



Terms of Reference (TOR) for National TB Reference Laboratory and Regional TB Reference Laboratories - Bangladesh

September 23, 2020



INFECTIOUS DISEASE DETECTION AND SURVEILLANCE (IDDS)



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List of Abbreviations

CDC	Chest Diseases Clinics
CDH	Chest Disease Hospital
DGHS	Directorate General of Health Services
DRTB	Drug resistant TB
DST	drug susceptibility testing
EQA	external quality assurance
FL-DST	First line drug susceptibility testing
FL/SL-LPA	First Line/Second Line Probe Assay
HED	Health Engineering Department
IDDS	Infectious Disease Detection and Surveillance
KPI	Key Performance Indicator
LD	Line Director
LED FM	light emitting diode fluorescence microscopy
LPA	Line Probe Assay
LF LAM	Lateral Flow urine Lipoarabinomannan
MDR-TB	multi-drug resistant TB
MOH	Ministry of Health
MOH&FW	Ministry of Health & Family Welfare
MTB	Mycobacterium Tuberculosis
MTB/RIF	Mycobacterium tuberculosis and resistance to rifampicin
NTM	non-tuberculous mycobacteria
NTP	National TB Control Program
NTRL	National TB Reference Laboratory
PT	proficiency testing
QA	quality assurance
QI	quality improvement
QMS	Quality Management System
RTRL	Regional TB Reference Laboratory
SM	smear microscopy
SRL	Supranational Reference Laboratory
TB	Tuberculosis

TOR	Terms of reference
TB -LAMP	Loop-Mediated Isothermal Amplification for the Detection of M. Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
WRD	WHO-approved rapid diagnostics
ZN	Ziehl–Neelsen

I.0. Introduction

Bangladesh has one of the highest Tuberculosis (TB) burdens in the world, with 357,000 estimated annual incident cases in 2018. Only 268,596 TB patients, approximately 75 percent, were diagnosed and notified in 2018. The diagnosis gap is worse for multi-drug resistant TB (MDR-TB) as only 21 percent of the estimated 5,900 MDR –TB patients were diagnosed. The TB laboratory network in the country plays an important role in the detection of TB and MDR-TB cases and for capacity building for TB diagnostics.

The National TB reference laboratory (NTRL) should be at the apex of the TB laboratory network in order to serve as a reference laboratory for the National TB Control Program (NTP). The reference laboratory plays an important role in the organization, planning, maintenance and oversight of the TB diagnostic network, guideline development, ensuring high quality and standardization of TB diagnostic equipment (GeneXpert, smear microscopy (SM), line probe assay (LPA), culture, and phenotypic drug susceptibility testing (DST) methods), TB labs staffs' capacity building, trainings, surveillance to detect all forms of TB, and to participate in epidemiological and operational researches.

The Regional TB Reference Laboratories (RTRLs) should be linked to the NTRL to get fundamental and comprehensive technical and supervisory support. RTRLs should provide technical and supervisory support to the lower tiered laboratories such as Peripheral Microscopy Centers, GeneXpert, EQA Center etc.

Currently, the NTRL and RTRLs do not have a terms of reference (TOR) that define their roles. Therefore, this TOR document will help to clearly define the NTRL and RTRL roles and responsibilities for the Ministry of Health and Family Welfare (MOH & FW) and stakeholders involved in the TB diagnostic network in Bangladesh. It further formalizes the reference laboratory structure within the MOH&FW system to ensure their oversight responsibilities that were outlined in the National TB Laboratory Strategic Plan 2016-2020. It is also envisioned that the approved TOR will help develop a roadmap to strengthen and sustain the institutional capacity of the NTRL and RTRLs to achieve the vision and mission of the NTP.

I.1. Organization of Tuberculosis (TB) Laboratory Network

The TB laboratory network is organized according to the four levels of the general health services to perform TB laboratory services under the NTP: national, regional, intermediate (district) and peripheral¹.

- There is one NTRL located in Dhaka where culture and DST (phenotypic), first line/second line-line probe assay (FL/SL-LPA), Xpert Mycobacterium tuberculosis and resistance to rifampicin (MTB/RIF) and microscopy are performed. There are approximately 272 GeneXpert Centers and one FL/SL-LPA test service, and it is estimated that NTRL spends 90% of its time performing routine tests and 10% conducting training and supervision. The RTRLs are located in Chattogram, Rajshahi, Khulna, and Sylhet and are equipped to perform culture and first line drug susceptibility testing (FL-DST), GeneXpert test and sputum smear microscopy test. However, not all RTRLs are currently offering culture and FL-DST because of various limitations.
- At the district level, Chest Disease Clinics (CDC), medical colleges and hospitals and district sadar (headquarters) hospitals have functional TB laboratories where sputum smears are

¹ National TB Laboratory Strategic Plan 2016-2020, NTP

examined. There are more than 1,200 microscopy centers under the TB Laboratory network of the NTP. Forty (40) external quality assurance (EQA) laboratories supervise peripheral level microscopy centers across the country.

- Peripheral laboratories are located at upazila (sub-district) and in some of the unions.
- There are no private laboratories in the microscopy network, which is currently operated and managed by the NTP and its partners. The network is gradually expanding with the introduction of new tools and services.

I.2. Rationale for developing the TOR for NTRL and RTRL

The absence of a TOR for the NTRL and RTRLs with clearly defined roles and responsibilities presents major challenges to developing a functional TB diagnostic network. There are no formal linkages, supervision, and reporting structures between the various levels of the TB diagnostic network and each mostly operates independently. The NTRL and RTRLs are currently engaged in providing routine TB test services only. They do not have the capacity and resources to perform reference laboratory functions such as supervision, quality oversight, monitoring of the TB diagnostic network and development of diagnostic policies and guidelines for various reasons including:

- Lack of clearly defined supervisory role of the NTRL and RTRLs over their respective lower tiered laboratories.
- NTRL and RTRLs legal policy and regulatory framework are not built within the organogram of the MOH&FW of the Government of Bangladesh.
- They do not have the institutional and regulatory mandate, capacity, and resources to perform their desired roles and responsibilities as outlined below.

The objective for developing the TORs for the NTRL and RTRLs is to formalize the structure within MOH&FW system and ensure their oversight responsibilities that has been outlined in the National TB Laboratory Strategic Plan 2016-2020 are followed. It is also envisioned that the approved TORs will help develop a roadmap to strengthen and sustain the institutional capacity of the NTRL and RTRLs to achieve the vision and mission of NTP.

I.3. NTRL: Roles and Responsibilities

The diagnosis and management of TB requires laboratory services, buttressed by an enabling policy framework. Lower level laboratories are guided by the national reference laboratory, which tend to have better infrastructure and human resources. Laboratory services should provide accurate diagnosis leading to prompt and appropriate treatment, and they should support treatment monitoring. The accurate diagnosis of multidrug-resistant (MDR) or extensively drug-resistant (XDR) TB allows for targeted and appropriate treatment, reduces morbidity, reduces mortality, and is cost effective. At the population level, it also facilitates public health surveillance, contact tracing and case hospitalization, all of which can reduce the risk of the disease spreading locally and across borders.

The National TB Laboratory Strategic Plan (2016-2020) described the NTRL roles and responsibilities as follows:

- Acts as the supervising reference laboratory for the regional laboratories inside the country
- Performs microscopy, culture for mycobacterium, DST, and species identification
- Performs routine services for the in and out-patient departments of the hospital, and if needed, for laboratories that lack testing capacity and/or require confirmatory or higher-level testing
- Trains staff and supervises activities of the regional laboratories

- Collaborates with a World Health Organization (WHO) accredited supranational reference laboratory outside the country
- Implements quality control for regional and if necessary, CDC/hospital, upazilla and other special services laboratories
- Provides guidance to the NTP in matters relating to the TB Laboratory Network
- Conducts operational research, studies, surveys, etc.
- Records and reports as per national policy

The NTRL roles can be divided into two complementary components: diagnostic and public health.

1. Diagnostic role: The NTRL is tasked with testing clinical samples to confirm or exclude TB and DRTB. This role is important and for that, they should be staffed, equipped, and resourced accordingly to fulfil these duties. This diagnostic role should be focused on culture, genotypic and phenotypic DST for specific cases and not routine diagnostic activities using GeneXpert.

The key diagnostic roles of the NTRL are the following:

- Development and implementation of diagnostic policies
- Maintaining diagnostic standards, training, and skills transfers
- Servicing and maintenance of equipment
- Provision of quality management systems (QMS)
- Information management in national reference laboratories

2. Public health role: The NTRL will complement the MOH&FW in TB surveillance and response. The key public health roles of the NTRL are the following:

- Surveillance and epidemic response
- Training, qualifications and continuing professional education
- Operational research for health
- Collaborating with a WHO-accredited supranational reference laboratory outside the country

The Bangladesh NTRL will ensure adherence to the agreed TB diagnostic standards by ascertaining that diagnostic tools (equipment) are appropriate, that the reagents which are introduced into the country are suitable for the intended diagnostic purposes, and that personnel are trained adequately to perform in the required areas. The NTRL will also play a role for an effective referral system of specimens within the TB diagnostic network. All these above activities will help the NTRL to fully ensure its leading role and improve service delivery on:

- Solid and liquid culture
- Phenotypic DST of mycobacterium isolates from cultures
- Molecular (Genotypic) based drug susceptibility and identification testing for (both first and second line)
- TB drug resistance surveillance and TB prevalence surveys
- TB research program
- Training and mentorship of peripheral sites
- Provision of Quality Assurance services to all TB laboratories performing microscopy and Xpert
- New Equipment/kits and reagents validations

For the NTRL to lead as outlined above, it is recommended that they significantly reduce their routine testing and serve more as the leader of the diagnostic network.

2.0 The recommended functions and responsibilities of a TB laboratory network following WHO / GLI (Global Laboratory Initiative) guidelines:

A network of TB laboratories within the public health system is organized in a tiered or pyramid structure, as illustrated below in Figure 1 from the 2015 WHO *Implementing tuberculosis diagnostics: A policy framework*. A large number of peripheral laboratories, Level 1, are accessible to most individuals being evaluated for TB, a moderate number of intermediate laboratories, Level 2, are usually located in mid-sized population centres and health facilities, and lastly the Central, Level 3, laboratory are at the provincial, state or national level. In large countries there may be several Level 3 laboratories depending on the situation², however, there is only one Level 3 laboratory in Bangladesh.

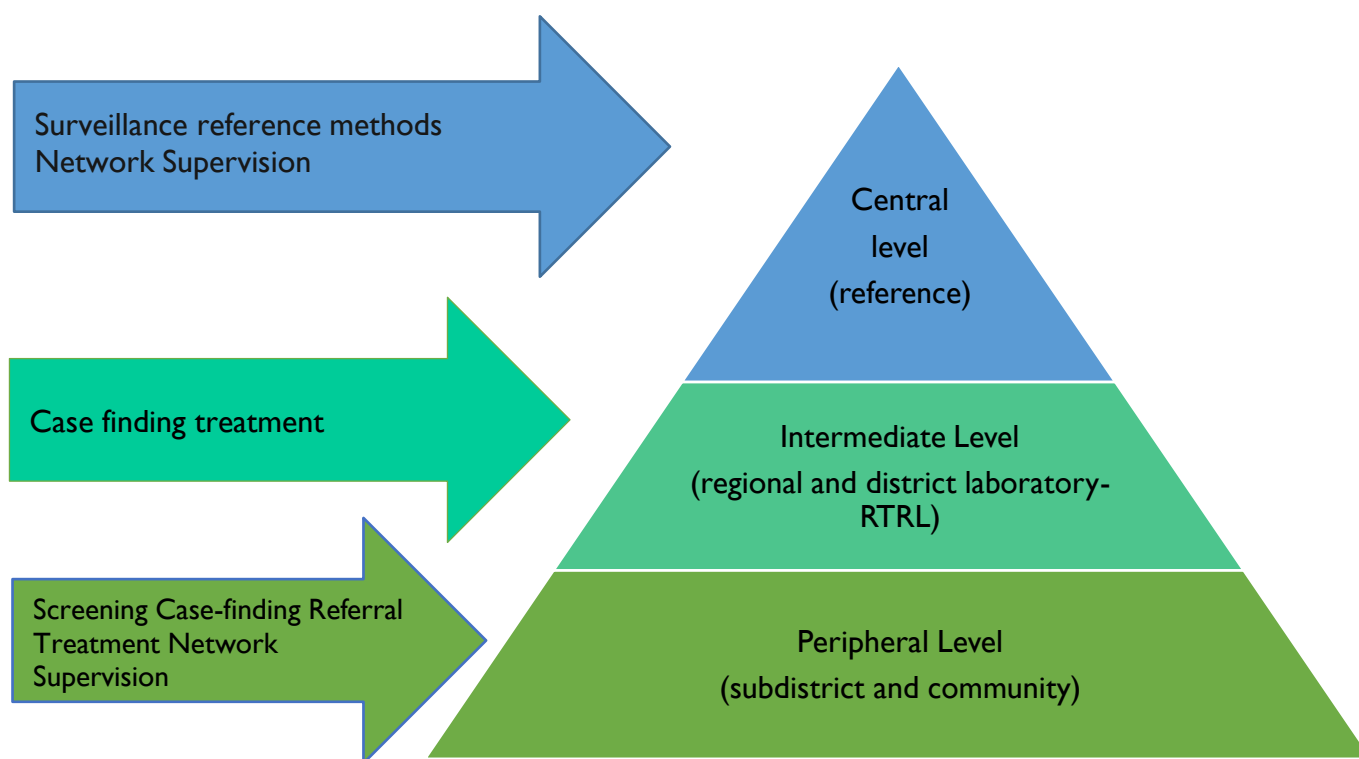


Figure 1: The three tiers of the network of TB laboratories

2.1. Level one (L1) laboratory - Peripheral (Or Community) Laboratory

The function and responsibility of the L1 laboratory are outlined below:

- Receives specimens
- Prepares, stains, and examines smears with Ziehl–Neelsen (ZN) or light emitting diode (LED) fluorescence microscopy

² GLI Practical Guide to TB Laboratory Strengthening, March 2017

- May use rapid molecular technologies like Xpert MTB/RIF, according to national diagnostic algorithms
- May use loop-mediated isothermal amplification (TB-LAMP) and lateral flow urine lipoarabinomannan (LF-LAM) according to national diagnostic algorithms
- Records and reports results, according to national guidelines
- Maintains laboratory registers
- Cleans and maintains equipment
- Manages reagents and laboratory supplies
- Uses appropriate quality control and quality assurance (QA) procedures
- Participates in EQA programs (e.g., blinded rechecking, panel testing, supervisory visits)
- Has appropriate biosafety measures in place

2.2. Level two (L2) - Regional Laboratory:

The function and responsibility of the L2 laboratory are outlined below:

- Performs all the functions of a Level 1 laboratory
- May use FL/SL-LPA with smear-positive sputum specimens, according to national diagnostic algorithms
- Performs digestion and decontamination of specimens, inoculates cultures and identifies MTB
- Performs DST or refers positive cultures and samples to appropriate reference laboratory for DST
- Trains microscopists and supervises peripheral-level staff in microscopy and the use of WHO recommended rapid diagnostic tests (e.g., Xpert MTB/RIF, TB LAMP) and LF LAM
- Prepares and distributes reagents for microscopy to peripheral laboratories
- Engages in proficiency testing (PT) and quality improvement (QI) activities for peripheral laboratories

Table 1 below shows the current situation of the RTRLs and their expected role compared to the GLI standards for an intermediate/regional level laboratory²

Table 1: RTRLs Current Functions and Services and Expected Role

GLI Standards for an intermediate Laboratory	RTRL Sylhet	RTRL Khulna	RTRL Chattogram	RTRL Rajshahi	Expected roles of RTRLs
Ensures the effective management of laboratories at the intermediate-level network, the quality of the testing, and the efficient use of the network's services and TB diagnostics	No	No	No	No	Same as GLI
Performs all the functions of a Level 1 and Level 2 laboratory	Yes	No	No	No	Same as GLI
Collaborates closely with the central level of the national TB programme	Yes	Yes	Yes	Yes	Same as GLI

Performs DST of MTB isolates to determine resistance to FL and SL anti-TB agents	Yes	No	No	No	Same as GLI
Performs molecular testing (FL and SL) for rifampicin resistance on positive cultures (alone or in combination with testing for resistance to isoniazid)	No FL LPA test facility	No FL LPA test facility	No FL LPA test facility	No FL LPA test facility	Same as GLI
Identifies NTM	No	No	No	No	Same as GLI
Performs digestion and decontamination of specimens, inoculates cultures and identifies MTB	Yes	Yes	Yes	No	Perform primary cultures and identify MTB
Refers positive cultures to appropriate reference laboratory for DST	No	No	No	No	Perform DST or refer to an
Trains microscopists and supervises peripheral-level staff in microscopy and the use of WHO recommended rapid diagnostic tests (WRD) (e.g., Xpert MTB/RIF, TB LAMP) and LF LAM	Yes	Yes	Yes	Yes	Train and supervise peripheral laboratories in WRDs
Prepares and distributes reagents for microscopy to peripheral laboratories	No	No	No	No	Prepare and distribute of reagents for microscopy to
Engages in PT and QI activities for peripheral laboratories	No	No	No	No	Engage in PT and QI activities for peripheral
Ensures the QA of all procedures performed at intermediate-level laboratories including microscopy, culture and DST	No	No	No	No	Same as GLI
Ensures laboratory equipment are checked, calibrated, and repaired periodically	No	No	No	No	Same as GLI
Ensures the updates and dissemination of laboratory manuals, including guidelines on diagnostic methods, equipment maintenance,	No	No	No	No	Same as GLI

training and supervision, and QA					
Ensures the distribution of reagents and consumables	No	No	No	No	Same as GLI
Conducts drug resistance surveillance	Yes	No	No	No	Same as GLI
Undertakes operational and applied research relating to the laboratory network and coordinates this with the requirements and needs of the NTP	Yes	No	No	No	Same as GLI
Ensures adequate safety measures are in place at intermediate and peripheral-level laboratories	Yes	Yes	Yes	Yes	Same as GLI

2.3. Level three (L3) - Central (or National) Laboratory

The function and responsibility of a L3 laboratory is to perform identification of MTB, first and second line DST and further responsibilities outlined below:

- Performs all the functions of Level 1 and Level 2 laboratories
- Collaborates closely with the central level of the national TB programme
- Provides strategic oversight to ensure the effective management of laboratories in the network, the quality of the testing, and the efficient use of the network's services and TB diagnostics
- Performs DST of MTB isolates to determine resistance to FL and SL anti-TB agents
- Performs molecular testing for rifampicin resistance on positive cultures (alone or in combination with testing for resistance to isoniazid)
- May use SL-LPA with positive cultures from rifampicin-resistant TB or MDR-TB patients, according to national diagnostic algorithms
- Identifies non-tuberculous mycobacteria (NTM)
- Arranges for a specialist to periodically check, calibrate, and repair laboratory equipment
- Updates and disseminates laboratory manuals, including guidelines on diagnostic methods, equipment maintenance, training and supervision, and QA
- May distribute reagents and consumables when requested by intermediate-level or peripheral level TB laboratories
- Supervises intermediate-level laboratories' implementation and use of bacteriological methods, as well as the laboratories' performance monitoring of peripheral laboratories
- Undertakes QA of all procedures performed at regional laboratories including microscopy, culture, and DST
- Ensures an appropriate human resource development programme is in place, including training, re-training, and competency assessment
- Conducts drug resistance surveillance
- Undertakes operational and applied research relating to the laboratory network and coordinates this with the requirements and needs of the NTP

- Establishes a formal collaboration agreement with a TB Supranational Reference Laboratory (SRL) for panel testing, for support in implementing and validating new diagnostics, assistance with laboratory development and expansion strategies, and referral for challenging cases who need specialized testing

Table 2 below shows the current functions and services of the NTRL and its expected roles when compared to the GLI standards for a central level laboratory

Table 2: NTRL Current Functions and Services and Expected Roles

GLI Standards for NTRL	NTRL Bangladesh
Performs all the functions of Level 1 and Level 2 laboratories	Yes
Collaborates closely with the central level of the national TB programme	Yes
Provides strategic oversight to ensure the effective management of laboratories in the network, the quality of the testing, and the efficient use of the network's services and TB diagnostics	No
Performs DST of MTB isolates to determine resistance to FL and SL anti- TB agents	Yes
Performs molecular testing for rifampicin resistance on positive cultures (alone or in combination with testing for resistance to isoniazid)	Yes
May use SL-LPA with positive cultures from rifampicin-resistant TB or MDR-TB patients, according to national diagnostic algorithms	Yes
Identifies NTM	Yes
Arranges for a specialist to periodically check, calibrate, and repair laboratory equipment	Partially
Updates and disseminates laboratory manuals, including guidelines on diagnostic methods, equipment maintenance, training and supervision, and QA	Partially
May distribute reagents and consumables when requested by intermediate-level or peripheral level TB laboratories	No

Supervises intermediate-level laboratories' implementation and use of bacteriological methods, as well as the laboratories' performance monitoring of peripheral laboratories	No
Undertakes QA of all procedures performed at intermediate-level laboratories including microscopy, culture, and DST	No
Ensures an appropriate human resource development programme is in place, including training, re-training, and competency assessment	No
Conducts drug resistance surveillance	Yes
Undertakes operational and applied research relating to the laboratory network and coordinates this with the requirements and needs of the NTP	Yes
Establishes a formal collaboration agreement with a TB SRL for panel testing, for support in implementing and validating new diagnostics, assistance with laboratory development and expansion strategies, and referral for challenging cases who need specialized testing	Partially
N/A	No
Has appropriate biosafety measures in place	No

3.0. TOR: Key functions

The NTRL should have the primary responsibility of the following:

- Overseeing the TB diagnostic network
- Conducting surveillance
- Performing reference methods for TB diagnostic testing
- Providing training
- Developing standard operation procedures, manuals, guidelines, and policies
- Evaluating new technologies
- Proposing revisions to the diagnostic algorithm
- Ensuring quality assurance
- Conducting routine monitoring and periodic supervision at intermediate and lower level.
- Ensuring that systems are in place for equipment maintenance
- Implement laboratory quality management systems (LQMS)
- Undertaking operational research
- Forecasting reagents need and distribution
- Providing strategic oversight to the TB diagnostic network in close collaboration with the NTP

The RTRL should have the primary responsibility in case finding using the diagnostic tools FL/SL-LPA, MTB Culture and DST (solid and liquid), Xpert MTB/RIF test, microscopy (only for reference purposes such as EQA by RTRL) and other tests as decided by the NTP and the NTRL. The RTRL should engage in PT and QI activities for peripheral laboratories and EQA centers and should also provide training on WRD suitable for the specific level of laboratory. As the NTP moves toward rapid expansion of GeneXpert network, the reliance on microscopy is declining gradually. Moreover, the NTRL and RTRLs should concentrate more on strengthening the coordination between the TB laboratory services and the TB programme and treatment facilities to ensure that all diagnosed cases are treated timely and properly.

Considering the magnitude of the activities that should be provided by the NTRL and RTRLs, the TOR is subclassified into categories: technical, recording and reporting, biosafety and biosecurity, leadership, supervision and monitoring, training and capacity building, QMS assurance, operational research and surveillance, human resources, and linkage with TB SRL and NTRL, respectively. The TOR for both NTRL and RTRLs are described in detail below:

3.1. RECOMMENDED NTRL TOR:

Technical:

- Performs GeneXpert, culture and DST of MMTB isolates to determine resistance to FL and SL anti-TB agents (solid and liquid)
- Performs molecular testing for rifampicin resistance on positive cultures (alone or in combination with testing for resistance to isoniazid)
- Uses SL-LPA with positive cultures from rifampicin-resistant TB or MDR-TB patients, according to national diagnostic algorithms
- Identifies NTM
- Arranges for a specialist to periodically check, calibrate, and repair laboratory equipment
- Updates and disseminates laboratory manuals, including guidelines on diagnostic methods, equipment maintenance, training, and supervision.
- Collects key performance indicators (KPIs) of WRD, analyze and provide feedback to NTP and RTRLs
- Oversees the national QMS

Recording and Reporting

- Ensure recording and reporting formats are up to date
- Ensure the uniformed recording and reporting throughout the network as per national policy

Biosafety and Biosecurity:

- Leads and implements the biosafety and biosecurity activities at all levels of the TB diagnostic network
- Manages the system to identify, investigate and report any spillages or accidents as well as takes steps to prevent re-occurrence

Leadership:

- Collaborates closely with the central level of the NTP and lead communication on all aspects of the TB diagnostic network
- Provides strategic oversight to ensure the effective management of laboratories in the network, the quality of the testing, and the efficient use of the network's services and TB diagnostics
- Provides input to the NSP and costing for the TB diagnostic network

Supervision and monitoring:

- Supervises regional and intermediate level laboratories' implementation and use of bacteriological methods, as well as the laboratories' performance monitoring of peripheral laboratories
- Establishes and manages a system to oversee, monitor and supervise all labs in the network either directly or through RTRLs under the oversight of the NTRL

- Proposed supervision plan is outlined below in Figure 2

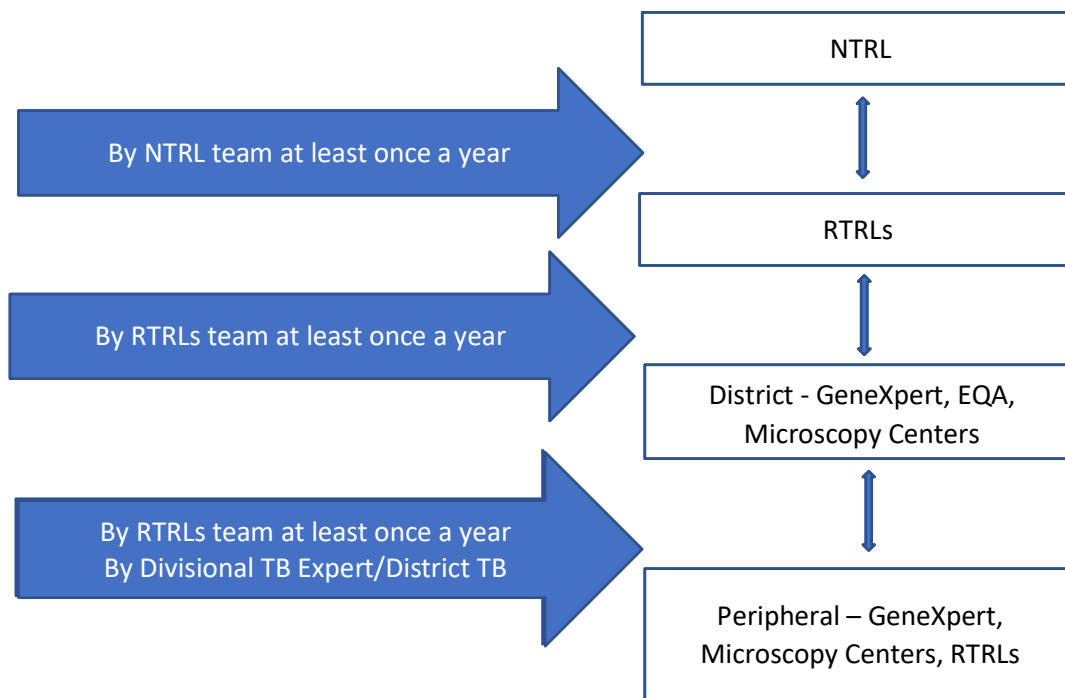


Figure 2: Proposed Supervision Plan for NTRL

Training and capacity building:

- Trains the national laboratory staff (private and public) on TB Diagnostics tools
- Develops a trained pool of TOTs cadres for supporting the TB diagnostic network
- Develops the capacity of RTRLs staff on equipment maintenance

QMS Assurance:

- Leads the national and sub national QMS program
- Manages QA of all procedures performed at intermediate-level laboratories including microscopy, culture, and DST

- Conducts EQA for GeneXpert, DST (genotypic and phenotypic) test and work as second controller for TB Microscopy laboratories

Operational Research & Surveillance:

- Conducts drug resistance surveillance
- Undertakes operational and applied research relating to the laboratory network, new diagnostic tests, and coordinates this with the requirements and needs of the NTP

Human Resources (HR):

- Ensures an appropriate HR development programme is in place, including training, re-training, competency assessment, and continuing medical education (CME)
- Provides information and recommendations to the NTP to ensure sustainable financing for sufficient human resources for the NTRL and the TB diagnostic network overall

Linkage with TB SRL:

- Collaborates with a WHO-accredited TB SRL outside the country for panel testing, for support in implementing and validating new diagnostics, assistance with laboratory development and expansion strategies, and referral for challenging cases who need specialized testing

3.2. RECOMMENDED RTRL TOR:

Technical:

- Performs GeneXpert, Culture and DST for MTB isolates to determine resistance to antiTB agents (solid and liquid)
- Performs FL/SL-LPA according to national diagnostic algorithms
- Performs digestion and decontamination of specimens, inoculates cultures
- Inoculates cultures to isolate and identify MTB
- Refers positive cultures to appropriate reference laboratory for extended DST as required and unable to perform
- Ensures laboratory commodity management systems are in place and functional for the respective tiers under the jurisdiction of the RTRL
- Checks compliance with the diagnostic algorithm and identifying issues with the diagnostic network in the region including GX performance

Recording and Reporting:

- Ensures that updated recording and reporting formats are being used in the region

Biosafety and Biosecurity:

- Implements the biosafety and biosecurity activities at peripheral level in coordination with NTRL

Supervision and Monitoring:

- Supervises and monitors the performance of peripheral laboratories and compliance
- Provides assistance to investigate and correct problems.

Training and Capacity Building

- Provides training at the regional level

Quality Assurance:

- Engages in PT and QI activities for peripheral laboratories
- Conducts EQA for TB Microscopy Laboratory as first controller
- Conducts regional supervision and mentorship for QMS
- Collects KPIs of WRD, analyze and provide feedback to NTP and Districts/upzilla in the region

Human Resources:

- Trains microscopists GX operator and supervises peripheral-level staff in microscopy and the use of WHO recommended rapid diagnostic tests

Linkage with NTRL:

- Collaborates with NTRL for panel testing, provided support in implementing and validating new diagnostics, assistance with laboratory development and implementing strategies.

4.0. Next steps to operationalize the TORs:

The next steps will be determined after further operational discussions with the NTP. It is expected that these will include:

- Determination of the order in which each specific RTRL will be upgraded to a functional RTRL as described in this TOR
- Development of a costed National TB Laboratory Strategic and operational plan to enable NTRL and RTRLs to fulfill the requirements and expectations of this TOR
- Development of a timeline to implementation of the operational plan at each RTRL and NTRL
- Agreement of the roles and responsibilities of the NTP, NTRL, RTRLs, and partners in implementation of the operational plan for each RTRL

Appendix

Appendix I: Draft costing of the TOR supervision

Activity	Frequency	Item	Unit Cost (USD)	Unit	Quantity	Total (USD)	Remarks
To supervise regional/intermediate level laboratories by NTRL	4-6 visit/year	Per diem + Logistics	400	/visit	6	2,400	Joint Supervision for a 4 person-3 days visit.
To supervise and monitor the performance and compliance of GeneXpert site by RTRL	10 visit/year*4 RTRL	Per diem	100	/visit	40	4,000	Conduct supervisory visit for 1 day for 2 persons
Participate in a proficiency testing scheme organized by NTRL	1 time/year/each RTRL	Provide logistics support + courier fee	200	/site	4	800	Per yearly All RTRL will be participated
Mentorship supervisory visit	10 visit/year	Per diem + Logistics	150	/visit	10	1,500	
	5 microscopy & 5 EQA centers visit in each quarter	Per diem, travel & lodging	150	/visit	10	1,500	QA program checks key pre-analytical, analytical, and postanalytical processes occurring at the testing site
Grand Total						10,200	