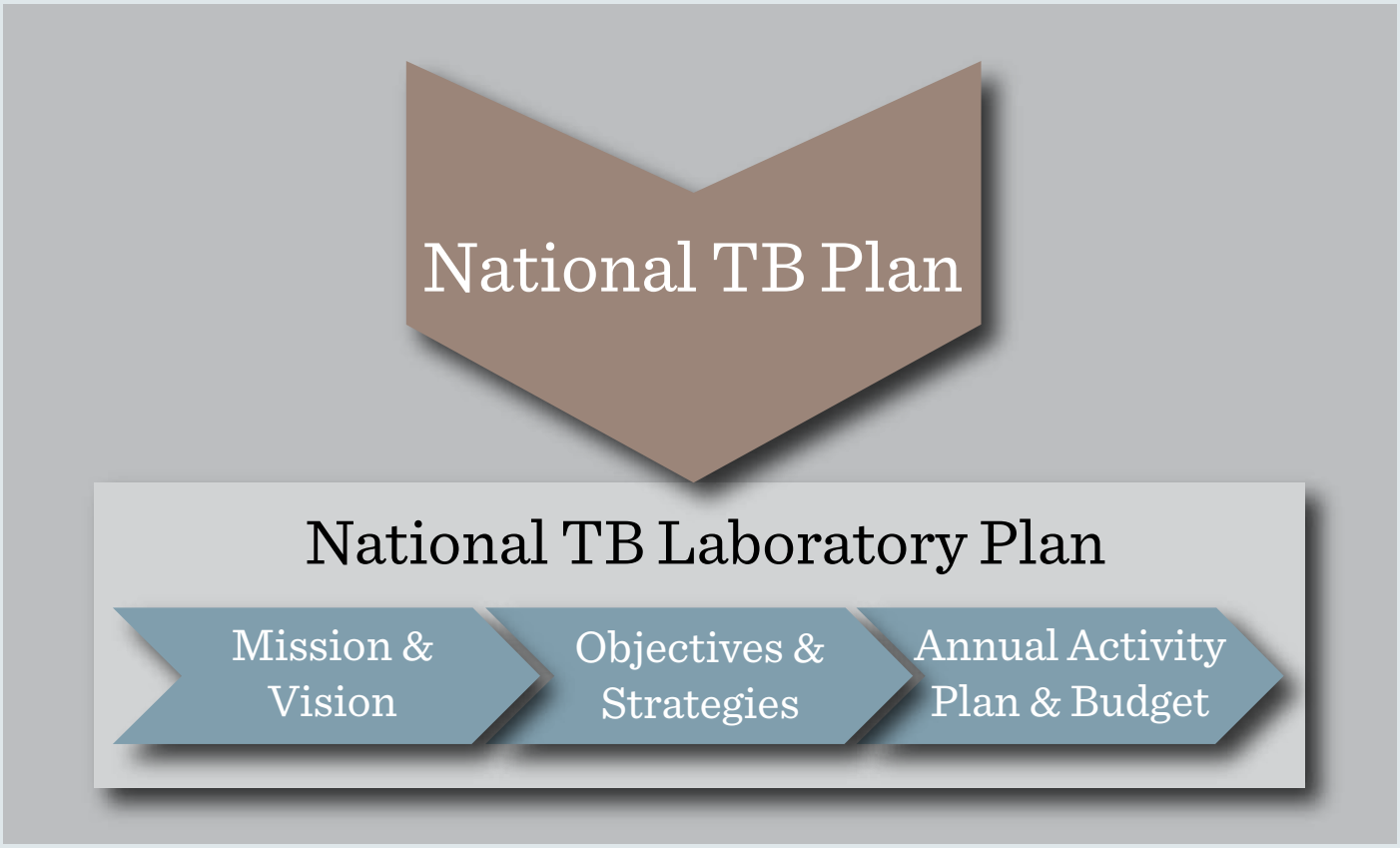
Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infected with and affected by HIV/AIDS, TB and Malaria, WHO Geneva/WHO Africa/US Centers for Disease Control and Prevention/Association of Public Health Laboratories, 2010.

Roadmap for ensuring quality tuberculosis diagnostics services within national laboratory strategic plans. Global Laboratory Initiative, 2010.

The Stop TB Partnership Global Plan to Stop TB 2011-2015: transforming the fight towards elimination of tuberculosis, WHO, 2011.

Laboratories are essential for diagnosis and treatment monitoring and are becoming increasingly complex with the expansion of quality-assured smear microscopy, culture, and drug-susceptibility testing (DST) as well as novel laboratory tools e.g. line probe assays (LPAs) and the GeneXpert MTB/RIF test. In the context of low- and middle-income countries, TB laboratories are often challenged to provide the services needed to maximize TB control. Once TB laboratory plans are developed, they should be utilized for concrete, time-delineated, and target-driven laboratory strengthening. TB laboratory plans may also be used for advocating resource-allocation and mobilization. This TB-specific strategic approach would be beneficial to integrate within a broader laboratory strengthening strategy such as a national medical laboratory strategic plan; however, this will not be focused upon in this handbook. This handbook also provides references for further consultation for both policies and technical recommendations.

The TB laboratory plan should be developed on the basis of contributing to the overall goal of the National Tuberculosis Program (NTP) plan. It should also be aligned with existing national TB diagnostic algorithms. An NTP plan and clear diagnostic algorithms are indeed prerequisites for the development of the TB laboratory plan. A country example of a diagnostic algorithm for the use of the GeneXpert MTB/RIF test may be found in **Annex 1**. Ideally, the NTP plan should be developed in a draft form but not finalized at the time of the TB laboratory plan development. This will provide an opportunity to harmonize strategies and objectives between the NTP and the national TB laboratory network in terms of laboratory strengthening. The starting point, however, could be later if the NTP plan has already been developed. For example, if the NTP plan has already been finalized and is, for example, in the third year of implementation, and could be a two-year plan: then at the fifth year both could be strategically aligned as new five-year plans. Conceptually, the TB laboratory plan should be embedded within the NTP plan. The figure on page 8 represents this concept.



Notwithstanding, the basis of a TB laboratory plan should also follow the Global Plan to Stop TB 2011-15, adapted to the country-specific epidemiologic situation. The essence of this Global Plan is to provide universal access to quality TB diagnostics for all TB patients by 2015. Historically, many TB laboratory networks in low- and middle-income countries have prioritized the detection of smear-positive cases, and hence are not designed to detect all forms of TB (smear-negative, extra-pulmonary and drug-resistant tuberculosis). In order to do this, an expansion and re-tooling of laboratory networks is necessary in many countries. This handbook uses this Global Plan as a basis for developing country-specific objectives, strategies and activities to detect all forms of TB in a quality-assured manner. The Global Plan objectives relevant to the TB laboratory plan are listed below:

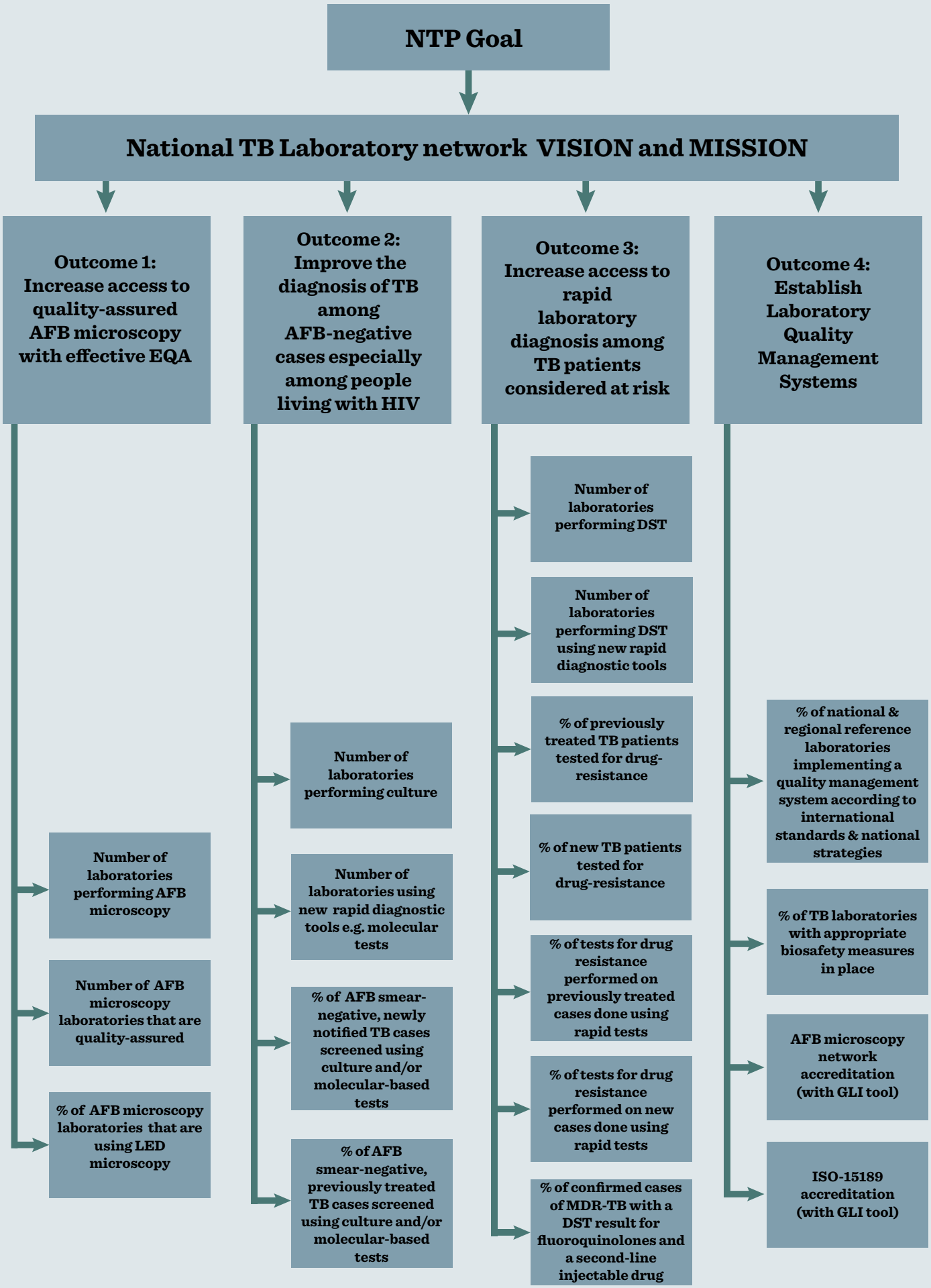
Conceptually, this handbook enables national TB programs to link their strategic goal with the TB laboratory plan via the Stop TB objectives. Each objective is further built upon by strategies and activities. Already planned lab-strengthening activities e.g. NTP, Global Fund and partner activities should also be included in the TB laboratory plan. Additional planned laboratory services will then need to be quantified and translated into planned activities in order to achieve them. All of the planned activities are then budgeted with an Excel costing tool designed specifically for TB laboratory plans. An M&E framework is also established to monitor processes to be achieved from the implementation of the TB laboratory plan with indicators and targets. Each of the objectives within this framework will be measured based on specific outcomes as illustrated the figure on page 9.

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV

Objective 3: Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB

Objective 4: Establish Laboratory Quality Management Systems


NTP Goal
National TB Laboratory network VISION and MISSION
Outcome 1: Increase access to quality-assured AFB microscopy with effective EQA
Outcome 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV
Outcome 3: Increase access to rapid laboratory diagnosis among TB patients considered at risk
Outcome 4: Establish Laboratory Quality Management Systems
Number of laboratories performing AFB microscopy
Number of AFB microscopy laboratories that are quality-assured
% of AFB microscopy laboratories that are using LED microscopy
Number of laboratories performing culture
Number of laboratories using new rapid diagnostic tools e.g. molecular tests
% of AFB smear-negative, newly notified TB cases screened using culture and/or molecular-based tests
% of AFB smear-negative, previously treated TB cases screened using culture and/or molecular-based tests
Number of laboratories performing DST
Number of laboratories performing DST using new rapid diagnostic tools
% of previously treated TB patients tested for drug-resistance
% of new TB patients tested for drug-resistance
% of tests for drug resistance performed on previously treated cases done using rapid tests
% of tests for drug resistance performed on new cases done using rapid tests
% of confirmed cases of MDR-TB with a DST result for fluoroquinolones and a second-line injectable drug
% of national & regional reference laboratories implementing a quality management system according to international standards & national strategies
% of TB laboratories with appropriate biosafety measures in place
AFB microscopy network accreditation (with GLI tool)
ISO-15189 accreditation (with GLI tool)

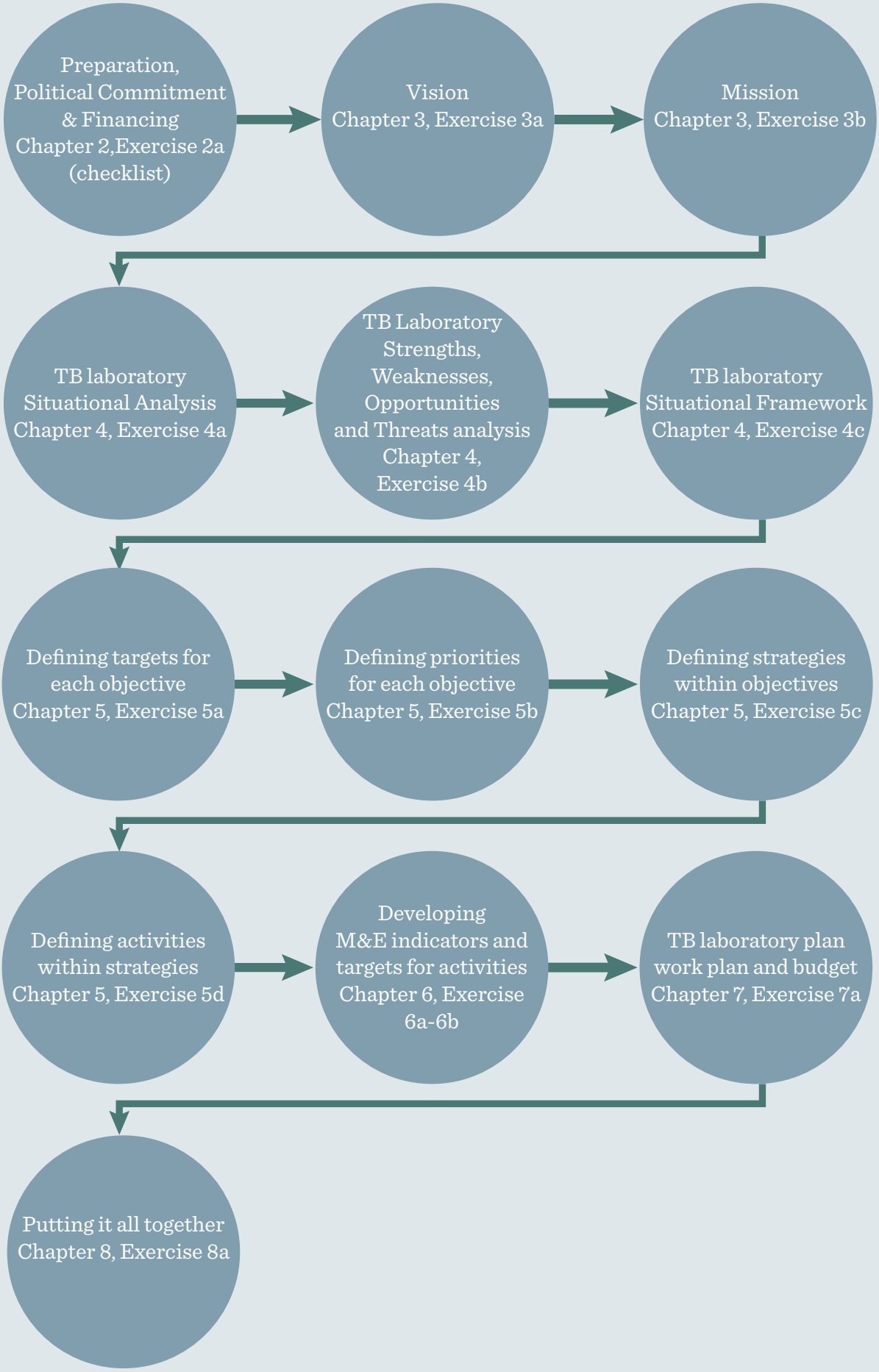
The primary target audience of this handbook is TB laboratory strengthening consultants, National TB reference laboratory (NTRL) administrators, and NTP management. The handbook delineates a sample format for TB laboratory plans with 14 exercises to develop each section. The exercises are summarized in each chapter whereas templates for each are provided in the participant's manual. A facilitator's manual is also available. Ideally, the exercises from this handbook should be facilitated by trained consultants. The consultant will closely facilitate the TB laboratory plan development with national stakeholders within the context of two one-week workshops. However, preparation for and follow-up beyond the workshops should be foreseen in this process; the next chapter (Chapter 2) provides a check-list of activities that are likely needed for preparation.

The first one-week workshop would focus on chapters 3-6 including developing a vision, mission, a situational analysis, a situational analysis framework, objectives, strategies, activities and a monitoring evaluation framework with indicators and targets. The second one-week workshop would be conducted within one annual quarter of the first workshop. The time between the first and second workshops will allow national stakeholders to harmonize and finalize the exercises from Chapters 3-6 that they have developed in the first workshop. The second workshop would focus primarily on Chapters 7-8 including a work plan, budget and putting it all together to have a final TB laboratory plan.

Alternatively, although not ideal, a consultant might be hired to finalize the chapters in between the 1st and 2nd workshop and after the second workshop with e-mail correspondence with at least one assigned NTRL and one member of NTP staff. Ideally, each workshop should include 10-20 stakeholders. However, although again not ideal, the number of participants in both workshops might be reduced to as few as 5 key persons to save costs. Nonetheless, in all subsequent chapters, this handbook assumes, the ideal situation (e.g. 10-20 stakeholders and two one-week workshops) to maximize country ownership of the TB laboratory plan as well as quality standards. We provide a flowchart in this chapter to summarize the architecture and steps of the handbook.

As mentioned previously, for the purposes of simplification, the TB-specific laboratory strategic plan will be referred to herein as the TB laboratory plan.

Flowchart for using the Handbook for the TB laboratory Plan



Chapter 2:

Preparation, Political Commitment, Financing and Planning for TB laboratory Plan Development

The first step prior to the workshop will be to identify the leadership responsible for developing the TB laboratory plan including the National TB Reference Laboratory (NTRL) and the NTP administrators. However, broader (higher-level) management in the National Medical Laboratory Services and Ministry of Health (MoH) should also be consulted, as endorsement on this level should be an eventual over-arching goal.

Resources needed for the TB laboratory plan development should be identified e.g. consultants, workshop venue. NTRLs could also consult with their supra-national reference laboratory for additional guidance. We provide steps and a checklist (**Annex 2**) that should be considered for planning a TB laboratory plan development workshop utilizing this handbook in the participants' manual.

A responsible person should be designated to collect and abstract guidance documents and information. Prior to the workshop, the national TB plan should be utilized to abstract relevant laboratory strengthening strategies and activities. Existing and anticipated revised TB diagnostic algorithms must be considered for the proposed national TB laboratory plan.

The NTRL management as well as regional and/or peripheral TB laboratory specialists should be invited to the workshop. Further, stakeholders involved in TB control from the NTP and partner organizations should also be invited to the workshop including those involved in DOTS strengthening, TB/HIV, programmatic management of MDR-TB (PMDT), and pediatric TB. Technical specialists in supply management, EQA, budgeting/finance, engineering, and broader laboratory services (e.g. national health laboratories) should also be considered for the workshop. Representatives from technical working groups should also be considered. To minimize distractions, the workshop could be done as a retreat as it requires a dedicated focus for its duration from all participants.

We provide a list in **Annex 2** of recommended national background materials needed to develop the TB laboratory plan. Further, we provide within each chapter a list of reference materials suggested for the development of each section of the TB laboratory plan. The most essential elements for the development of the TB laboratory plan, however, are the NTP plan(s), the TB epidemiologic situation of the country and national TB diagnostic algorithms. The following exercise should be utilized for preparation for both the 1st and 2nd workshops. Further, we provide examples of workshop agendas in **Annex 2a** and **Annex 2b**.

Exercise 2a: Preparation for the TB laboratory plan workshop

Chapter 3:

Define a Vision and a Mission

The WHO AFRO guidelines describe well the process of developing a vision and mission. As they describe:

Generally, a vision statement expresses what the organization aspires to, and gives an overarching definition of where the future lies for the entity. It is a longer narrative than the mission statement and provides a cogent explanation of the future for the laboratory system.

Generally a vision statement is written in the present tense, and represents an idealized future. As an example, we modified a non-TB specific example from the Management Sciences for Health's Managers Who Lead as follows: *"Our TB laboratory network is known for consistently producing excellent service results and patients can count on our services for TB diagnostics. Further, surrounding country laboratories can count on our capacity to further validate their own results. As a result of our TB laboratory network, we have improved TB diagnostics and therefore saved lives and improved quality of life for patients not only in our own country but in surrounding countries in the region."*

A mission statement is concise and succinctly describes what the organization does, why it exists, who it serves and how it does its work. A mission statement must be understood at all levels of the system and provide a compelling explanation of the greater purpose of the organization. As an example, we modified a non-TB specific WHO AFRO laboratory strategic guidelines example as follows: *"To improve the health status of our country and region by advancing the capacity of all laboratories performing TB diagnostics."*

For a TB laboratory plan, consideration should be given to vision and mission statements of the NTP plan as well as the national medical laboratory plan, should they exist. However, the TB laboratory plan vision and mission should be largely attributable to the combination of activities and qualities the TB laboratory network has envisioned. Therefore, such statements would not refer to treatment of TB patients nor laboratory diagnosis of non-TB diseases.

Once you have completed your vision and mission statements, you should display them throughout both workshops to maintain a focus on achieving these with all aspects of developing the TB laboratory plan. Country examples of vision and mission statements may be found on the next page.

Resources recommended for this chapter:

- NTP mission and vision
- NHL mission and vision (if available)
- Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infection with and affected by HIV/AIDS, TB and Malaria 2010.
- Managers Who Lead. A Handbook for Improving Health Services. Management Sciences for Health, 2005

Key concepts to consider:

- Quality-assured
- Timely
- Advancement
- Reliable
- High-quality
- Customer satisfaction
- Accurate
- Internationally-recognized

Country Example

Botswana

Vision:
To become a recognized Center of Excellence in the sustained provision of quality tuberculosis laboratory services in Botswana and internationally. Our concept of quality includes timeliness, high level of accuracy, and reliability of laboratory services to the satisfaction of our customers. As a recognized Center of Excellence, we pride ourselves in utilizing the most up-to-date internationally-recommended diagnostic technologies.

Mission:
The Botswana national tuberculosis reference laboratory exists to provide its customers with high-quality services by utilizing the latest recommended TB diagnostic technologies, research, training and quality-assurance to aid wider efforts of TB control

Country Example

Nigeria

Vision:
By 2017, TB diagnostic services in Nigeria will be easily accessible, sustainable and acceptable both nationally and internationally. The TB laboratory network will provide high quality, reliable, accurate, and timely diagnostic services that consistently meet customers' satisfaction using appropriate technologies.

Mission:
Our TB laboratory network exists to support the TB Control Program by providing quality diagnostic services for early detection and management of tuberculosis at all levels in Nigeria through continuous improvement in close collaboration with partners and stakeholders

Country Example

Benin

Vision:
Tuberculosis is controlled until it is no longer a public health problem in Benin.

Mission:
Our mission is to provide high quality laboratory services and to strengthen the national tuberculosis laboratory diagnostic network through leadership and expert guidance in support of the national tuberculosis control program to reduce the burden of tuberculosis in Benin.

Exercise 3a: Development of a TB laboratory plan vision statement

Exercise 3b: Development of a TB laboratory plan mission statement

Chapter 4:

TB Laboratory Situational Analysis

This chapter describes how to develop a TB laboratory situational analysis of the TB laboratory network which provides both a contextual and technical overview of the current situation. Further, a TB laboratory contextual framework is also described at the end of the chapter. Exercises are provided for the development of each. The TB laboratory situational analysis includes 13 elements which are described below starting with a TB laboratory contextual analysis. In general, for each of the 13 elements, you should not expect to write more than a one-page description.

Most important inputs required for this chapter:

- Country TB epidemiologic situation
- NTP plan with laboratory and diagnostic targets
- National TB diagnostic algorithms

Exercise 4a: TB-specific situational analysis

Contextual analysis - Resources Needed:

- NTP guidelines
- NTP plan (MANDATORY)
- National Medical Laboratories Strategic Plan, if it exists
- NTRL strategic plan, if it exists
- WHO Global Report on TB (most recent)
- NTP surveillance, policy and technical reports
- Review/assessment reports
- Latest drug-resistance survey (DRS) report
- HIV/AIDS

4.1. The TB-specific contextual analysis of the laboratory services

This includes the following 7 components (a-g):

a. Epidemiological situation for TB

This description should be obtained from the NTP. The following information should be obtained from the NTP Strategic Plan or other sources from the NTP:

- Estimated TB incidence, TB prevalence, TB mortality, estimated numbers of smear-positive and smear-negative cases, estimated child TB cases (from TB prevalence surveys or latest WHO data)
- HIV positivity in TB patients (from surveillance, surveys, or WHO estimates)
- MDR-TB prevalence in new patients and retreatment patients (from surveillance, surveys, or WHO estimates)
- This section should be no longer than page.

b. Laboratory objectives and targets according to the NTP strategic plan and current linkages with the NTP

This section is the key to further development of the TB laboratory plan. Here you should describe the existing laboratory-related strategies and key activities from the existing NTP Strategic plan. The NTP Strategic Plan may be inadequate for the laboratory objectives and targets and may need adaptation to accommodate the laboratory objectives and targets. This should be discussed with the NTP during the course of the workshop and the development of the TB-specific national TB laboratory strategic plan. In this section you only need to briefly describe the NTP's laboratory strategy, it should be no more than half a page. You should also include here planned drug resistance and prevalence surveys. You should also briefly describe the official linkages between the NTP and the NRL. If you have an organogram for this linkage, this may be included. Please note that Chapter 4 will provide an exercise for developing TB laboratory plan objectives.

NOTE: Achieving quality-assured laboratory targets for national diagnostic algorithms should be a main driver of the TB laboratory plan.

c. National TB diagnostic and treatment guidelines

This section is also vital for the further development of the TB laboratory plan. Here you should extract from the existing national guidelines the following information:

- Types of laboratory tests recommended, per established policies, for diagnosing TB:
  - Smear-positive pulmonary TB
  - Smear-negative pulmonary TB
  - Extra-pulmonary TB
  - Pediatric TB
  - HIV-associated TB
  - MDR-TB
- Algorithms for:
  - Suspect and confirmed MDR/XDR-TB cases
  - Suspect and confirmed TB/HIV cases
- Case definition of a smear positive case:
  - Number of positive smears
- Smear negative cases:
  - National policy and procedures for the diagnosis of smear-negative cases
- Number of tests per suspect:
  - For diagnosis
  - For follow-up during treatment
- Current culture and DST policy:
  - Levels where culture is recommended
  - Policy for first- and second-line drugs testing
- Recommendations for rapid diagnostic tests:
  - Routine drug resistance surveillance
  - Routine DST: categories of patients recommended

d. Linkages with supra-national reference laboratories

Describe here the linkages with supra-national reference laboratories, including terms of reference (ToR).

e. Linkages with the general health system

Describe the linkages of the TB laboratory services with the general health services, including human resource development, specimen referral, supply chain management and logistics, equipment and maintenance, quality management systems, supervision, information and data management.

f. Linkages with private sector

Describe here the linkages with the private non-profit and private-for-profit sectors, including TB diagnostic and treatment follow-up facilities in these sectors, training of TB laboratory staff, supply management, equipment validation and maintenance, quality management, supervision, information and data management

g. Regulatory, legal, political and economic issues

Describe the government policies, laws, statutes, regulatory, professional and financial bodies, that enact country legislation to control the use of TB diagnostics and facilitates the implementation of internationally recommended polices and technologies.

TB Specific Tests - Resources Needed:

- National Medical Laboratories Policy
- NTRL quality manual
- Microscopy, culture, drug susceptibility testing (DST), molecular assays statistics
- Statistics on the number of TB diagnostic laboratories and work-load

National diagnostic algorithms should drive the TB laboratory plan

Structure - Resources Needed:

- National Medical Laboratories Policy
- TB laboratory network organogram

Small or large countries may have one level less, or one level more respectively. There may be one more additional peripheral level with specimen collection with or without preliminary processing e.g. sedimentation, preservation and preparation of smears.

4.2. TB specific TESTS CURRENTLY AVAILABLE and Coverage

Describe the tests currently done at each level of the TB laboratory network and level of coverage, whether they meet strategic objectives of the NTP and the diagnostic recommendations of the national diagnostic and treatment guidelines. Relevant TB-specific tests should generally be described within the following categories:

- Smear microscopy: Ziehl Neelsen, Fluorescence Microscopy-conventional vs. LED, direct vs. concentrated
- TB culture: Solid culture medium, liquid culture medium
- Mycobacterium TB identification tests: MTB complex versus NTM or specific mycobacterial species identification e.g. via biochemical identification, strip specification etc.
- First line DST: by conventional slow methods e.g. direct or indirect test; solid or liquid culture medium, drugs tested, concentration of drugs tested; proportion, absolute concentration or resistance ratio method
- Second line DST: by conventional slow methods e.g. solid culture medium, drugs tested, concentration of the drugs
- Tests for rapid detection of TB e.g. GeneXpert MTB/RIF test
- Tests for rapid detection of drug resistant TB (MDR, XDR) e.g. GeneXpert MTB/RIF and line probe assays

4.3. STRUCTURE OF THE LABORATORY NETWORK of TB diagnostics

Describe the existing laboratory network with its tiers and the specific responsibilities of each tier. Usually there are three distinctive levels of TB laboratory services: national, intermediate and peripheral levels. The structure should include private laboratories. The number of TB laboratories at the different levels, the responsibilities of the network at the different levels, the linkages between the different levels, the authority under which the NRL resorts, the coordination mechanism between the NTP and the NRL should be included here. A pyramid of the existing laboratory network with the number of laboratories with TB services, linkage with private laboratories and linkages between the different levels may be included. Further, the population coverage by microscopy, culture, DST and rapid methods should also be described.

Infrastructure - Resources Needed:

- NTP review/assessment reports
- Laboratory network review/assessment reports from partners
- Biosafety manual
- Infection control (IC) guidelines
- National waste management regulations

4.4. INFRASTRUCTURE OF THE LABORATORY NETWORK for TB diagnostics

For this section, you should provide a description of the available buildings of the laboratory services, including design and lay-out, present biosafety measures, including infection control and waste management, in relation to the TB technical procedures at the different levels of the network. In addition, describe the available equipment at the different levels, availability of water and electricity.

4.5. HUMAN RESOURCES for the TB laboratory network

Elaborate here on the human resources in the TB laboratory network, as well as training, development and the retention of staff.

- Available work force
  - If a national inventory of the TB laboratory workforce is available, include the data. If the information is not available, do a rapid sample survey to gather it.
  - Cadres of laboratory staff responsible for TB diagnostic procedures at the different levels: smear microscopy, culture, DST- first- and second line drugs, molecular testing, EQA for smear microscopy
- Training
  - Availability of a training plan for the TB laboratory work force; year of preparation
  - Types of training conducted: in-country, internationally, continuous education
  - Pre-service and in-service training on TB for laboratory technicians/technologists/microscopists/others

- TB training for new laboratory workers
- Technical training on new TB and MDR-TB diagnostics
- Training in leadership for NRL/Intermediate level lab management staff

- Development and retention of staff
  - Measures to retain staff
  - Career development paths
  - Incentives schemes

4.6. EQUIPMENT MAINTENANCE AND VALIDATION of TB lab equipment

Present systems and schedules for validation and maintenance of equipment, including biosafety cabinets, microscopes, equipment for (rapid) drug susceptibility testing and other equipment.

4.7. LABORATORY QUALITY MANAGEMENT SYSTEMS within the TB laboratory network

Specify the implemented quality assurance systems for smear microscopy, for culture, identification, DST and laboratory biosafety and whether there are written guidelines and Standard Operating Procedures (SOPs) on planning and implementation of the quality management systems.

Describe the policy for internal quality control and which EQA measures for smear microscopy are implemented: on-site supervision, rechecking of a random sample of the smears and/or panel testing. If rechecking of a random sample of the smears is implemented, include the sample size(s), the expected number and percentage of TB microscopy facilities (as based on NTP policy) covered and the number of first and of second controllers. If panel testing is implemented, include where the slides are prepared, the frequency of testing and the microscopy facilities included. Include latest annual results of rechecking/panel testing.

Describe which quality assurance measures are implemented for culture, DST and biosafety. Include the latest annual results of C/DST e.g. by supra-national laboratories for DST for NTRLs, internal quality systems for culture at NTRL and other in-country culture labs, NTRL results for DST EQA for any other in-country DST labs.

Human Resources - Resources Needed:

- MoH strategic human resource development (HRD) plan
- NTP HRD strategic plan
- NTP review reports
- AFB microscopy EQA reports
- Reports on external assessments of the NTRL and laboratory network
- Laboratory School curricula

Equipment Maintenance and Validation- Resources Needed:

- National Medical laboratories policy
- NTRL quality manual
- NTP review reports
- Reports on external assessments of the NTRL and laboratory network regulations

Laboratory Quality Management Systems - Resources Needed:

- National Medical laboratories policy
- NTRL quality manual
- AFB microscopy EQA plan
- DST EQA plan
- EQA reports on smear microscopy and DST
- Reports on external assessments of the NTRL and laboratory network

4.8. MANAGEMENT OF LABORATORY COMMODITIES AND SUPPLIES within the TB laboratory network

Describe the following:

- Who is responsible for the specification of TB laboratory supplies and equipment and for their procurement; whether TB quality standards are respected in procurement
- Origin and quality of reagents and the control mechanisms; whether ready-made stains or chemicals for local preparation of reagents are ordered and the level(s) stains for smear microscopy and TB culture media are prepared
- Distribution system for equipment and supplies, including to private sector laboratories
- Storage management at the different levels (manual or electronically), availability of guidelines; quality of storage facilities, at national and intermediate levels
- Buffer stocks of supplies and spare parts and the level(s) buffer stocks are stored; recent (last 2 years) history of stock-outs and at which level(s).

Management of Laboratory Commodities and Supplies - Resources Needed:

- National Medical laboratories policy
- National Medical laboratories policy
- NTP/assessment review reports
- Central Medical Stores (CMS)/Supply and commodities management system (SCMS)
- List of supplies
- NTRL external assessments reports

4.9. LABORATORY INFORMATION AND DATA MANAGEMENT for TB laboratory network

Describe the personnel responsible for data keeping and reporting[1].

Describe the TB laboratory documentation, paper and electronic systems, including recording and reporting e.g. standardized forms, registers and reports at the different levels of the TB laboratory network .

Describe the availability of an intermediate and central level data monitoring, analysis, evaluation and feedback system of incoming data and generation of a national report.

Describe the existence of a separate TB data management system or a system integrated into a national public health laboratory data management system.

Laboratory Information and Data Management - Resources Needed:

- Mycobacterial request/report form
- Microscopy and culture/DST register
- MDR-TB report tool
- TB/HIV request and report tool
- Manuals/SOPs for laboratory informational systems in use

1. Instead of listing all documentation, reference can be made to the TB Laboratory manual, EQA manual, NTP manual and other documents.

4.10. SAMPLE REFERRAL SYSTEMS for the TB laboratory network

Include whether SOPs for specimen referral and transport and for returning results are available.

Describe where the TB suspect or patient delivers samples within the network e.g. clinic and/or laboratory setting. Is this different for smear microscopy vs. culture/DST/molecular testing?

Describe the smear microscopy referral and transport system including what is referred and whether it is a specimen and/or prepared slides.

Describe the culture and DST referral and transport system including what is referred original and/or partially processed specimens e.g. using a preservative.

Describe biosafety procedures related to sample referrals and transport.

Describe the existing cold-chain transport systems (if any).

Describe the procedure for communication of results for referred specimens e.g. posted mail, electronic, telephone, etc.

Describe the turn-around time (TAT) it usually takes to get samples to the laboratories and for the results to return. Please describe TAT separately for smear microscopy, culture, DST and molecular testing.

Describe the expected number and percentage of specimens received at the culture/DST laboratories, as based on the NTP policies and plans.

Sample Referral Systems - Resources Needed

- National Medical laboratories policy
- Specimen collection and transportation manual
- NTP Clinical Management Manual

4.11. OPERATIONAL RESEARCH regarding the TB laboratory

Describe the available capacity of TB laboratory staff for operational research (OR), present and planned OR activities involving the laboratory, involvement of national TB laboratory staff in identification of priority research, and the national research coordinating mechanism (if one exists).

Describe collaboration with university(ies) and institutes in defining and executing research. Describe the proportion of the work performed by the NTRL for research. Describe how much of this research is performed for the country/NTP compared to external entities.

Operational Research - Resources Needed:

- NTP Strategic Plan
- National Medical Laboratories plan (if it exists)
- NTRL strategic plan (if an earlier version exists)
- Partners' plans

4.12. LEGAL AND POLICY REVIEW for TB

Describe the government regulatory bodies/ persons responsible for approving laboratory procedures and products.

Legal and policy review - Resources Needed:

- National Medical laboratories policy

4.13. FINANCES for TB laboratory services

List the funding sources and commitments during the next few years (in so far as they are available) for the TB laboratory services, including government contributions, specified by source for investment and recurrent budget (using the table below). If there is a financial gap, summarize which laboratory services these gaps affect. Include the authority responsible for financial management.

Finances - Resources Needed:

- NTP plan
- National Medical Laboratories plan (if it exists)
- Donors/Partners' plans and agreements

	Actual		Planned	
	Last year:	**This year:**	**Next year:**	**Year after next:**
DOMESTIC FUNDING RESOURCES for TB Laboratory Services				
Domestic source A1: Loans and debt relief → provide name of source here				
Domestic source A2: National funding resources				
Domestic source A3: Private sector contributions (national)				
LINE A: Total current & planned DOMESTIC resources → Total of Section A entries				
EXTERNAL FUNDING RESOURCES for TB Laboratory Services				
External source B1: → provide source name here				
External source B2: → provide source name here				
External source B3: Private sector contributions (International)				
LINE B: Total current & planned EXTERNAL resources → Total of Section B entries				
LINE C : Total current and planned resources for TB Laboratory Services → Line C = Line A+ Line B				

Exercise 4b: TB laboratory plan-SWOT analysis by Stop TB objectives

After the TB-specific situational analysis narrative description, it is important to analyze for each of the 13 elements specific strengths, weakness, opportunities and threats. This can be done via a well-known Strengths, Weakness, Opportunities and Threats (SWOT) analysis framework.
We provide an example below for Stop TB objectives 1 and 2 in the context of the 13 elements from the situational analysis. A descriptive summary of the SWOT process may be found in **Chapter 4** of the facilitators manual as well as examples of SWOT for all 4 Stop TB objectives.

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis	Laboratory objectives and targets for AFB-microscopy have been included in a 5-year Laboratory Strategic Plan	The NTP Strategic Plan has still to be adapted to incorporate the TB-microscopy objectives and targets	Increased strengthening of collaboration between the NRL and the NTP	Inadequate attention of NTP to maintaining close collaboration with the NRL
TB specific tests currently available and coverage	The NTP has agreed to gradually replace ZN microscopy with LED fluorescence microscopy	A policy on priority labs for LED microscopy has still to be developed	Increasing interest from international agencies to provide LED fluorescence microscopes	Decreasing quality of smear microscopy due to insufficient training capacity of laboratory staff in the use of LED fluorescence microscopes
Structure of the laboratory network of TB diagnostics	Increasing NTP focus on collaboration with the private sectors in strengthening the TB laboratory network	A strategy and plan for collaboration with the private sectors does not yet exist	Increasing interest and commitment from private sectors to collaborate with the NTP	Inadequate NTP engagement with private sectors may result in loss of interest and commitment
Infrastructure of the laboratory network of TB diagnostics	Sound laboratory infrastructure to strengthen the TB microscopy network	Insufficient human resources at all levels of the TB microscopy network	Increasing international emphasis on strengthening the TB microscopy network	Decreasing international financial support due to financial constraints
Human resources for the TB laboratory network	MoH is substantially increasing the training facilities for laboratory staff	Only a small proportion of trained laboratory staff are motivated for a career in TB	Many international opportunities for laboratory staff to attend laboratory training courses on technical and management skills	Lack of an appropriate Government human resource capacity building plan with an incentive structure to recruit and retain competent staff

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Maintenance and validation of TB laboratory equipment	NTP has developed SOPs for the maintenance and validation of TB microscopy equipment	SOPs are hardly implemented, as Government maintenance services are very limited	The number of private national agencies that provide maintenance services for laboratory equipment is increasing	Government policy does not permit private agencies to maintain equipment at Government facilities
Quality management systems within the laboratory network	NRL has developed guidelines for the EQA of smear microscopy	EQA for smear microscopy is implemented in only 40% of TB diagnostic facilities	Local partners are committed to providing human resources for the extension of EQA of smear microscopy	Insufficient guarantee for gradual expansion of EQA because of high turn-over of staff employed by local partners
Management of laboratory commodities and supplies within the TB laboratory network	NRL has developed specifications and quality standards for smear microscopy commodities and supplies	Quality standards for smear microscopy supplies and equipment are often not respected by the procurement dept. of MoH	Increasing international support in the provision of high quality supplies and equipment	Decreasing capacity and increasing delays by agencies in delivery supplies and equipment
Laboratory information and data management for the TB laboratory network	NRL has developed an electronic laboratory data management system, distributed it to regions and districts and trained the staff	Only 45% of districts use the electronic data management system	International support has been offered in strengthening the implementation of the data management system	Frequent international recommendations for the revision of the data management system
Sample referral system for the TB laboratory network	NRL has developed and distributed guidelines for the referral of samples for smear microscopy	Only 40% of samples reach the laboratories in a timely manner	Decreasing reluctance by public transport organizations to transport sputum specimens	Decreasing national support for sample referral
OR regarding the TB laboratory	Increasing MoH interest in and commitment to research	Lack of national capacity for research	Increasing international focus on research	Decreasing collaboration with NTP in defining research priorities

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Legal policy and review for TB	35% of TB microscopy is done by locally trained microscopists	Recent MoH policy is that only certified laboratory technicians should carry out TB microscopy	Government has given priority for microscopists to be trained as laboratory technician	A legal policy for the retaining of microscopists trained as technicians for the TB services does not exist
Finances for the TB laboratory services	A gradual increase in the MoH budget for the TB microscopy services	The NRL has no control over the MoH budget for the TB laboratory services	Access to multiple international sources of funding	Complicated government regulations lead to under-utilized expenditures which in turn jeopardizes future government contributions

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
TB specific contextual analysis	Algorithms for the diagnosis of TB among AFB-negative cases, including HIV+ individuals, have been defined	Only 25% of HIV+ individuals are referred for TB testing	Collaboration between the NTP and the NAP has been strengthened substantially	Inadequate attention to maintaining strong collaboration between NTP and NAP
TB specific tests currently available and coverage	The NTP has identified GeneXpert as the test for the diagnosis of TB in HIV+ individuals	Access to GeneXpert is limited to the national, and some regional and district laboratories	Increasing international support for the expansion of GeneXpert	Insufficient government resources for the procurement of supplies for GeneXpert
Structure of the laboratory network of TB diagnostics	X-ray facilities are available at all district hospitals	There are frequent stock-outs of X-ray films and chemicals	Increasing budget allocations by the government for the procurement of X-ray films and chemicals	Complicated government budget allocation and procurement procedures, jeopardizing timely availability of supplies

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Infrastructure of the laboratory network of TB diagnostics	GeneXpert has been installed in five facilities	13 GeneXpert machines have not yet been installed, awaiting release of funding for air-conditioning and generator	Increasing international support in providing funding for infrastructure improvement for installation of GeneXpert machines	Insufficient government allocation of funds for fuel for generators
Human resources for the TB laboratory network	Four laboratory staff have attended international training on GeneXpert	A local training course for laboratory staff on GeneXpert has not been developed	The WHO has established a regional training course on GeneXpert	Trained staff may leave the government service for better job opportunities in the private sector
Maintenance and validation of TB laboratory equipment	A maintenance plan for X-ray machines has been included in the NRL Strategic Plan	Maintenance of X-Ray machines is not yet functional due to shortage of technical staff	Private companies have shown interest in the maintenance of the X-Ray machines	Government procedures for contracting-out maintenance may take a long time
Quality management systems within the laboratory network	Both the NTP and NRL are committed to implementing the quality management of GeneXpert	There are no international guidelines for the quality management of GeneXpert	The Global Laboratory Initiative has initiated preparation of guidelines for quality management of GeneXpert	The quality of GeneXpert may decline because of unavailability of quality management guidelines
Management of laboratory commodities and supplies within the TB laboratory network	NTP has prepared quality standards for X-Ray films and chemicals	Quality standards are often not respected by the procurement department of the MoH	MoH has agreed to follow international guidelines for quality standards	Delays in implementation because of government bureaucratic procedures
Laboratory information and data management for the TB laboratory network	NTP has revised the recording and reporting formats incorporating diagnosis of TB among HIV-positive patients by GeneXpert	The revised recording and reporting formats have not yet been incorporated into the national electronic data base	International donors require information on GeneXpert testing of HIV+ patients for TB	No funding for TA to revise the national electronic data base

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Element of TB laboratory specific situational analysis	**Strengths**	**Weaknesses**	**Opportunities**	**Threats**
Sample referral system for the TB laboratory network	Procedures for sample referral from HIV-positive patients for GeneXpert have been included in the SOP for sample referral	Supplies for sample referral are not available	International donor has provided funding for one year of supplies	Shortage of supplies after the one year of international support
OR regarding the TB laboratory	OR on the use of GeneXpert at district level is planned	The NRL has insufficient capacity to carry out/guide OR	An international agency has expressed willingness to provide TA for conducting OR on GeneXpert	Government policy does not allow international consultants to carry out OR
Legal policy and review for TB	The government has legalized the use of GeneXpert for the diagnosis of pulmonary TB/HIV and MDR-TB suspects.	Only certified laboratory technicians, who are in shortage at district level, are allowed to use GeneXpert	Government has given priority for microscopists to be trained as laboratory technicians	Laboratory technicians may leave the government services for better job opportunities in the private sector
Finances for the TB laboratory services	Inputs for GeneXpert, equipment, supplies, training funds and operational costs, have been provided by international donors	There is no budget for GeneXpert in the 5-year strategic NTP plan	The government has expressed commitment to include a budget for GeneXpert in its budget plans	Government funding may not be available after the one year external funding for supplies and operational costs

Exercise 4c: TB laboratory plan situational analysis framework with major challenges and potential solutions by Stop TB Objective

After the TB-specific Plan situational analysis including the SWOT, an analysis of the main weaknesses of and the gaps in, the current situation and identification of their potential solutions will assist TB laboratory management in defining the priorities and strategies for the development of objectives and activities for the TB laboratory services. An example of this analysis, including one example for each of the topics of the situation analysis, is given below for Stop TB Objectives 1 and 2. Examples of all objectives may be found in Chapter 4 of the facilitators manual.

Example of Situational Analysis Framework for a TB Laboratory Network

Objective 1: Increase Access to Quality-assured AFB Microscopy with Effective EQA				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
TB specific contextual analysis	The NTP Strategic Plan does not include a policy for the use of LED microscopes	LED microscopes should replace light microscopes at laboratories with a high microscopy workload	Distribution of LED microscopes is not according to microscopy workload	NTP, in cooperation with NRL, should develop guidelines for laboratories eligible for a LED microscope, to be included in the NTP and NRL Strategic Plan
Tests currently available	LED microscopes are available at the regional laboratories	LED microscopes should be available at regional and district laboratories and at peripheral laboratories with high microscopy workload by the end of 2013	Many district laboratories have a high microscopy workload which jeopardizes the quality of smear microscopy	A plan for the gradual replacement of light microscopes with LED microscopes should be prepared and implemented
Structure	Only 10% of private laboratories are collaborating with the NTP in smear microscopy	Gradual expansion of involvement of private laboratories, reaching 40% coverage in 2015	Substantial delays in partnership with private laboratories; the existing national coordinating committee is not functional	Revive the national coordinating committee; prepare and implement a plan for expansion of TB microscopy in private laboratories and follow-up progress in implementation quarterly
Infrastructure	40% of peripheral laboratories need basic renovation	Smear microscopy laboratories should have adequate hand-washing facilities and sufficient bench space to perform duties	Lack of renovation affects the quality of work in the peripheral laboratories	Develop a phased implementation plan for physical renovation of peripheral laboratories and present this plan to the government for funding

Objective 1: Increase Access to Quality-assured AFB Microscopy with Effective EQA				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Human Resources	In 40% of laboratories smear microscopy is done by microscopists (8th grade leavers who have been trained for 3 weeks in smear microscopy)	The government policy is that TB microscopy should be done by graduated laboratory technicians	Shortage of laboratory technicians, especially in rural areas	Prepare a 5 year plan to gradually phase out microscopists, based on expected output of graduated laboratory technicians, with incentives for work in remote areas and have this approved by the relevant authorities
Equipment validation and maintenance	Regular maintenance of microscopes is not done	Microscopes should be routinely checked (every 2 years)	There is no information on the condition of microscopes and if replacement of microscopes/parts is needed	Prepare an annual plan for maintenance of microscopes and present this to the MoH for implementation by the government maintenance unit
Laboratory quality management systems	Rechecking of a sample of smears is implemented in only 45% of the AFB-microscopy laboratories	All AFB microscopy laboratories should implement rechecking by the end of 2013	Substantial delay in the expansion of rechecking, mainly because of long absence of the national EQA laboratory technician	Revise the rechecking expansion plan, covering the remaining 55% of laboratories within 2 years
Management of laboratory commodities and supplies	There are frequent shortages of AFB-microscopy consumables at laboratories	Laboratories should have sufficient quantities of AFB microscopy supplies	Frequent shortages of AFB microscopy supplies due to the long process of ordering supplies and delays in distribution from the national level to the peripheral levels	Gradually build-up a buffer stock of laboratory supplies; negotiate with the procurement authority to shorten the procurement process and ensure 3-monthly supplies to the peripheral level based on requirements and stock positions

Objective 1: Increase Access to Quality-assured AFB Microscopy with Effective EQA				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (National/International)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Laboratory information and data management	About 15% of laboratories either do not report to the national level, or report incomplete data	All laboratories should report complete data in a timely manner	National data are incomplete and there is no feedback system for non-reporting or incomplete data	Develop a mechanism for feedback to reporting levels on non-reporting or incomplete data, follow-up quarterly, and emphasize the importance of complete and timely data during training and supervision
Sample referral systems	Over 50% of smears prepared at community smearing centers reach the laboratory after 3 days	Smears prepared at community smearing centers should reach a laboratory within 3 days	Shortage of funds to transport the smears to the laboratories	NTP should obtain funds for transportation of smears to laboratories
Operational Research	There is no research planned or implemented	OR should focus on finding solutions for problems experienced in access to diagnosis and the quality of smear microscopy under local conditions	Several operational problems in improving access to diagnosis, and the quality of smear microscopy are not addressed	NTP/NRL should seek assistance from national and international institutions to carry out OR to find solutions for the operational problems
Legal and policy review	The procurement authority does not allow the inclusion of quality standards of supplies in the procurement request	TB diagnostic facilities should be supplied with high quality supplies, based on international recommendations	Substandard quality of some supplies, in particular oil immersion and stains	Develop national standards for supplies, according to international recommendations; lobby authorities responsible for procurement policies and regulation to include these standards in procurement requests
Finances	35% of the recurrent budget for laboratory supplies is covered by the government, compared to 45% two years ago	The government will gradually increase the recurrent budget for laboratory supplies	The quantities of laboratory supplies ordered by the government do not cover the needs, resulting in frequent shortages	Lobbying at the ministerial level to maintain the government commitment for increasing the budget for laboratory supplies

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
TB specific contextual analysis	Due to a shortage of functional government X-Ray facilities, about 50% of patients requiring an X-Ray have to attend private facilities for which they have to pay	According to government policy chest X-Ray examination for the diagnosis of TB in HIV+ individuals is free of charge	Although the number of government X-Ray facilities is sufficient, many face frequent shortages of films and/or chemicals	Convince the MoH that this key, and in case of a funding issue support them to secure funding to provide sufficient X-Ray films and chemicals to hospitals and chest clinics
Tests currently available	At the regional hospitals GeneXpert machines are available for testing HIV+ individuals suspected of having of TB	All HIV+ individuals with symptoms suggestive of TB and with negative sputum smears should be tested with GeneXpert	Only 30% of HIV+ individuals have access to GeneXpert	Distribute additional GeneXpert machines committed by international donors to areas with a high prevalence of HIV
Structure	GeneXpert machines are available at the NRL and two regional TB reference laboratories	All HIV+ individuals with symptoms suggestive of TB and with negative sputum smears should be tested with GeneXpert	GeneXpert is in practice exclusively used for MDR/ Rif testing of retreatment TB patients	Inform hospital doctors, regional TB coordinators, the NRL and regional TB reference laboratories that the GeneXpert machines should also be used for the diagnosis of TB among HIV+ individuals
Infrastructure	Only 50% of the population has access to X-Ray facilities at government hospitals	Smear-negative patients with persistent symptoms, managed according to NTP policy, should have a chest X-Ray	The diagnosis of TB, based on X-Ray reading at private facilities, in patients referred to the government centers can often not be confirmed by government doctors	Establish a diagnostic committee of government and private doctors on the consensus of chest X-Ray readings

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Human Resources	A training program has been developed for operation of GeneXpert machines	Staff assigned to operate GeneXpert machines should be trained	7 out of the 10 facilities where GeneXpert machines will be stationed have not yet selected staff to operate the machines causing delays in making the machines operational and in using the cartridges before these expire	Request the regional TB coordinators and in-charges of facilities where the GeneXpert machines will be installed to urgently select the required staff; and inform them about the dates for training of the staff
Equipment validation and maintenance	Annual validation of GeneXpert has been included in the NRL SOPs	GeneXpert machines should be validated annually	The government does not have the technical expertise for the validation of GeneXpert machines	Seek advice and funding from the international donors of the GeneXpert machines on the development of a mechanism for annual validation of the machines
Laboratory quality management systems	In 35% of HIV+ individuals referred for TB examination, smear examination is not done (according to NTP policy). They are diagnosed with smear-negative TB based on X-Ray examination or on clinical grounds, particularly at private hospitals and clinics	Smear examination should be done in all HIV+ individuals suspected of having TB	A higher than expected % of HIV+ individuals are reported as smear-negative, but in reality they have not even been appropriately bacteriologically evaluated.	Discuss this issue at the national and regional PPM committees insisting on smear examinations of all TB suspects, including HIV+ individuals and follow-up during subsequent meetings presenting results. Instruct regional and district TB coordinators to examine smears in all patients referred with the diagnosis PTB without smear results

Objective 2: Improve the Diagnosis of TB among AFB-negative Cases Especially among People Living with HIV				
Situational Analysis Topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Management of laboratory commodities and supplies	Supplies for GeneXpert are provided by international donors	NTP, in collaboration with NRL, should provide specification of laboratory supplies and prepare annual quantities for procurement	Quantities of supplies provided by donors are not based on needs; time needed to operationalize the donated GeneXpert machines was longer than anticipated; so far in only a few HIV+ individuals GeneXpert has been used	Request donors who have indicated support to provide supplies for GeneXpert supplies to collaborate with NTP/NRL in calculation and timing of the support
Laboratory information and data management	Diagnosis of TB in HIV+ individuals has been included in the national electronic data base	Diagnosis of TB among HIV+ individuals should be reported to the NTP	20% of districts do not report TB cases detected among HIV+ individuals	Alert regional and district TB coordinators on routine reporting of TB detection among HIV+ individuals and include this in the refresher trainings and meetings of the TB coordinators
Sample referral systems	SOPs have been prepared for specimen referral and transport	Specimens of HIV+ patients for detection of TB should be collected at the district laboratories	Patients face problems with transport costs to attend the district laboratories	Explore the practicality and feasibility of the collection of specimens at the peripheral health facilities
Operational Research	No OR is planned or implemented	OR should identify operational requirements for use of GeneXpert at district and lower levels	Insufficient government staff to carry out OR	International organizations have offered assistance in carrying out OR on the requirements and use of GeneXpert at peripheral facilities

Objective 2: Improve the Diagnosis of TB among AFB-negative Cases Especially Among People Living with HIV				
Situational Analysis topic	**Current Situation**	**Current Policies/ Expectations/Standards (national/international)**	**Main Weaknesses/Gaps**	**Potential Solutions**
Legal and policy review	The government regulatory authority has approved the use of GeneXpert at district health facilities	The use of GeneXpert should be approved by the government regulatory authority	Algorithms for the use of GeneXpert have not yet been prepared; the 10 donated machines are awaiting distribution and part of the cartridges will soon expire	NTP should develop and distribute algorithms for the use of GeneXpert, and distribute the machines as soon as possible, while instructing regional TB coordinators to inform the facilities receiving the machines to strictly adhere to algorithms
Finances	The NTP budget for 2012-2016 does not include a budget for GeneXpert cartridges and annual validation of the machines	A budget for the operation of GeneXpert machines should be available	The cartridges donated with GeneXpert machines last for about 6 months	Negotiate with MoH and external donors to provide a budget for cartridges and validation of GeneXpert machines

Chapter 5:

Prioritization of Strategies and Activities within Stop TB Objectives

TB laboratory priorities should be derived from the NTP plan. The NTP objectives should be translated into laboratory strategies and activities. The strategies and activities are country-specific, as they are influenced by several factors, including the burden of TB, MDR-TB and HIV, diagnostic algorithms, the in-country laboratory infrastructure and capacity, human and financial resources, and existing quality management systems. As noted in the previous section, the NTP plan may not adequately address TB laboratory issues. These issues can subsequently be added to the NTP strategic plan; for example, you may find that during the NTP strategic planning process that rapid diagnostic methods were not considered but during the TB laboratory plan development this was identified as a priority. For certain, the TB laboratory plan should include the latest priority activities as identified between the NRL and NTP. If possible, the NTP strategic plan should be revised simultaneously with the development of this TB laboratory plan provided any additional laboratory strengthening activities identified and which the NTP did not foresee are agreed upon. Otherwise, these updated laboratory issues should be included within the NTP annual implementation plans. When we speak of strategic plans in TB control, we mean medium-term plans with a duration of 5 years.

The WHO AFRO guidelines provide additional guidance for setting strategic priorities as follows:

The importance of defining appropriate country strategic objectives for the Plan cannot be overemphasized. Agreement on objectives is a critical early step, as the entire process should flow from these objectives. The objectives will vary among countries, as they will in part be influenced by disease prevalence and the current situation of the available in-country capacity, infrastructure, and systems. The careful negotiation of a limited number of country objectives for each theme area is the key to successful implementation but takes time and skill. The setting of objectives must be based on certain considerations:

- *Too many objectives can be a hindrance to effective implementation. Three to five objectives for each major component or theme of the laboratory system are usually adequate. These become the basis for all that is to follow. It is crucial that participants understand the difference between an objective and its associated work plan.*
- *The objectives should be rigorously scrutinized to ensure that they are based in reality "on the ground."*
- *The objectives should be feasible within the timeline of the Plan, not be long-term aspirations, and should stimulate progress on major issues that will make a difference in health.*

As mentioned previously, we have harmonized the objectives for the TB laboratory plan to those of the Global Plan to Stop TB (2011-2015) and these are pre-defined as follows:

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA
Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV
Objective 3: Increase access to rapid laboratory diagnosis among TB patients considered at risk for M/XDR-TB
Objective 4: Establish laboratory quality management systems

These four objectives are in accordance with the WHO-AFRO guidance document recommendations but the last factor that they should be feasible and will make a difference, should be constantly scrutinized when developing your TB Laboratory plan. The strategies and activities that you have will be dependent

on the SWOT and situational analysis you conducted in the last chapter as well as the NTP plan laboratory-related targets, epidemiologic situation and diagnostic algorithms. This chapter will help you to arrive at the strategies and activities needed for your TB laboratory network with the aforementioned considerations.

We will introduce you first to the strategies that we recommend you utilize for building your TB laboratory plan. The existing laboratory roadmaps have mostly overlapping guidance for setting strategic priorities. The table below reconciles the WHO AFRO guidelines and the GLI roadmap, using the GLI terminology where both overlap. In addition, we include OR as a strategy as this is a Global Stop TB Plan priority. A more detailed list of components can be found in **Annex 3**.

Strategy	Components
Strengthen laboratory infrastructure including biosafety	• Building, renovation, upgrading and maintenance of the physical structure of the TB laboratory • Infection control measures including natural and mechanical ventilation • Electricity and water supply • Waste management • Development of plans related to laboratory infrastructure and infection control
Improve laboratory human resource development	• Building human resource capacity through training • Development of training materials, programs and plans, manuals and standard operating procedures • Assessment of human resource capacity • Development of human resource strategies and plans including supportive supervisory and retention plans
Develop and maintain laboratory quality management systems	• Development of quality assurance guidelines, plans and training programs for laboratory quality management • Provision of EQA services to all levels of the laboratory network • Enrollment in EQA programs • Implementation of QA guidelines • Enrollment in certification/accreditation programs • Assessment of quality management systems
Enhance management of laboratory commodities and supplies including equipment validation and maintenance	• Procurement of laboratory equipment, commodities and supplies • Development of plans for procurement • Development of plans for equipment maintenance including validation and calibration • Contract equipment maintenance services • Assessment of supply chains
Fortify specimen transport and referral mechanisms	• Establishment/improvement of specimen transport mechanisms including courier systems and cold-chain biosafe tools • Assessment of specimen transport and referral mechanisms
Improve laboratory information and data management systems	• Development of plans and tools for standardized recording and reporting of laboratory results • Development of reporting/recording systems (paper-based or electronic) through all tiers of the TB laboratory network including linkage to NTP • Implementation of laboratory informational systems • Development of monitoring and evaluation systems
Establish a laboratory regulatory framework	• Strengthen the legal and regulatory framework to support implementation of national laboratory policy • Development and dissemination of national standards for TB laboratory equipment & reagents, package of test and infrastructure design
Develop operational research capacity	• Implement special surveys including nationally-representative prevalence and drug-resistant surveys • Conduct other country-specific OR that improves laboratory services

When considering a TB laboratory plan following the guidance above, you should ask the following questions:

1. Which laboratory issues need to be addressed to appropriately detect smear-positive cases?
2. Which laboratory issues need to be addressed to appropriately detect smear-negative cases?
3. Which laboratory issues need to be addressed to appropriately detect MDR-TB cases?
4. Which laboratory issues need to be addressed to appropriately implement a quality management systems approach?

To answer these questions, you should also consider at an early stage which targets you wish to achieve from the TB laboratory plan. You must first link the expected outcome and impact of the NTP plan with the TB laboratory plan. Examples of outcome and impact indicators that you might use to link the NTP goal with the TB laboratory plan targets include:

- The number of new laboratory-confirmed TB cases notified
- The prevalence of laboratory-confirmed TB
- The prevalence of laboratory-confirmed MDR-TB
- The prevalence of laboratory-confirmed XDR-TB

Further, you should establish targets for each of the Global Plan Stop TB objectives. Examples of indicators for which you might establish targets are as follows:

Objective 1. *Percentage of laboratories providing sputum smear microscopy services that are using LED microscopy for the diagnosis of smear-positive TB*

Objective 2. *Percentage of acid-fast bacilli (AFB) smear-negative, newly notified TB cases screened using culture and/or molecular-based tests*

Objective 3. *Percentage of previously treated TB patients tested for MDR-TB*

Objective 4. *Percentage of national and regional reference laboratories implementing a quality management system according to international standards.*

For the purposes of the TB- laboratory plan described by this handbook, an **objective** is a pre-defined (per Global Plan Stop TB Objectives 1-4) as a broad goal by technical area where you want the national TB laboratory network to be in 5 years whereas a **strategy** is a sub-objective to achieve the objective. The strategies should include elements of the WHO AFRO-GLI priorities as previously defined.

A full list of indicators related to the NTP goal and the Stop TB objectives is in **Annex 4a**. Output indicators, such as the number of persons trained, will be linked to the activities that you propose subsequently to achieve your objectives and will be considered further in the next chapter.

Exercise 5a: Establishing targets for detection of smear-positive TB, smear-negative TB, MDR-TB and for quality management systems

Stakeholders should use the epidemiologic context, the current situation and achievements (i.e. percentage of estimated smear-positive new cases detected, child proportion among new smear-negative cases, proportion of TB patients tested for HIV, proportion of TB patients who are HIV+, proportion of MDR-TB cases detected, capacity to successfully treat TB/HIV and MDR-TB) and the NTP strategic plan to prioritize strategies and activities. If HIV prevalence is high e.g. HIV-positivity among TB patients is greater than 20%, smear-negative TB case detection should have a high priority. Similarly, if the prevalence of MDR-TB is more than 1% among new cases and/or more than 5% among retreatment patients, it should have a high priority. You should specify which proportion of cases should be detected by the end of the strategic planning period, or which increment above current performance should be detected.

Exercise 5b: Priority areas for detection of TB (smear-positive and smear-negative cases), priorities for detection of MDR-TB cases and priorities for quality management systems

The methods and techniques required to achieve these four priority objectives and how they should be deployed, may be quite different from each other. The development of the TB laboratory plan should generally be preceded by a separate consultative process to determine which diagnostic tools and accreditation schemes the country is aiming for with appropriate diagnostic algorithms in place. However, you should consider several factors when you are re-tooling your TB laboratory network. In most low-middle income settings, microscopy remains the initial tool for any TB diagnosis. However, detection of smear-negative cases will also require culture and/or molecular methods for laboratory-confirmed diagnoses. Detection of MDR-TB cases will require culture and DST and/or molecular methods. For all methods, variations are possible (i.e. light Ziehl-Neelsen versus LED fluorescence microscopy (LED FM); liquid versus solid media culture and/or DST; molecular: GeneXpert versus LPA). Each has its distinct indications in relation to the technical area but also the setting, which should be considered to set priorities. If routine culture and DST are already available in-country, the need for the immediate and wide-spread introduction of rapid diagnostics would be less of an issue than if culture and DST were not yet routinely available. In terms of quality management systems, you need to consider which laboratories would be relevant for ISO-15189 accreditation. This process takes generally 3-5 years, dependent on the baseline systems and infrastructure in place. Further, a new GLI tool can be used to accredit AFB microscopy networks. You may find guidance tools for ISO-15189 accreditation and AFB microscopy network accreditation on the GLI website (www.gli.org).

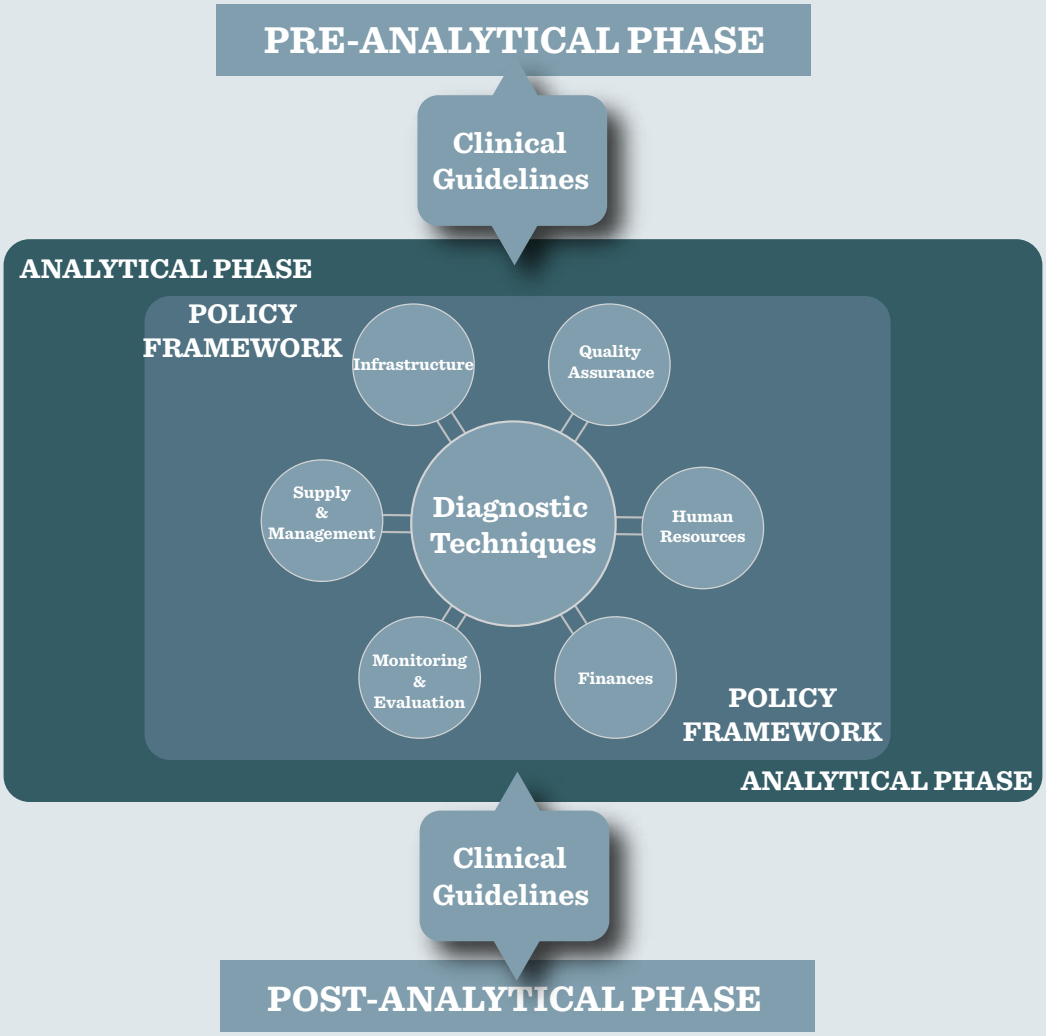
The activities required to achieve the priorities also need to be described. For example, LED FM may have to be expanded up to the lower-intermediate level within the coming five years as part of the priority to increase detection of TB when HIV-prevalence is high, and if rolling out the GeneXpert MTB/RIF test up to this level is not a realistic option. This would be part of the first objective to strengthen smear-microscopy capacity which will need a good number of activities. These activities should be identified by going through the GLI strategies list at the start of this chapter. So, for instance, expansion of LED FM would require activities falling under each including, for example, procurement of equipment (Strengthen laboratory infrastructure including biosafety), training (Improve laboratory human resource development), setting up or revising EQA (Develop and maintain laboratory quality management systems), supplies e.g. staining reagents (Enhance management of laboratory commodities and supplies including equipment validation and maintenance) and monitoring and evaluation to guide the expansion (Improve laboratory information and data management systems). Activities are defined as the broad processes needed to achieve the strategies within each of the corresponding pre-defined objectives.

As mentioned, most TB laboratory networks in low- and middle-income countries are not yet designed to detect all forms of TB, in contradiction to the current recommendations in the Global Plan to Stop TB. Therefore, you will need to consider re-tooling your laboratory network. You should consider the most recent WHO policy statements for TB laboratory networks which may be found on the WHO and GLI websites (www.who.int/tb/laboratory/policy_statements/en/index.html) and (www.gli.org), respectively. At the time of writing this first edition of the handbook, some highlights of policy recommendations for laboratory tools include:

- LED FM should be phased in as an alternative for conventional ZN light microscopy for both high- and low-volume laboratories
- Automated liquid culture and DST should be integrated into the TB laboratory network in a phased manner beginning with the national reference laboratory (NRL)
- Rapid speciation of *Mycobacterium tuberculosis* to distinguish from non-TB mycobacteria with strips should be established where culture is utilized
- Line probe assays may be used for rapid detection of Rifampicin resistance in the context of MDR-TB case detection using AFB smear-positive sputum samples
- Standardized second-line drug susceptibility testing should be conducted for injectables and fluoroquinolones
- The GeneXpert MTB/RIF test should be used as the initial diagnostic test in individuals suspected of pulmonary MDR-TB or TB/HIV

with sputum samples only
- You should not only consider the introduction of new tools but also how existing tools are utilized in the context of WHO policy recommendations:
- WHO now recommends that the former case definition of 3 diagnostic AFB smears may be replaced with 2 diagnostic AFB smears, assuming that EQA systems are in place for the microscopy network
- WHO also recommends front-loading with 2 smears done during the same visit to reduce diagnostic delay (preferably with at least one early morning specimen)

An example schematic of the pre-analytical, analytical and post-analytical phase for TB diagnostics within a laboratory network with WHO-recommended tools and inter-related processes is demonstrated below:



Further, new WHO policy recommendations are likely to be published on at least an annual basis after the printing of this edition and you should consult the aforementioned WHO website when developing your TB laboratory plan as well as annual TB laboratory implementation plans. Although not yet recommended, it might be expected, for instance, based on cumulative evidence and expert opinion that some extra-pulmonary samples e.g. gastric aspirates might be suitable for the GeneXpert MTB/RIF test and that selected 2nd line DSTs might be acceptable for LPAs with improved tools available.

Exercise 5c: Prioritizing strategies within STOP TB objectives

You should prioritize strategies within each Stop TB objective as per the skeletal structured example below for Objective 1. Within your country context, it may not be necessary to have all of the strategies covered within each of the four Stop TB objectives, but this should also not be completely ruled-out.

Objective 1: Increase access to quality-assured AFB microscopy with effective EQA	
Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	
Sub-activity 1.1.1.1	
Sub-activity 1.1.1.2	
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	
Sub-activity 1.2.1.1	
Sub-activity 1.2.1.2	
Sub-activity 1.2.1.3	
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	
Sub-activity 1.3.1.1	
Sub-activity 1.3.1.2	
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	
Sub-activity 1.4.1.1	
Sub-activity 1.4.1.2	
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	
Sub-activity 1.5.1.1	
Sub-activity 1.5.1.2	
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	
Sub-activity 1.6.1.1	
Sub-activity 1.6.1.2	
Strategy 1.7	**Establish a laboratory regulatory framework**
Activity 1.7.1	
Sub-activity 1.7.1.1	
Sub-activity 1.7.1.2	
Strategy 1.8	**Develop operational research capacity**
Activity 1.8.1	
Sub-activity 1.8.1.1	
Sub-activity 1.8.1.2	

Exercise 5d: Prioritizing main and sub- activities by strategies within STOP TB objectives

Regardless of which strategies you decide to use, you will need to develop specific activities to comprehensively achieve the overall objectives and strategies you have chosen over the 5-year duration of your TB laboratory plan. You first develop main activities then break these down into sub-activities at which level they can be subsequently budgeted for.

An example of identified strategies, main activities and sub-activities for selected objectives may be found below:

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**
Activity 1.1.1	Improve infection control measures in microscopy laboratories
Sub-activity 1.1.1.1	Develop laboratory specific infection control plans based on on-site assessments
Sub-activity 1.1.1.2	Provide selected microscopy laboratories with extraction fans
Strategy 1.2	**Improve laboratory human resource development**
Activity 1.2.1	Improve human resource capacity for microscopy laboratories
Sub-activity 1.2.1.1	Conduct assessment of training needs
Sub-activity 1.2.1.2	Develop training materials
Sub-activity 1.2.1.3	Train laboratory technicians
Strategy 1.3	**Develop and maintain laboratory quality management systems**
Activity 1.3.1	Conduct EQA for microscopy
Sub-activity 1.3.1.1	Support visits to peripheral laboratories
Sub-activity 1.3.1.2	Procure panel slides
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 1.4.1	Improve the supply of reagents/commodities to microscopy labs, as well as the maintenance of equipment
Sub-activity 1.4.1.1	Procure reagents for fluorescent microscopy
Sub-activity 1.4.1.2	Contract equipment maintenance services
Strategy 1.5	**Fortify specimen transport and referral mechanisms**
Activity 1.5.1	Improve turn-around time for specimen delivery and the reporting of results
Sub-activity 1.5.1.1	Contract courier services for specimens delivery
Sub-activity 1.5.1.2	Purchase airtime for the reporting of results
Strategy 1.6	**Improve laboratory information and data management systems**
Activity 1.6.1	Improve data management in the TB laboratory network
Sub-activity 1.6.1.1	Develop national data collection tools
Sub-activity 1.6.1.2	Print national data collection tools
Strategy 1.7	**Establish a laboratory Regulatory framework**
Activity 1.7.1	Strengthen the legal and regulatory framework to support the implementation of a national laboratory policy
Sub-activity 1.7.1.1	Develop, establish and disseminate national standards for TB laboratory equipment & reagents
Sub-activity 1.7.1.2	Develop a quality assurance program for TB laboratory services
Strategy 1.8	**Develop Operational Research capacity**
Activity 1.8.1	Conduct an operational research study to measure the potential reduction in initial default with front loading AFB microscopy services
Sub-activity 1.8.1.1	Develop a study protocol in a workshop with external technical assistance
Sub-activity 1.8.1.2	Implement a study in selected sites which includes ethics approval, data abstraction, and data entry
Sub-activity 1.8.1.3	Analyze and report results in a workshop with policy change considerations dependent on the findings

Objective 2: Improve the diagnosis of TB among AFB-negative cases especially among people living with HIV	
Strategy 2.1	**Strengthen laboratory infrastructure including biosafety**
Activity 2.1.1	Ensure a stable, uninterrupted electricity supply for GeneXpert labs
Sub-activity 2.1.1.1	Minor renovations to improve electricity supply
Sub-activity 2.1.1.2	Procure backup generators, power surge protectors and solar panels
Strategy 2.2	**Improve laboratory human resource development**
Activity 2.2.1	Train and re-train lab and medical staff on GeneXpert
Sub-activity 2.2.1.1	Conduct training of trainers
Sub-activity 2.2.1.2	Conduct district-level trainings for laboratorians and clinicians
Strategy 2.3	**Develop and maintain laboratory quality management systems**
Activity 2.3.1	Participate in internationally recognized EQA program for GeneXpert
Sub-activity 2.3.1.1	Procure GeneXpert EQA panels
Sub-activity 2.3.1.2	Establish remedial measures for low performers e.g. re-training, increased supervision, re-assignment of staff
Strategy 2.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**
Activity 2.4.1	Procure and maintain a stable supply chain of GeneXpert cartridges
Sub-activity 2.4.1.1	Establish a supply chain protocol
Sub-activity 2.4.1.2	Procure cartridges with a buffer stock
Strategy 2.5	**Fortify specimen transport and referral mechanisms**
Activity 2.5.1	Establish (maintain) a courier system for sample transport to GeneXpert sites
Sub-activity 2.5.1.1	Procure motorcycles
Sub-activity 2.5.1.2	Procure petrol
Strategy 2.6	**Improve laboratory information and data management systems**
Activity 2.6.1	Establish and maintain a recording and reporting system with GeneXpert integrated
Sub-activity 2.6.1.1	Revise recording and reporting system with GeneXpert integrated
Sub-activity 2.6.1.2	Print revised forms and registers
Strategy 2.7	**Establish a laboratory Regulatory framework**
Activity 2.7.1	Ensure national authorities have recognized use of GeneXpert
Sub-activity 2.7.1.1	Meeting(s) with national authorities
Sub-activity 2.7.1.2	Pay regulatory licensing fee and legal fees (if relevant)
Strategy 2.8	**Develop Operational Research capacity**
Activity 2.8.1	Evaluate the added value of GeneXpert in SS- detection among PLWHAs
Sub-activity 2.8.1.1	Develop a study protocol with a stakeholder workshop facilitated by an external epidemiologist
Sub-activity 2.8.1.2	Implement study protocol including training, printing of data collection forms, ethics approval, data entry
Sub-activity 2.8.1.3	Analyze and report data in the form of a stakeholder workshop. Develop policy recommendations based on the findings

Chapter 6:

Identifying Indicators and Targets in a Monitoring and Evaluation Framework

In this section, you should develop Monitoring and Evaluation (M&E) indicators and targets for each activity. For each activity described by strategy within objectives, you should use the SMART framework for developing indicators and targets (See box right). The indicators should, as much as possible, be similar to those used by Stop TB and WHO for TB-laboratory strengthening (**see Annex 4b for indicators by strategy**). The indicators should also conform as much as possible to those indicators already defined in the NTP plan. However, you may need to custom build some indicators for your TB laboratory plan as the list we provide is not exhaustive. The indicators should be developed only for the main activities and not for the sub-activity level.

Similar to the objectives, the basis of the TB laboratory targets is the NTP plan. The NTP targets should be translated into laboratory targets. The targets are country-specific, as they are influenced by several factors, including the burden of TB, MDR-TB and HIV, the in-country laboratory infrastructure and capacity, human and financial resources, and existing quality management systems. When we speak of strategic plans in TB control, we generally consider medium-term plans with targets that are a maximum of 5-years in duration; however, some of your targets might be reached earlier e.g. by the 2nd year.

SMART Indicators:

Specific: Clearly written to avoid different interpretations

Measurable: To allow you to monitor and evaluate progress toward achieving the result

Appropriate: To the scope of your program or work activities, so that you can influence or make changes

Realistic: Achievable within the time allowed

Time bound: With a specific time period for completion

Exercise 6a: Developing M&E indicators for activities within STOP TB objectives

Exercise 6b: Developing M&E targets for activities within STOP TB objectives

Strategy 1.1	**Strengthen laboratory infrastructure including biosafety**	**Indicators**	**Targets**
Activity 1.1.1	Improve infection control measures in microscopy laboratories	# (%) of laboratories with improved infection control during a specified period of time	35 (80%) laboratories with improved infection control by September 2015
Sub-activity 1.1.1.1	Development of laboratory specific infection control plans		
Sub-activity 1.1.1.2	Provision of microscopy laboratories with extraction fans		
Strategy 1.2	**Improve laboratory human resource development**		
Activity 1.2.1	Improve human resource capacity	# (%) of laboratories with trained staff during a specified period of time	378 (90%) technicians trained by February 2016
Sub-activity 1.2.1.1	Conduct assessment of training needs		
Sub-activity 1.2.1.2	Develop training materials		
Sub-activity 1.2.1.3	Train laboratory technicians		
Strategy 1.3	**Develop and maintain laboratory quality management systems**		
Activity 1.3.1	Conduct EQA for microscopy	# (%) of laboratories involved in EQA during a specified period of time	97 (100%) laboratories involved in EQA program by December 2014
Sub-activity 1.3.1.1	Support visits to peripheral laboratories		
Sub-activity 1.3.1.2	Procurement of panel slides		
Strategy 1.4	**Enhance management of laboratory commodities and supplies including equipment validation and maintenance**		
Activity 1.4.1	Improve supply of microscopy laboratories with reagents and commodities and maintenance of equipment	# (%) of laboratories with no stock-outs during a specified period of time	65 (95%) laboratories without stock-outs by July 2014
Sub-activity 1.4.1.1	Procurement of reagents for fluorescent microscopy		
Sub-activity 1.4.1.2	Contracting equipment maintenance services		

Strategy 1.5	**Fortify specimen transport and referral mechanisms**		
Activity 1.5.1	Improve the turnaround time for specimens delivery and reporting of results	# (%) of laboratories reporting results within acceptable turnaround time during a specified period of time	80 (90%) laboratories reporting results within acceptable turnaround time by August 2013
Sub-activity 1.5.1.1	Contract courier services for specimens delivery		
Sub-activity 1.5.1.2	Purchase of airtime for reporting of results		
Strategy 1.6	**Improve laboratory information and data management systems**		
Activity 1.6.1	Improve data management in the TB laboratory network	# (%) of laboratories submitting regular reports during a specified period of time	56 (85%) laboratories submitting regular reports by November 2015
Sub-activity 1.6.1.1	Development of national data collection tools		
Sub-activity 1.6.1.2	Printing of the national data collection tools		
Strategy 1.7	**Establish a laboratory Regulatory framework**		
Activity 1.7.1	Strengthen the legal and regulatory framework to support implementation of national laboratory policy	# (%) of support documents available during a specified period of time	2 (100%) planned support documents available by May 2014
Sub-activity 1.7.1.1	Develop, establish and disseminate national standards for TB laboratory equipment & reagents		
Sub-activity 1.7.1.2	Develop Quality Assurance program for TB laboratory network		
Strategy 1.8	**Develop operational research capacity**		
Activity 1.8.1	Conduct an operational research study to measure potential reduction in initial default with front loading AFB microscopy services	# (%) of operational research studies conducted related to smear-microscopy out of planned in a specified time period	1 (100%) operational research study is conducted related to smear-microscopy by January 2014
Sub-activity 1.8.1.1	Develop a study protocol in a workshop with external technical assistance		

Sub-activity 1.8.1.2	Implement a study in selected sites including ethics approval, data abstraction and data entry		
Sub-activity 1.8.1.3	Analyze and report results in a workshop with policy change considerations dependent on findings		

Chapter 7:

Develop a TB Laboratory Work Plan and Budget

A budgeted work plan defines activities, costs, persons in charge, expected difficulties and schedules that are required to achieve the objectives of the TB laboratory plan. It breaks each strategy into steps and shows how each step will be achieved.

For the TB laboratory plan to be successfully implemented, it is essential that work plans and budgets are in line with the objectives, strategies, activities and targets established. The work plan should also address constraints and any potential problem (e.g. financial, political, etc.) that must be overcome in order to meet the objectives and reach set targets.

A work plan is a management tool which provides a framework for the planning, execution and implementation as well as monitoring and evaluation of work. A work plan is thus used at multiple steps: i. initially by the program to convince decision makers and funding agencies for allocation of resources and ii. by responsible agencies for release of funds, iii. and subsequently it is used as a guiding document by implementers for the set of activities to be carried out during specified time period. It should thus be shared within all persons involved in the implementation of the TB laboratory plan, particularly laboratory managers at all levels of the TB laboratory network.

The exercises in this handbook should have provided you with a building blocks necessary for finalizing your work plan. If you have followed the exercises, you should already have identified strategies, activities and targets for each objective. You may have also established sub-activities if you chose to go for a detailed work plan which is more accurate than costing on the activity level.

Before developing a detailed work plan, strategies under each objective need to be prioritized and a set of activities required to implement these strategies need to be clearly defined in logical sequence and the time required for each activity needs to be estimated realistically in the country context. If you decide to utilize a detailed work plan, you will need to do this by sub-activity.

Besides this core team will need:

- Objectives and targets to be achieved and defined priority areas during the given period
- Contextual situation analysis with SWOT analysis
- If available, an audit report of the preceding period including strengths, weakness and recommendation
- Funds already available or which can be released on time to perform activities
- Persons available to perform activities.

The work plan is presented in a logical way, from each objective, there are strategies, from each strategy within each objective there are several activities and from each activity, several sub-activities. However, for the purpose of strategic planning, activities defined under each strategy are sufficient. A detailed activity plan can be developed for implementation once financial resources have been allocated. It should be taken into account that:

- Some activities need to be completed before starting the next one
- Some activities can go on simultaneously
- Some activities are ongoing processes lasting the entire 5-year span of the TB laboratory plan.

Estimating the time needed to finish an activity is often challenging, therefore you should keep the following questions in mind:

- How long would it take to accomplish the task optimistically, probably and pessimistically?
- How many people will be working on the task simultaneously?

Some tasks have an obvious time span and are easy to estimate. The ease of estimation also comes with the experience of the core team with similar projects. Other tasks need more careful consideration.

For the purpose of planning and budgeting, important considerations for each strategy are listed below:

7.1 STRENGTHEN LABORATORY INFRASTRUCTURE including biosafety

Based on a needs assessment and defined priority areas, activities need to be included in the work plan for improving laboratory infra-structure (excluding equipment), for instance, establishing new microscopy laboratories or upgrading DST laboratories to WHO recommended biosafety standards. Alternatively, you may propose structural changes within existing culture laboratories to introduce molecular techniques e.g. line probe assays.

The work plan for the TB laboratory plan should be developed keeping the country capacity to design and build laboratories in mind. If there is limited capacity with local consultants, you might propose external technical assistance at different stages of execution e.g. in designing, commissioning or validation but this should be budgeted within the next category for human resources.

Based on a needs assessment, you may also need to include costs of utilities e.g. electricity and water for some laboratories. In view of the general situation prevailing in country, you should also consider alternate sources of power for an uninterrupted power supply including both capital costs (e.g. generator and/or solar power units for culture and DST, LPA and GeneXpert MTB/RIF tests laboratories) as well as running costs (e.g. fuel charges and maintenance costs for power surge protectors).

It is also important to understand that some infrastructure activities may be slow to implement as they involve various steps requiring approval and coordination of different stakeholders for execution. For example, targets for new culture and DST laboratories are often difficult to achieve in the short-term. Therefore, a realistic approach should be adopted while estimating time required for completion of infrastructure related activities.

7.2 IMPROVE LABORATORY HUMAN RESOURCE DEVELOPMENT

This strategy addresses Human Resource Development (HRD) including training needs for operating TB laboratories at different tiers of the TB laboratory network and for local or international technical assistance:

- If gaps in HRD have been identified and the recruitment of additional staff is an agreed activity, you should develop an induction plan for new staff and budget accordingly for annual salaries as well as for recruitment processes e.g. advertisements and interviews
- Similarly, if performance-based incentives for any category of TB laboratory staff have been agreed upon, you should also include these while costing work plans
- You should incorporate all identified training needs into the work plan e.g. trainings on microscopy, culture and DST, new tools (i.e. GeneXpert MTB/RIF and LPA testing), and laboratory management and information systems. Training activities should be in incorporated realistically within work plan keeping in mind not only the availability of staff but also the availability and capacity of training venues and facilitators
- You should also align the timing of any HRD plan (e.g. recruitment and training) with the budget for the re-tooling of the laboratory network e.g. if new laboratories are planned in the 3rd year budget and you need to consider when they will be functional and when you should budget for new staff induction, trainings etc.
- If the need for development or revision of

HRD plans or training curricula is identified, you should include budget for local and/or international consultants and/or for consultative meetings in work plan
- Budget for International assessment missions and country-based staff from international agencies providing technical assistance to the NTP should also be included as per identified need
- Coordination with other programs and departments and other aspects of HRD e.g. participation in international training, conferences and meetings should also be budgeted under this strategy.

7.3 DEVELOP AND MAINTAIN LABORATORY QUALITY MANAGEMENT SYSTEMS

For each objective, activities are defined for improving quality of diagnosis. The Quality System for the microscopy network includes internal quality control, EQA, e.g. onsite supportive supervision, blinded rechecking and/or panel testing. You should make certain to budget for these activities. You may also consider investing in the accreditation of the microscopy network with a new GLI tool which will require a budget as well.

Intermediate laboratories with the GeneXpert MTB/RIF tests will require control strains for the assessment of performance.

The NRL will require participation in an international EQA scheme for DST and a budget should be established for this. Similarly, other laboratories in country doing culture and DST will need to have an EQA scheme which should be budgeted. If your country decides to use a step-wise accreditation approach to achieve compliance with the ISO 15189 standard for clinical laboratories, a budget will also be required.

Broadly, activities defined for quality management systems include the costs for supervision and monitoring (travel and per diem), preparation and shipment of panels or control strains and accreditation fees. However, you should make certain, that budgets for salaries and consultant fees e.g. HRD costs, are not duplicated.

7.4 ENHANCE MANAGEMENT OF LABORATORY EQUIPMENT, COMMODITIES AND SUPPLIES

Equipment: Planning for new equipment will depend on a situation assessment of the existing equipment, the projected need for replacement of existing equipment within the next five years, and plans to introduce new diagnostic tools and/or to establish new laboratories.

For new laboratories, a set of equipment will be required based on the expected scope of work; however, for enhancing the capacity of existing laboratories, a budget will be only be required for specific equipment e.g. LED microscopes for microscopy laboratories at intermediate or peripheral level, MGIT for adding liquid culture to existing culture laboratory using solid media, new diagnostic tools such as the GeneXpert MTB/RIF test in the existing laboratories, depending on defined priorities. For high burden countries, certain equipment is available at a negotiated price, but for other equipment if reduced country specific costs for equipment are not available, the **WHO budgeting tool** may be referred to for costing (WHO TB Control Planning and Budgeting tool. http://www.who.int/tb/dots/planning_budgeting_tool/en/).

Equipment procurement, maintenance and validation cost: While planning for equipment procurement (for instance, LED microscopes, MGIT or GeneXpert through direct contracting at FIND negotiated prices), you should add procurement costs to cover freight, custom clearance, storage and distribution. Furthermore, equipment maintenance costs should be included to address maintenance costs as well as the costs to establish viable annual service contracts. Problems with equipment under warranty are covered during their warranty but an additional budget may be required to extend the warranty, e.g. if you decide not to replace the equipment during its normal warranty period. Therefore extended warranties should be included in the maintenance costs for the next year after procurements with a one year warranty. In general, maintenance costs can be calculated as a fraction (10%) of the total cost of the equipment (see the latest version of the tool for the current estimate of equipment maintenance and annual

estimates of validation and maintenance of GeneXpert or BSL-3). When budgeting for maintenance costs, you should bear in mind that these costs largely depend on the quality of the electricity supply, water and the remoteness of the setting, among other factors.

Procurement and distribution of lab supplies and reagents:
For microscopy laboratories, you should budget carefully based on the country plan to shift from ZN to LED FM microscopy. Total cost can be calculated by multiplying the estimated number of smears per year by the cost of a smear plus the procurement cost.

For culture and DST laboratories, you should separately cost liquid and solid media. Budgeting for procurement and distribution for culture and DST supplies should be done, separating solid media for first-line drug tests, solid media for second-line drug tests and the same for liquid media according to the workload.

For molecular tests, you should include the cost per test and the cost of consumables.
TB WHO planning and budgeting tool or alternatively TBCAP/TB CARE I laboratory tools can be used for cost estimation or quantification of different items for microscopy, culture and DST supplies (**See Selected References and Resources** at the end of this handbook).

7.5 FORTIFY SPECIMEN TRANSPORT AND REFERRAL MECHANISMS

As per identified need and proposed strategies for improving access to microscopy, culture, DST and new diagnostic tool services in the TB laboratory plan, you should consider planning and budgeting for the hiring of courier services and cool transport boxes. You should estimate how much the transport of smear samples to the next laboratory, and sputum specimens for GeneXpert MTB/RIF testing or for culture and culture isolates for DST to higher laboratories costs.

When budgeting for the national/international transportation of biological specimens, you should keep in mind the estimated minimum costs for shipment of samples (see the latest version of WHO budgeting tool for the current estimate).

7.6 IMPROVE LABORATORY INFORMATION AND DATA MANAGEMENT SYSTEMS

Information and data management systems can be quite costly if not properly planned for. Potential expenses that should be considered include:

- Personnel time for data preparation, management, documentation and preservation.
- Hardware and/or software needed for data management, backing up, security, documentation and preservation. Annual user licenses for software should also be taken into account
- Costs associated with submitting the data to an archive.

Maintenance costs of hardware and software updating needs to be taken into account. Also you should consider the physical environment in which the systems will be hosted. For example, a high volume server may require special environmental and security conditions.

7.7 ESTABLISH LABORATORY REGULATORY FRAMEWORK

Although a lot of the work involved in establishing a regulatory framework is in the nature of advocacy, there are some costs that must not be omitted. Estimate and include the costs for holding advocacy meetings and/or workshops and seminars at all levels. Include the consultant costs for baseline assessments and/or drafting legislation e.g. for imposing a ban on the use of serological test for diagnosis of TB in private laboratories. You should also include the costs for designated laboratory staff to attend regulatory meetings, once the framework is in place.

7.8 DEVELOP OPERATIONAL RESEARCH CAPACITY

Successful OR requires a close collaboration between the program manager and the research team during the design, implementation, monitoring, analysis and dissemination phases of the research project. It is important, therefore, to estimate the costs of adequately training program managers and researchers. You should also budget for the costs of any technical assistance

that will be required to achieve this. The cost of the research projects to be undertaken should be estimated and budgeted accordingly. Drug resistance and prevalence surveys typically have many costs that can sometimes exceed 500,000 and 1,000,000USD, respectively. Finally, you should include a budget for the cost of developing any materials or curricula needed in training the managers and researchers, statistical software and fees for ethical clearance.

Budgeting Tool

The National Laboratory Strategic Plan Budgeting and Work plan Tool has been developed to assist TB laboratory strengthening consultants, National TB reference laboratory and national TB program management in planning for and costing laboratory specific programs.

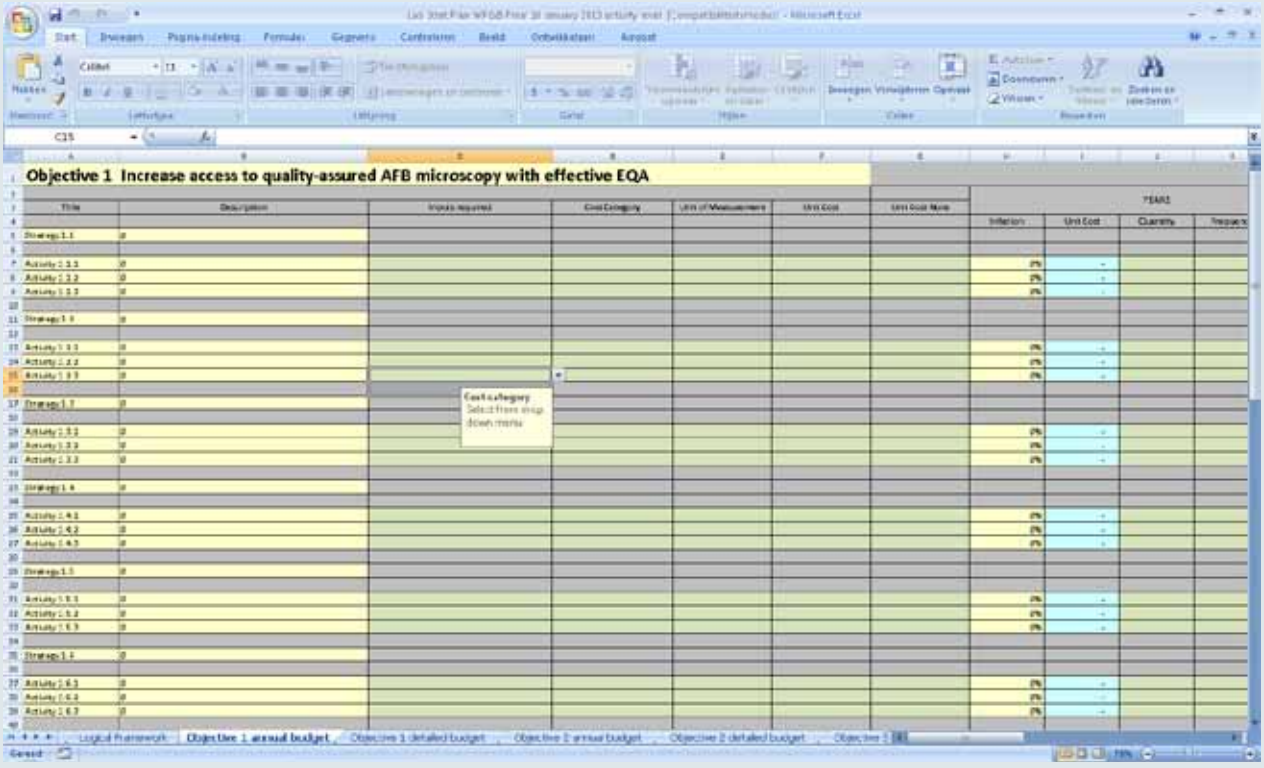
The design of the tool is based on a review of various tools used for costing TB Control and other health initiatives, and attempts have been made to incorporate, as far as possible, favorable features of such tools as expressed by various users, while maintaining a user-friendly interface. It is a simple Excel tool similar to the WHO budgeting tool, which provides a simple and methodical approach to strategic planning and budgeting, beginning by allowing the user to outline fundamental assumptions. These include variables such as the currency in which the budget will be reported, inflation and exchange rates incorporated in the budget, and any other general assumptions.

In the next stage for the use of the tool, the Logical Framework for the Plan is developed in which goals, objectives, strategies and activities to be accomplished are specified (as indicated in **Chapter 5**). Next, indicators are also selected or written in (as indicated in **Chapter 6**). In order to enhance uniformity, the tool restricts the user to pre-determined objectives and strategies through the use of pull-down menus. Indicators can be entered both via drop-down menus and by writing them in manually.

The development of the Logical Framework is followed by translating this into a work plan by adding targets (as indicated in **Chapter 6**) and timeframes over the period of the strategic plan. The planning periods are split annually, but for those requiring more detailed, planning, the tool allows the user to plan quarterly for the first two years of the plan.

Finally, the activities and/or sub-activities are budgeted and the whole work plan is translated into a budget by applying unit costs to the targets.

Two versions of the tool are available. The first version allows planners in budgeting of **strategic plan** and provides details and cost up to the main activity level for each objective. A second version



is also available for developing detailed **annual implementation** plans and allows accurate costing up to the sub-activity level. The tool is based on an activity-based approach, enabling the user to examine costs and activities by objectives and strategies within summary sheets for the work plan and detailed budget. It also allows a cost category delineation of the strategic plan with automatically generated summary reports.

Unit Costs

The tool allows the input of cost data at any level of detail, but it is recommended to provide for input costs at the lowest level of each input cost unit (simple unit cost). Examples of unit costs include the cost of a computer or motor vehicle, one salary day for consultants, one salary month for regular staff, one day for venue rental, one day of per diem and allowances for workshop participants, one airfare, one packet of reagent, and so on.

However, where several input costs can be combined to arrive at an aggregate input cost and all input costs can be included in a single cost category, then use of aggregated input costs is encouraged. For example, the cost of a supervisory visit could consist of fuel, subsistence and travel allowances. These could be aggregated into a single compound cost for a standard 5-day trip.

For uniformity, the tool requires input cost data to be standardized across different activities. The same input cost must be used for all activities. For example, an international consultant hired for 5 days for a particular activity and another for 14 days for another activity, should be budgeted at the same unit cost e.g. per day or per week.

Similarly, for uniformity and to enhance the comparison between different plans, predetermined unit cost categories have been incorporated in the tool through the use of drop down menus.

A worksheet showing all unit cost calculations can be inserted in the workbook. Once the sheet has been completed, it can be printed or copied electronically and used to source input costs for defined items. This may require giving certain sections of the input cost sheet to various government officials or employees in a procurement agency, who can then assist by completing the actual cost for each item identified.

Unit costs are available from various sources, but care must be taken to make sufficient enquiry about the proposed sources of equipment and supplies cost.

Users Manual: *A detailed description on the use of the National TB Laboratory Budgeting and Work plan Tool is provided in* **Annex I of the Facilitators Manual.**

Exercise 7a: Work plan and budget-costing (sub-) activities

Chapter 8:

Putting it All Together

At this point, if you followed the chapter-by-chapter exercises starting with **Chapter 2** in this handbook, you should have a working draft of a TB laboratory plan. However, this plan is likely to have some gaps. You are also likely to have some sections that still need polishing and perhaps other sections that have not been worked on at all.

Check if completed ✓	Component
	Title page with appropriate logos and date.
	I. Table of contents
	II. Foreword
	III. Acknowledgments of contributors
	IV. Executive summary highlighting the key elements for an overview of the TB laboratory plan
	V. Abbreviations
	VI. Mission and vision statement [derived from Exercises 3a-3b]
	VII. TB-specific situational analysis including:
	Narrative of sections 4.1-4.13 [derived from Exercise 4a]
	Strengths, Weaknesses, Opportunities and Threats (SWOT) of TB laboratory network [derived from Exercise 4b]
	Situational analysis framework by key challenges and specific areas with potential solutions [derived from Exercise 4c]
	VIII. Defined Priority targets, priorities by objective, strategies, activities and sub activities of the TB laboratory plan [derived from Exercises 5a-5d]
	IX. Monitoring and Evaluation framework for activities of TB laboratory plan [derived from Exercises 6a-6b]
	X. Work plan and budget of TB laboratory plan [Exercise 7a]
	XI. References
	XII. Annexes
	Editing for consistency of terms within the Plan and between the Plan's mission as well as the NTP and NHL Plans
	Editing for grammar and language
	Spell-check
	Endorsement by an appropriate official with forward (executive summary)
	Printing
	Distribution

Appendix:

Selected References and Internet Resources

References

Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs, World Health Organization, WHO/HTM/TB/2004.344

Early detection of tuberculosis: an overview of approaches, guidelines and tools. World Health Organization. WHO/HTM/TB/PSI/2011.21.

Global Plan to Stop TB 2011-2015: Transforming the fight towards elimination of tuberculosis. World Health Organization, 2010.

Global Laboratory Initiative TB Laboratory Accreditation tools: http://www.stoptb.org/wg/gli/accreditation.asp

Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infection with and affected by HIV/AIDS, TB and Malaria, WHO Geneva/WHO Africa/US Centers for Disease Control and Prevention/Association of Public Health Laboratories, 2010.

Managers Who Lead. A handbook for Improving Health Services. Management Sciences for Health, 2005

MDR-TB Indicators, A minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programs, WHO/HTM/TB/2010.11

Policy Framework for Implementing New Tuberculosis Diagnostics, World Health Organization, 2010.

Policy statement: automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: GeneXpert MTB/RIF system, World Health Organization WHO/HTM/TB/2011.4

Roadmap for ensuring quality tuberculosis diagnostics services within national laboratory strategic plans. Global Laboratory Initiative, 2010.

TB CARE I Laboratory tools package. http://www.tbcare1.org/publications/toolbox/lab/

Tuberculosis Laboratory Biosafety Manual. World Health Organization. 2012. WHO/HTM/TB/2012.11. http://www.tbcare1.org/publications/toolbox/tools/ic/WHO_TB_Laboratory_Biosafety_Manual.pdf

Tuberculosis Prevalence Surveys: A Handbook. World Health Organization, WHO/HTM/TB/2010.17.

UNITAID Tuberculosis diagnostic technology landscape, World Health Organization, 2012.

WHO TB Control Planning and Budgeting tool. http://www.who.int/tb/dots/planning_budgeting_tool/en/

Internet Resources:

Global Laboratory Initiative:
http://www.gli.org

KNCV Tuberculosis Foundation:
http://www.kncvtbc.org

Management Sciences for Health:
http://www.msh.org/

StopTB Partnership:
http://www.stoptb.org

TB CARE I:
http://www.tbcare1.org/

The Union against Tuberculosis and Lung Disease:
http://www.theunion.org/

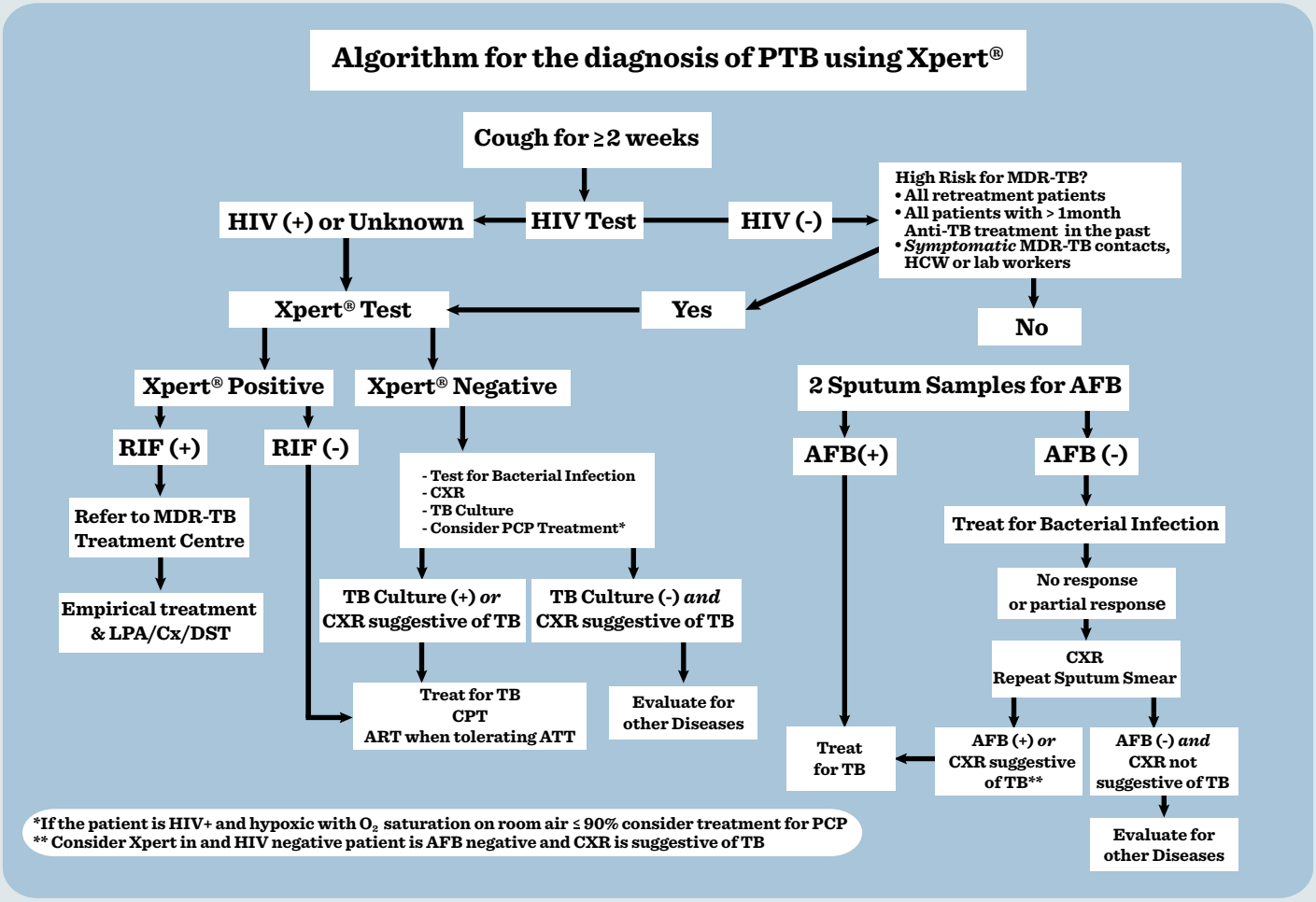
United States Centers for Disease Control and Elimination:
http://www.cdc.gov/

United States Agency for International Development:
http://www.usaid.gov/

World Health Organization:
http://www.who.int/en/

Annex 1:

Country Example of a Diagnostic Algorithm using the Xpert MTB/RIF Test



Annex 2:

Reference Materials Recommended by Chapter

CHAPTER 3
Developing a Vision and a Mission National TB Program (NTP) vision and mission Current National TB reference laboratory (NTRL) vision and mission, if it exists National Medical Laboratory vision and mission, if it exists
CHAPTER 4
TB-specific contextual analysis NTP guidelines NTP plan (MANDATORY) National Medical Laboratories Strategic Plan, if it exists Current NTRL strategic plan, if it exists WHO Global Report on TB (most recent) NTP surveillance, policy and technical reports Review/assessment reports Latest drug-resistance survey (DRS) report HIV/AIDS surveillance, policy and technical reports
TB-specific TESTS CURRENTLY AVAILABLE and Coverage
Medical Laboratories Policy NTRL quality manual Microscopy, culture, drug susceptibility testing (DST), molecular assays statistics Statistics on number of TB diagnostic laboratories and work-load
STRUCTURE OF THE LABORATORY NETWORK of TB diagnostics
Medical Laboratories Policy TB laboratory Network Organogram
INFRASTRUCTURE OF THE LABORATORY NETWORK for TB diagnostics
NTP review/assessment reports Laboratory network review/assessment reports from partners Biosafety manual Infection Control (IC) guidelines National waste management regulations
HUMAN RESOURCES for the TB lab network
MoH strategic human resource development (HRD) plan NTP HRD strategic plan National Medical Laboratories Strategic Plan, if it exists NTP review reports AFB microscopy EQA reports Reports on external assessments of the NTRL and laboratory network Laboratory School curricula

EQUIPMENT MAINTENANCE AND VALIDATION of TB lab equipment
Medical laboratories policy NTRL quality manual NTP review reports Reports on external assessments of the NTRL and laboratory network
LABORATORY QUALITY MANAGEMENT SYSTEMS within the TB lab network
Medical laboratories policy NTRL quality manual AFB microscopy EQA plan DST EQA plan EQA reports on smear microscopy and DST Reports on external assessments of the NTRL and laboratory network
MANAGEMENT OF LABORATORY COMMODITIES AND SUPPLIES within the TB lab network
Medical laboratories policy NTP/assessment review reports Central Medical Stores (CMS)/Supply and commodities management system (SCMS) List of supplies NTRL external assessments reports
LABORATORY INFORMATION AND DATA MANAGEMENT for the TB lab network
Mycobacterial request/report form Microscopy and culture/DST register MDR-TB report tool TB/HIV request and report tool Manuals/SOPs for laboratory informational systems in use
SAMPLE REFERRAL SYSTEMS for the TB lab network
Medical laboratories policy Specimen collection and transportation manual NTP manual
OPERATIONAL RESEARCH regarding the TB laboratory network
NTP strategic plan National Medical Laboratories Strategic Plan, if it exists Current NTRL strategic plan, if it exists Partners' plans
LEGAL AND POLICY REVIEW for TB
Medical laboratories policy NTRL quality manual
FINANCES for TB laboratory services
National Medical Laboratories Strategic Plan, if it exists NTP plan Partners' agreement documents, reports and plans
CHAPTER 5
NTP plans Diagnostic algorithms
CHAPTER 6
NTP plan indicators and targets
CHAPTER 7
Minimum budget available/pledged by source for 5-year TB laboratory plan (as many years as possible)

Annex 2a:

Example Workshop Agenda for 1st One-Week Workshop

{COUNTRY} National TB laboratory plan workshop:
Agenda
{DATE]
{LOCATION}

Day 1 Monday {DATE}

8:30-8:45
Opening
NHL/NTP

8:45-9:00
Introductions
All stakeholders

9:00-9:15
Proposed objectives and agenda for workshop
Consultant or national coordinator of workshop

9:15-10:30
Developing a vision for a TB laboratory plan
Stakeholders divided into 4 groups

10:30-10:50
Tea/Coffee break

10:50-12:30
Developing a vision and mission for a TB laboratory plan
Stakeholders divided into 4 groups
Exercise 3a: Vision (continued)
Exercise 3b: Mission
Presentations of visions and mission by group and agreement on which draft to utilize

12:30-13:30
Lunch

13:30-15:00
Situational analysis of TB laboratory network
Stakeholders divided into 4 groups
Exercise 4a: Situational analysis

15:00-15:20
Tea/Coffee break

15:20-16:20
Situational analysis of TB laboratory network
Exercise 4a (continued): Drafts to be turned in by end of session

16:20-16:30
Closure for the Day

DAY 2 Tuesday {DATE}

8:30-10:30
Situational analysis of TB laboratory network
Presentations and discussion of situational analysis

10:30-10:50
Tea/Coffee break

10:50-12:30
Situational analysis of TB laboratory network: SWOT
Stakeholders divided into 4 groups
Exercise 4b: Situational analysis SWOT

12:30-13:30
Lunch

13:30-15:00
Situational analysis of TB laboratory network SWOT
Exercise 4b (continued): continued and group presentations

15:00-15:20
Tea/Coffee break

15:20-16:20
Situational analysis of TB laboratory network: framework
Stakeholders divided into 4 groups
Exercise 4c: Situational analysis framework

16:20-16:30
Closure for the Day

DAY 3 Wednesday {DATE}

8:30-10:30
Situational analysis of TB laboratory network
Presentations and discussion of situational analysis framework

10:30-10:50
Tea/Coffee break

10:50-12:30
Defining targets by goal and objectives
Stakeholders divided into 4 groups
Exercise 5a: Targets:
1. Detection of smear-positive TB
2. Detection of smear-negative TB
3. Detection of MDRTB
4. Quality management systems

12:30-13:30
Lunch

13:30-15:00
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b: 4 groups

15:00-15:20
Tea/Coffee break

15:20-16:20
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b (continued): 4 groups

16:20-16:30
Closure for the Day

DAY 4 Thursday {DATE}

8:30-9:30
Prioritization of gaps and weakness identified in the situational analysis framework
Exercise 5b (continued): Finalization, presentations and discussion

9:30-10:30
Setting strategies within objectives for a TB laboratory plan
Exercise 5c Setting strategies: break into 4 groups

10:30-10:50
Tea/Coffee break

10:50-12:30
Setting strategies within objectives for a TB laboratory plan
Exercise 5c Setting strategies (Continued): break into groups
Finalization and discussion

12:30-13:30
Lunch

13:30-15:00
Setting strategic activities within identified objectives and strategies
Exercise 5d Setting strategic activities: break into 4 groups

15:00-15:20
Tea/Coffee break

15:20-16:20
Setting strategic activities within identified objectives and strategies
Exercise 5d (Continued) Setting strategic activities: break into groups

16:20-16:30
Closure for the Day

DAY 5 Friday {DATE}

8:30-10:30
Setting strategic activities within identified objectives and strategies
Exercise 5b (continued): Finalization, presentations and discussion

10:30-10:50
Tea/Coffee break

10:50-12:30
Developing indicators and targets for TB laboratory plan
Exercises 6a-6b: Indicators and targets
Break into groups

12:30-13:30
Lunch

13:30-15:00
Developing indicators and targets for TB laboratory plan
Exercise 6a-6b (Continued): Indicators and targets
Break into groups
Finalization and presentation

15:00-15:20
Tea/Coffee break

15:20-16:20
Wrapping up and closure

Annex 2b:

Example Workshop Agenda for 2nd One-week Workshop **(Customized per country, dependent on gaps identified in the draft TB laboratory plan prior to this workshop)**

{COUNTRY} National TB Laboratory Plan Workshop:
Agenda
{DATE]
{LOCATION}

Day 1 Monday {DATE}

8:30-8:45
Opening
NHL/NTP

8:45-9:00
Introductions
All stakeholders

9:00-9:15
Proposed justification, objectives and agenda for workshop
Consultant or national coordinator of workshop

9:15-10:30
Overview of the draft TB-specific lab strategic plan handbook and "Where we are now" with the 1st draft of the {COUNTRY} National TB Reference Laboratory (NTRL) Strategic Plan from the 1st workshop in {DATE}
Consultant or national coordinator of workshop

10:30-10:50
Tea/Coffee break

10:50-11:30
Introduction to the Monitoring and Evaluation (M&E) framework for the lab strategic plan
Consultant or national coordinator of workshop

11:30-12:30
Retrospectively (moving backward) :
Update the existing draft NTRL strategic plan sections not fully completed from the previous workshop including the situational analysis and priorities
Prospectively (moving forward):
Develop M&E section from scratch for the draft NTRL strategic plan

Stakeholders divided into 3 groups:
1. Retrospective: Situational analysis update [Chapter (Ch.) 4 of Laboratory Plan Handbook]
2. Retrospective: Priorities update [Ch. 5]
3. Prospective: M&E development [Ch. 6]

12:30-13:30
Lunch

13:30-15:00
Retrospectively:
Updating the existing draft NTRL strategic plan including situational analysis and priorities
Prospectively:
M&E section for the draft NTRL strategic plan continued
Stakeholders divided into 3 groups:
1. Retrospective: Situational analysis update [Ch. 4]
2. Retrospective: Priorities (particularly focused on Objective 2 (Improve the diagnosis of TB among AFB-negative cases) as this was not developed fully in the last workshop) update [Ch. 5]
3. Prospective: M&E development [Ch. 6]

15:00-15:20
Tea/Coffee break

15:20-16:20
Retrospectively:
Update existing draft NTRL strategic plan-key strategic activities
Prospectively:
M&E section for the draft NTRL strategic plan continued

Stakeholders divided into 4 groups:
1. Retrospective: Activities
Objective 1 (Increase access to quality-assured AFB microscopy) [Ch. 5]
2. Retrospective: Activities
Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
3. Retrospective: Activities
Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
4. Prospective: M&E development [Ch. 6]
Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 2 Tuesday {DATE}

8:30-9:30
Introduction to the work plan framework
Consultant or national coordinator of workshop

9:30-10:30
Retrospectively:
Update existing draft NTRL strategic plan-key strategic activities
Prospectively:
Prepare work plan from scratch for the draft NTRL strategic plan

Stakeholders divided into 4 groups:
1. Retrospective: Activities- Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
2. Retrospective: Activities-Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
3. Retrospective: Activities-Objective 4 (Establish laboratory quality management systems for TB) [Ch. 5]
4. Prospective: Develop work plan with already defined activities (by objective and strategy) and simultaneously plug in information from Groups 1-3. [Ch. 7]

10:30-10:50
Tea/Coffee break

10:50-12:30
Retrospectively (moving backward) :
Update existing draft NTRL strategic plan: key strategic activities
Prospectively (moving forward):
Work plan for the draft NTRL strategic plan continued

Stakeholders divided into 4 groups:
1. Retrospective: Activities-Objective 2 (Improve the diagnosis of TB among AFB-negative cases) [Ch. 5]
2. Retrospective: Activities-Objective 3 (Increase access to rapid laboratory diagnosis for those at risk for M/XDRTB) [Ch. 5]
3. Retrospective: Activities-Objective 4 (Establish laboratory quality management systems for TB [Ch. 5]
4. Prospective: Develop work plan with already activities (by objective and strategy) and simultaneously plug in information from Groups 1-3. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Introduction to budget tool and costing
Consultant or national coordinator of workshop
[Chapter 7 of the TB Laboratory Plan Handbook]

15:00-15:20
Tea/Coffee break

15:20-16:20
Retrospectively:
Updating existing draft NTRL strategic plan: monitoring and evaluation framework and work plan
Prospectively:
Work plan for the draft NTRL strategic plan continued
Prospectively:
Begin budget development from scratch for the draft TB laboratory plan

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Goal and Objectives 1-4 [Ch. 6]
2. Prospective: Develop work plan with already identified activities (by objective and activity) and simultaneously plug in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 3 Wednesday {DATE}

8:30-9:30

Retrospectively:
Updating existing draft NTRL strategic plan: monitoring and evaluation framework and work plan
Prospectively:
Work plan for the draft NTRL strategic plan continued
Prospectively:
Budget for the draft NTRL strategic plan continued

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Objectives 1-4 [Ch. 6]
2. Prospective: Develop work plan with already known activities (by objective and strategy) and plug in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known objectives, strategies and activities and simultaneously plugging in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

DAY 3

10:30-10:50
Tea/Coffee break

10:50-12:30
Retrospectively :
Updating existing draft NTRL strategic plan: monitoring and evaluation framework
Prospectively :
Work plan for the draft NTRL strategic plan continued
Prospectively :
Budget for the draft NTRL strategic plan continued

Stakeholders divided into 3 groups:
1. Retrospective: Indicators and targets for Objectives 1-5 [Ch. 6]
2. Prospective: Develop work plan with already known objectives, strategies and activities and simultaneously plugging in information from Retrospective (group). [Ch. 7]
3: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group 1 and Group 2. [Ch. 7]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Where are we now? Putting it all together
Plenary with MOH (NTRL/NTP) and consultant

15:00-15:20
Tea/Coffee break

15:20-16:20
Prospectively:
Budget for the draft NTRL strategic plan continued
Prospectively:
Budget for the draft NTRL strategic plan continued

Putting it all together introduced

Stakeholders divided into 3 groups:
1. Prospective: Develop work plan with already activities and indicators. [Ch. 7]
2: Prospective: Cost work plan with already known activities and simultaneously plug in information from Group [Ch. 7]
3. Putting it all together: Identify gaps and assign individuals and groups to complete including content, formatting, etc.... [Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 4 Thursday {DATE}

8:30-9:30

Putting it all together: Identify areas to be completed and fill in gaps

Putting it all together
Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP strategic plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

10:30-10:50
Tea/Coffee break

10:50-12:30
Putting it all together:
Identify areas to be completed and fill in gaps continued

Putting it all together: Group and individual assignments
[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-15:00
Putting it all together: Identify areas to be completed and fill in gaps continued

Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization
9. Master document editing for consistency

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

15:00-15:20
Tea/Coffee break

15:20-16:20

Putting it all together: Identify areas to be completed and fill in gaps continued

Putting it all together: Group and individual assignments [Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

16:20-16:30
Closure for the Day

Day 5 Friday {DATE}

8:30-9:30

Putting it all together: Identify areas to be completed and fill in gaps continued

Putting it all together
Group and individual assignments for (for example):
1. Layout-table of contents, foreword, acknowledgements, list of abbreviations
2. Executive summary
3. Making narrative from tables e.g., Situational analysis
4. Conclusion
5. References
6. Annexes
7. Ensure contextual linkages with NTP strategic plan and Overall Health Systems Lab Strategic Framework
8. Budget harmonization
9. Master document editing for consistency

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

10:30-10:50
Tea/Coffee break

10:50-12:30
Putting it all together: Identify areas to be completed-Finalization of TB laboratory strategic plan

Putting it all together-Final Round
Group and individual assignments continued

[Ch. 8]

Electronic drafts to be turned in by end of session.
Time-permitting plenary for discussion

12:30-13:30
Lunch

13:30-14:30
Review of compiled NTRL draft laboratory plan

All stakeholders go through compiled document and discuss in plenary

14:30-14:45
Discuss next steps for endorsement

MOH/NTP

14:45-15:00
Feedback on the workshop and tools used

All Stakeholders

15:00-15:20
Tea/Coffee break

15:20-16:00

Wrapping up and closure

DAY 5

Annex 3:

Strategies and their Components

Strengthen Laboratory Infrastructure Including Biosafety*

- Building, renovation, upgrading and maintenance of TB laboratory physical structure
- Infection control measures including mechanical ventilation
- Electricity and water supply
- Waste management
- Development of plans related to laboratory infrastructure and infection control

Infrastructure

- Develop an implementation plan for TB laboratory physical structure upgrading and maintenance (design, layout or renovation of TB laboratory from Level 1 to Biosafety Lab level 3)
- Electricity, water sources, ventilation (sputum collection area, etc.)
- Waste management (disposal, etc.)
- Infection control measures

Maintenance contracts and standardization of equipment and infrastructure

- Development of contracts
- Standardization and specification of equipment maintenance contracts, standardization and specification of equipment)

* The WHO policy framework for Implementing New Tuberculosis Diagnostics from March 2010 includes biosafety in this objective

Improve Laboratory Human Resource Development

- Building human resource capacity through training
- Development of training materials, programs and plans, manuals and standard operating procedures
- Assessment of human resource capacity
- Development of human resource strategies and plans including retention.

Capacity

- Prepare a national inventory of the current TB laboratory workforce (numbers, qualification and levels of training, in-service training courses attended, years of service) and staff placement needs
- Quantify the numbers and types of laboratories providing TB diagnostic services and the distribution of lab workers by numbers, categories and workload at different levels of the laboratory network
- Analyze the causes of existing shortages of TB lab workers and assess the factors that contribute to the availability of workers to perform productively and effectively.

Development of HR and retention strategies

- Creating relevant posts, appropriate remuneration packages and career paths for all levels and types of laboratory staff required within the TB laboratory according to the level of activities
- Developing capacity retention strategies, including incentive schemes for staff working outside of countries and wishing to return
- Review career and governance structures that may impact on TB laboratory human resource performance and development, addressing reasons for lack of interest in the profession
- Consider incentives for laboratory staff working in remote and rural settings, including remuneration, training, and benefits such as housing, home travel, and children's education, to attract and retain staff to these areas for a period of time.

Development of HR and retention strategies

- Develop a Laboratory HR training plan with major focus on sustainability strategies link to the NTP strategic plan development.
- Develop a HR data base for the TB Lab network
- Design and conduct a series of in-service TB training modules to prepare each category/level of personnel to enter the next level in the organization
- Design an appropriate pre-service and in-service delivery of TB training including the monitoring of the training outcomes and impact.

Salary Structure

- Develop a recruitment plan that reflect the skills appropriate to the organizational structure and function
- Develop targeted recruitment strategies
- Develop an evaluation system of staff in terms of proficiency and readiness for promotion or in grade increases in salary.

Develop and Maintain Laboratory Quality Management Systems

- Development of quality assurance guidelines, plans and training programs for laboratory quality management
- Provision of EQA services to all levels at the network
- Subscription for EQA programs
- Implementation of QA guidelines
- Enrollment in certification/accreditation programs
- Assessment of quality management systems

Promote accurate, precise and reliable TB laboratory data for the sample country population.

- Develop and implement standard training program for Laboratory Quality Management (e.g. GLI Tools developed for TB Lab tier network, GLP and GCP Program)
- Develop training module and develop a pool of TOT to sustain the QMS program in the TB lab network
- Develop and manage national QA guidelines (including safety) for different levels of the TB network, and the scope of testing supporting program needs for each level of the tier laboratory
- Implement National Lab QA guidelines and enroll labs in Certification or accreditation program according to the package of activities
- Employ and train Lab QA Managers for the central and NRL TB laboratory involve in the accreditation program
- Develop a national roll out plan of accreditation and budgeted for fund mobilization and support
- Monitor and evaluate the TB Lab QA service at the national level
- Develop and manage an EQA program nationally (microscopy, culture, DST, molecular tests, etc.)

Create and establish quality circles within TB lab system and include QA indicators in job descriptions and performance evaluations of staff.

- Revise Job Description of staff to include quality component and performance management
- Develop and implement staff advancement program (refer to HR plan)

Advocate for legislation promulgation in collaboration with the NTP Program

- Provide regulatory framework for both public and private TB laboratory operation

Enhance Management of Laboratory Commodities and Supplies Including Equipment Validation and Maintenance

- Procurement of laboratory equipment, commodities and supplies
- Development of plans for procurement
- Development of plans for equipment maintenance including validation and calibration
- Contract equipment maintenance services
- Assessment of supply chains

Procurement system

- Develop and implement a TWG involving all partners and national TB Program, supply chain management to avoid duplication
- Standardization of lab equipment and commodities according to the SOP available in the country and at each level of TB laboratory
- Advocate and develop an effective and efficient national TB procurement plan for TB reagents and commodities for the TB network integrated with the NLIS (National laboratory information system)
- Develop mechanisms for procurement of standard equipment (considering using also the FIND mechanism for endorsed TB technologies by WHO on low costs and single source)
- Establish appropriate systems for the validation and maintenance of essential biosafety equipment to ensure a quality diagnosis and adequate protection of TB laboratory staff as *M. tuberculosis* is classified as a Risk Group 3 pathogen
- Implement an appropriate negative pressure systems, biological safety cabinets, safety centrifuges, and a whole range of related laboratory equipment and supplies

Maintenance and Validation of equipment

- Develop a regular schedule for validation, calibration and maintenance of equipment as an imperative
- Develop a training plan of local staff in preventive maintenance and specialized engineer to be located in the country for better support to the TB lab network and for sustainability.

Fortify Specimen Transport and Referral Mechanisms

- Establishment/improvement of specimen transport mechanisms including cold-chain bio-safe tools
- Development of plans and tools for reporting and reporting of laboratory results
- Assessment of specimen transport and referral mechanisms
  - Develop a sample transportation system to support the referral of sample according to the tier TB network available in the country
  - Establish appropriate specimen transport mechanisms for TB bacteriology, including cold-chain systems and delivery of specimens to laboratories with the shortest possible delay. The referral of samples for molecular testing using line probe assays do not require organisms to be viable, hence are less vulnerable to sample deterioration than samples referred for culture.
  - Develop, train staff on the packaging and transport of specimens suspected of containing infectious disease according to international standards, including those of the aviation industry when such specimens are sent by air.
  - Develop a plan and Tools for Reporting and recording system of results feedback to sites.

Improve Laboratory Information and Data Management Systems

- Development of reporting/recording systems (paper-based or electronic) through all tiers of the TB laboratory network including linkage to NTP
- Implementation of laboratory informational systems
- Development of monitoring and evaluation systems
  - Develop a clear and proper recording and reporting system through the all TB tier network (Paper based and electronic model according to the needs, funds available and level of laboratory (e.g. microscopy center versus culture and DST laboratory)
  - Develop clear responsibilities on designated staff who have to collect, keep data and doing analysis
  - Develop; implement a Lab information system (LIS systems) and how well they link between the tiers
  - Develop a training program in the use of the laboratory information tools and relevant software
  - Procure IT equipment and service contracts for the LIS and IT equipment for the all TB network
  - Develop and implement a manual on laboratory TB data procedure and Tools
  - Develop and implement a ME system for the all tier network in collaboration with the NTP
  - Develop a ME training program for the staff in collaboration with the NTP and stakeholders to avoid duplication and good integration of data used and dissemination
  - Develop, establish and implement an effective support supervisory system and ME procedures.

Establish a Laboratory Regulatory Framework	• Strengthen the legal and regulatory framework to support implementation of national laboratory policy • Development and dissemination of national standards for TB laboratory equipment & reagents, package of test and infrastructure design - Strengthen the legal and regulatory framework to support implementation of national laboratory policy - Strengthen the capacity of NRL to lead the accreditation program in the country in accordance to ISO 15189 (using WHO AFRO schemes and GLI) - Develop a program to evaluate, certify and register laboratory personnel - Develop, establish and disseminate national standards for TB laboratory equipment & reagents, package of test and infrastructure design - Develop Quality Assurance (QA) and Continuous Quality Improvement (CQI) programs for TB laboratory services validated by a number of laboratories in compliance with the required standards.

Annex 4a:

Selected M&E indicators for Goal and Objectives in the TB laboratory Plan

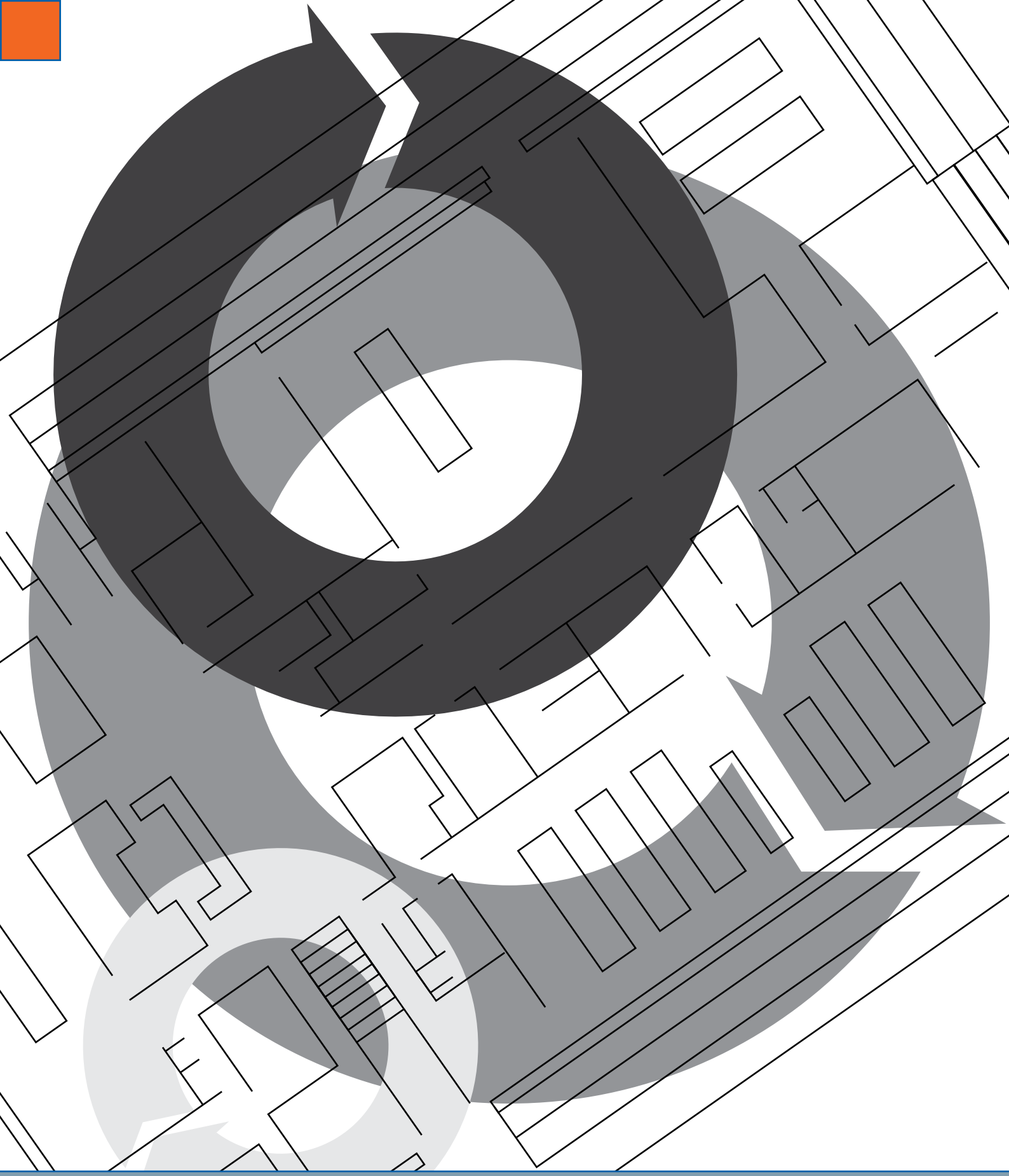
	OUTCOME AND IMPACT INDICATORS FOR GOALS
1	# of cases notified (all forms)
2	# of new laboratory-confirmed TB cases notified
3	Prevalence of laboratory-confirmed TB
4	Prevalence of laboratory-confirmed MDR-TB
	OUTPUT AND OUTCOME INDICATORS FOR OBJECTIVES
I	**INCREASE ACCESS TO QUALITY ASSURED AFB MICROSCOPY WITH EFFECTIVE EQA**
1	# of laboratories performing AFB microscopy
2	# (%)of AFB microscopy laboratories that are quality-assured
3	# (%) of AFB microscopy laboratories that are using LED microscopy
II	**IMPROVE THE DIAGNOSIS OF TB AMONG AFB NEGATIVE CASES ESPECIALLY AMONG PEOPLE LIVING WITH HIV**
1	# of laboratories performing culture
2	# of laboratories using new rapid diagnostic tools e.g. molecular tests
3	% of acid-fast bacilli (AFB) smear-negative, newly notified TB cases screened using culture and/or molecular-based tests
4	% of AFB smear-negative, previously treated TB cases screened using culture and/or molecular-based tests
III	**INCREASE ACCESS TO RAPID LABORATORY DIAGNOSIS AMONG TB PATIENTS CONSIDERED AT RISK FOR M/XDR-TB**
1	# of laboratories performing DST
2	# of laboratories performing DST using new rapid diagnostic tools
3	% of previously treated TB patients tested for drug-resistance
4	% of new TB patients tested for drug-resistance
5	% of tests for drug resistance performed on previously treated cases done using rapid tests
6	% of tests for drug resistance performed on new cases done using rapid tests
7	% of confirmed cases of MDR-TB with a DST result for fluoroquinolones and a second-line injectable drug
IV	**ESTABLISH LABORATORY QUALITY MANAGEMENT SYSTEMS**
1	% of national and regional reference laboratories implementing a quality management system according to international standards according to national strategies
2	% of TB laboratories with appropriate biosafety measures in place
3	AFB microscopy network accreditation (with GLI tool)

Annex 4b:

Selected M&E indicators for Activities by Strategy for the TB Laboratory Plan

	STRENGTHEN LABORATORY INFRASTRUCTURE INCLUDING Biosafety
1	Report on Infrastructure needs assessment available during a specified time period
2	# (%) of NEW laboratories constructed/established out of planned during a specified time period
3	# (%) of laboratories reconstructed/upgraded out of planned during a specified time period
4	# (%) of laboratories with improved infection control out of planned during a specified time period
	IMPROVE HUMAN RESOURCE DEVELOPMENT
5	Report on HRD needs assessment available during a specified time period
6	# (%) of posts filled according to HRD plan during a specified time period
7	# (%) of training materials/manuals/SOPs developed out of planned during a specified time period
8	# (%) of health facilities (laboratories) with at least one worker trained/re-trained out of all staff during a specified time period
9	Proportion of training courses organized as scheduled during a specified time period
10	# (%) of conferences attended out of planned
11	# (%) of meetings conducted out of planned
	DEVELOP AND MAINTAIN LABORATORY QUALITY MANAGEMENT SYSTEMS
12	# (%) of laboratories received documented support visits from upper level out of planned during a specified time period
13	# (%) of laboratories participated in blinded re-checking program out of those planned during a specified time period
14	# (%) of laboratories with adequate performance in EQA for smear microscopy during a specified time period
15	# (%) of laboratories received panel testing out of planned during a specified time period
16	# (%) of laboratories with QMS in place out of planned during a specified time period
17	#(%)Laboratories showing that the proportion of culture positive results in AFB-positive TB patients (not yet initiated on treatment), is >90% among the laboratories that undertake culture examination during the reporting period
18	# (%)Laboratories showing at least 95 percent proficiency for isoniazid and rifampicin drug susceptibility testing among the total number of laboratories that undertake drug susceptibility testing during the reporting period .
19	# (%) of laboratories accredited out of planned during a specified time period
	ENHANCE MANAGEMENT OF LABORATORY COMMODITIES AND SUPPLIES including EQUIPMENT VALIDATION AND MAINTENANCE
20	# (%) of laboratories equipped with new diagnostic Tool (GeneXpert/MGIT/LPAs)

21	# (%) of laboratories reporting no stock outs of reagents and supplies during a specified time period
22	# (%) of laboratories with no delays in equipment maintenance during a specified time period
	FORTIFY SPECIMEN TRANSPORT AND REFERRAL MECHANISMS
23	Report on specimen transport needs assessment available during a specified time period
24	Plan available for specimen transport and referral system during a specified time period
25	# (%) laboratories using courier services out of planned during a specified time period
26	# (%) laboratories using biosafety cold chain transportation equipment out of planned during a specified time period
27	# (%) of laboratories with refrigerators for storage TB specimens prior transportation during a specified time period
	IMPROVE LABORATORY INFORMATION AND DATA MANAGEMENT SYSTEMS
28	Laboratory Information System (LIS) Plan available during a specified time period
29	# (%) of laboratories with LIS out of planned during a specified time period
30	# (%) of laboratories linked to clinical database during a specified time period
31	# (%) of laboratories reporting results using electronic techniques during a specified time period
32	# (%) of reports done out of planned during a specified time period
33	# (%) of meetings conducted out of planned
	ESTABLISH A REGULATORY FRAMEWORK
34	New diagnostic methods approved for standard use by national authorities
35	Annual TB-specific lab work plan available during a specified time period
36	Annual TB-specific lab Strategic plan available during a specified time period
37	TB-specific lab strategic plan integrated within general lab strategic plan during a specified time period
	DEVELOP OPERATIONAL RESEARCH CAPACITY
39	Prevalence survey(s) achieved per national strategies
40	Drug resistance survey(s) achieved per national strategies
41	# (%) of TB-specific laboratory operational research projects completed per national strategies
42	# (%) of TB-specific laboratory operational research projects approved for funding per national strategies



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