National Tuberculosis (TB) Laboratory Strategic Plan 2021-2025

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INFECTIOUS DISEASE DETECTION AND SURVEILLANCE (IDDS)

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List of Abbreviations

BSMMU	Bangabandhu Sheikh Mujib Medical University
CXR	Chest X-ray
DGHS	Directorate General of Health Services
DHIS2	District Health Information Software, version 2
DR-TB	Drug-resistant Tuberculosis
DRS	Drug Resistance Survey
DST	Drug Susceptibility Testing
EPTB	Extra-pulmonary Tuberculosis
EQA	External Quality Assurance
FLD	First-line Drug
GX	GeneXpert
HQ	Headquarters
KPI	Key Performance Indicator
LPA	Line Probe Assay
MDR-TB	Multidrug-resistant Tuberculosis
MOHFW	Ministry of Health and Family Welfare
NGO	Non-governmental Organization
NTP	National Tuberculosis Control Program
NTRL	National Tuberculosis Reference Laboratory
PPM	Public-Private Mix
PR-2	Principal Recipient
QMS	Quality Management Systems
RMD	Rapid Molecular Diagnostics
RR-TB	Rifampicin-resistant Tuberculosis
RTRL	Regional Tuberculosis Reference Laboratory
SLD	Second-line Drug
SOP	Standard Operating Procedure
SRL	Supranational Laboratory
TAT	Turnaround Time
TB	Tuberculosis
ToR	Terms of Reference
UH&FPO	Upazilla Health & Family Planning Officer
WHO	World Health Organization
XDR-TB	Extensively Drug-resistant Tuberculosis

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1 Introduction

Laboratories are essential for diagnosis and treatment monitoring. The World Health Organization's (WHO) End Tuberculosis (TB) Strategy calls for the early diagnosis of TB, including universal drug susceptibility testing (DST). A prerequisite for any national TB program to reach this goal is a quality-assured laboratory network equipped with rapid diagnostics. Everyone identified with TB should have access to the rapid diagnostics tools and services they need for prompt diagnosis, treatment, and care. This is a matter of social justice, fundamental to the aim of achieving Universal Health Coverage and Sustainable Development Goals.

In the context of low- and middle-income countries, TB laboratories often face challenges to provide the services needed to maximize TB control. The country needs a National TB Laboratory Strategic Plan to guide concrete, time-delineated, and target-driven laboratory system strengthening efforts (STOP TB, 2014). TB laboratory plans may also be used as an advocacy tool for resource allocation and mobilization. This National TB Laboratory Strategic Plan (2021-2025) outlines the vision, mission, objectives, strategies, and activities to accelerate progress toward achieving the overall goal of the National TB Control Program (NTP) in Bangladesh (National Tuberculosis Control Program, 2020a). This plan also provides references for further consultation for both policies and technical recommendations.

2 TB-specific Contextual Analysis

Although Bangladesh has achieved notable progress in TB diagnosis and treatment over the last decade, TB remains a major public health concern in the country. With an estimated population of 164 million, Bangladesh is listed among the 30 high TB burden and 27 high MDR-TB countries. In 2019, a total of 292,942 TB patients were registered with the NTP. In 2019, the estimated TB incidence was 221 per 100,000 population and TB mortality was 24 per 100,000 population (WHO, 2020). In the most recent Bangladesh TB Prevalence Survey 2015-2016, the prevalence of bacteriologically confirmed TB was reported at 287 (95% CI: 244-330) per 100,000 adult population and smear positive TB was reported at 113 (95% CI: 87-139) per 100,000 adult population (National Tuberculosis Control Program, 2018d). Bacteriologically confirmed TB was found to be higher in men compared with women and in urban relative to rural settings, and it increased with age, with a particularly notable higher prevalence in the elderly population over 65 years of age. The higher prevalence in the older population indicates that the TB epidemic is aging—possibly attributable to latent TB infection relative to new infections.

The NTP has carried out its second nationwide drug resistance survey (DRS) in TB patients in collaboration with WHO and Supranational TB Reference Laboratory, Antwerp, Belgium, in 2018-2019. The results of the DRS will soon be published by the NTP and WHO (National TB Control Program, 2020a)

The TB laboratory network is an integral part of the NTP and operates under the directorate of the Mycobacterial Disease Control of the Directorate General of Health Services of the Ministry of Health and Family Welfare (MOHFW).

3 National TB Diagnostics and Treatment Guidelines

3.1 Diagnostics for TB and Drug-resistant TB

Following the advancement in new diagnostic technologies such as rapid molecular testing (nucleic acid amplification for rapid and simultaneous detection of TB and rifampicin-resistant TB [RR-TB]) and WHO recommendations for TB diagnosis, the NTP revised the national TB diagnostic algorithm and started implementing the diagnostic algorithm as shown in Figure 1 (National Tuberculosis Control Program, 2020b).

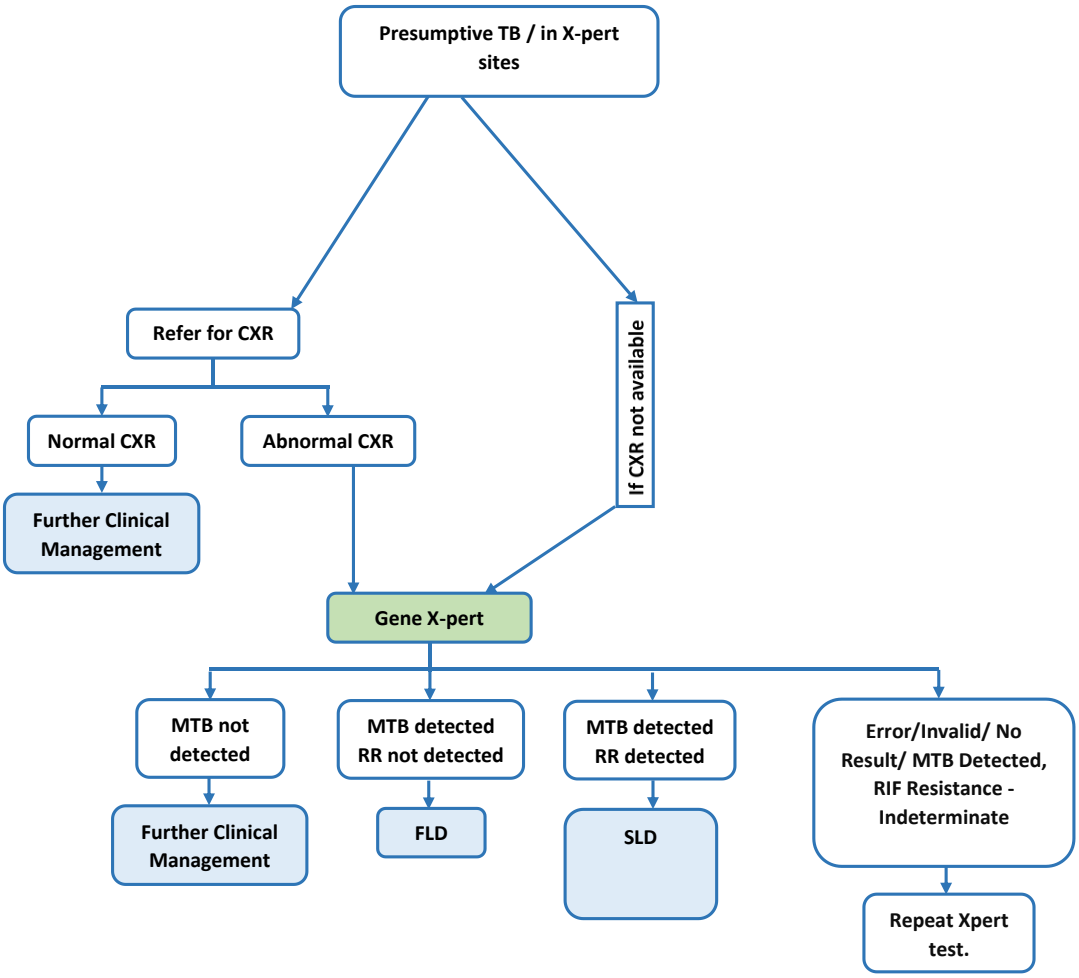

Figure 1: TB Diagnostic Algorithm

CXR=Chest X-ray, FLD=First-line Drug, SLD=Second-line Drug

In health facilities equipped with X-ray and rapid molecular diagnostics (RMD) machines (GeneXpert [GX]), CXR is performed first for TB screening followed by GeneXpert (GX) for bacteriological confirmation of TB. In sites without X-ray, all presumptive TB cases (including drug-resistant TB [DR-TB]) referred from other sites are being tested by GX. The NTP plans to implement the new diagnostic algorithm countrywide during 2021-2025 through expansion of RMD. Although NTP finds that the revised

algorithm makes the best use of available diagnostic resources, addition of other similar RMD (e.g., Truenat) as an initial diagnostic tool is desired to ensure accelerate rapid detection of TB and DR-TB aligned with WHO recommendations. Initially, the NTP will conduct a pilot of Truenat use in 38 sites and will decide further expansion based on the findings of pilot.

3.2 Diagnostics for Drug Susceptibility Testing

WHO defines universal access to DST for at least rifampicin among all patients with bacteriologically confirmed TB, and further DST for at least fluoroquinolones among all TB patients with RR-TB. The effective management of TB and RR/MDR-TB relies on rapid diagnosis and effective treatment of resistant bacteria. Culture-based phenotypic DST methods are considered the gold standard for drug resistance detection. Susceptibility testing is critical for guiding the choice of chemotherapy to be given to a patient, confirming whether drug resistance has appeared when a patient has failed to show a satisfactory response to treatment, and conducting surveillance of emerging drug resistance and detection of extensively drug-resistant TB (XDR-TB). Rapid molecular tests such as GX for RR and further line probe assays (LPA) for isoniazid and fluoroquinolone resistance are preferred to guide appropriate treatment regimen.

4 Structure of TB Laboratory Network

The TB laboratory network is organized to perform TB laboratory services under the NTP, aligned with the national, regional, intermediate (district), and peripheral levels of the national health services delivery structure. There is one NTRL in Dhaka and three functional regional laboratories located in Chittagong, Khulna, and Sylhet. Regional Tuberculosis Reference Laboratory (RTRL) Rajshahi and the 250-bed Shyamoli TB Hospital are being renovated and upgraded to biosafety level 2+ to perform as a fully functional RTRL providing LPA, culture, and phenotypic DST services. The NTP plans to set up additional RTRLs in Barisal and Rangpur division. At the district level, all the chest disease clinics, medical college hospitals, and district hospitals have functional laboratories in which sputum smears are examined. Most of these facilities also have GX. In addition, 40 external quality assurance (EQA) laboratories spread across the country supervise the peripheral-level smear microscopy centers.

There are no national standards for the infrastructure of TB laboratories with risk-based biosafety levels. Laboratory waste management is performed according to national regulations. Laboratory waste for smear microscopy is mostly burnt in either pits or drums on an open fire. At NTRLs and RTRLs, phenol and alcohol solutions are used as tuberculocidal disinfectants before disposal of the contaminated materials. In some places, the waste collection and disposal have been outsourced to PRISM Bangladesh Foundation.

4.1 Key Requirements and Tasks Specific to the Different Levels of a Laboratory Network

Figure 2 represents the different levels of TB laboratory networks (WHO, 2015). Many 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 centers and health facilities. The central laboratories, Level 3, are at the provincial, state, or national level. In large countries, there may be several Level 3 laboratories, depending on the situation; however, Bangladesh only has one Level 3 laboratory.

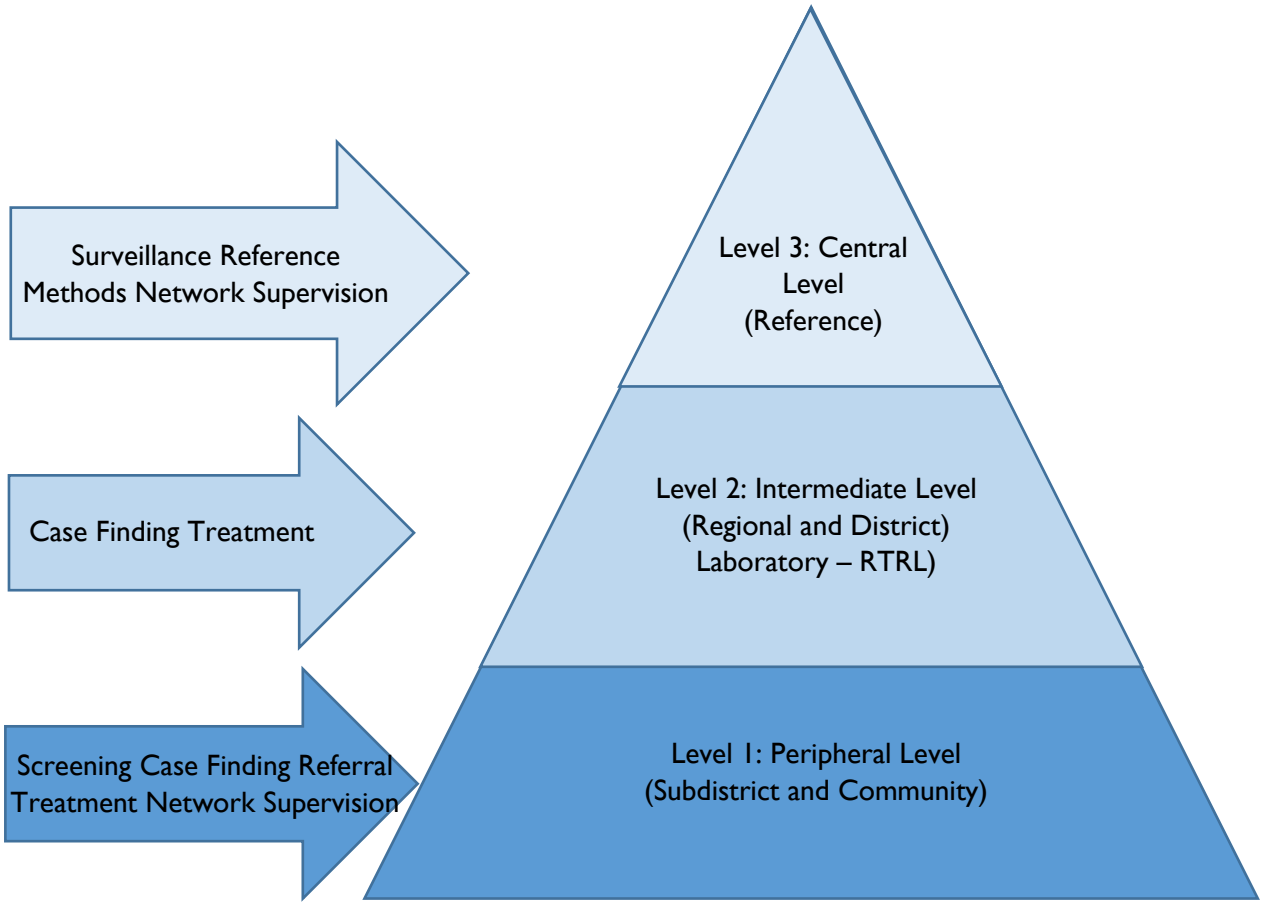

Figure 2: Structure of TB Laboratory Network

4.1.1 Peripheral Laboratories

Located at the Upazila Health Complex and the union level, the peripheral laboratories commonly provide smear microscopy services. The NTP is currently implementing a phase-wise plan to expand coverage of rapid molecular tools, GX, and other RMD at the peripheral level for diagnosis of TB by replacing Ziehl-Neelsen and LED microscopy. Until full coverage is ensured, smear microscopy will be continued. If any location with an RMD becomes nonfunctional, specimens will be transferred to a nearby diagnostic site. The presumptive extra-pulmonary TB (EPTB) cases will be referred to the higher-level facilities (intermediate and regional-level facilities, including medical colleges, RTRLs, and chest disease hospitals) for specimen collection and testing. Specimens needed for culture and DST should be transported to the NTRL or RTRL following standard protocols. All peripheral laboratories are responsible for proper recording and reporting of test results as per the national guidelines.

4.1.2 Intermediate/Regional-level Laboratories

4.1.2.1 District Level

The intermediate laboratories at the district level provide the same diagnostic services as at the peripheral level. In addition, these laboratories will test specimens for the diagnosis of EPTB with available molecular

technology. District and medical college hospitals will screen presumptive EPTB patients referred from the peripheral laboratories and perform the procedures for the collection of non-sputum specimens (e.g., cerebrospinal fluid, biopsy, fine needle aspiration cytology materials, body fluid, tissue, wound swab). The specimens will be used both for bacteriological diagnosis and histopathology/cytopathology. The NTP will ensure the baseline investigations required to initiate DR-TB treatment in collaboration with government hospitals or outsource those to private hospitals as appropriate.

4.1.2.2 Regional Level

In addition to molecular diagnostic technology, all RTRLs will be equipped with LPA (both first- and second-line) or 10-color GX and liquid culture (Mycobacteria Growth Indicator Tube). Although liquid culture will be prioritized for treatment monitoring, if it becomes nonfunctional, then solid culture will be used. All regional laboratories will receive EPTB specimens for bacteriological confirmation and to facilitate histopathology/cytopathology in collaboration with the medical colleges in the area. The RTRLs will mentor the district-level laboratories to ensure the quality of testing. The regional laboratory will continue to support EQA for smear microscopy; however, it is anticipated that diagnostic smear microscopy workload will be substantially reduced, and thus, the EQA for microscopy network will require restructuring. These regional laboratories will play a leading role in establishing and implementing EQA for molecular diagnostics. The specimens needed for culture and DST will be transported following the standard protocol.

4.1.3 Central-level Laboratories

The central-level laboratories will perform the same diagnostic tasks as the regional levels. In addition, the central-level laboratories will lead the development and updating of the policies and guidelines, manuals, diagnostic algorithms, standard operating procedures (SOPs), training curricula, and materials; design the laboratory information management system; establish quality assurance systems for genotypic and phenotypic tests; organize trainings; conduct operations research; and monitor and supervise the lower-level laboratories. These laboratories will also participate in EQA organized by the Supranational Laboratory (SRL), The central-level laboratories will provide oversight to ensure that the biosafety measures are taken based on biological risk assessment, collection, and transportation of specimens for culture and DST following the standard protocol, and infrastructure development at the intermediate and peripheral levels. Furthermore, the central-level laboratories will also explore possibilities for performing the histopathological examination in collaboration with Bangabandhu Sheikh Mujib Medical University, Dhaka Medical College Hospital, and other leading national institutions.

5 Vision and Mission

5.1 Vision

The people of Bangladesh have easy and fair access to high-quality TB laboratory services throughout the country.

To achieve this vision, the NTP will build the ability of the laboratories to produce accurate, reliable, and timely results, fostering progress toward a TB-free Bangladesh and working toward the elimination of TB from Bangladesh.

5.2 Mission

To provide high-quality TB laboratory services to all to diminish the social and economic impact and the inequities that TB imposes.

To achieve this mission, the NTP will engage in long-term laboratory system strengthening strategies through setting up and sustaining effective and efficient diagnostic systems, quality assurance, advanced molecular diagnostic technologies, and research and strategic partnerships.

6 Country-specific Objectives

6.1 Ensure Universal Access to RMDs and Gradual Phase-out of Smear Microscopy

Key intervention areas are as follows:

6.1.1 Use WHO-recommended RMDs

The NTP has been using GX to diagnose TB and RR-TB. The network of GX is currently being scaled up in a phased manner to the sub-district (Upazila) level following the plan outlined in the National Strategic Plan 2021-2025 (1,260 machines by 2025), with an aim to use RMD as an initial diagnostic tool replacing microscopy. The new sites will be renovated appropriately, meeting all essential requirements, including a back-up power supply for improved functionality and use of the RMDs. The NTP has already developed the GX SOPs, supervision checklist, training materials, and implementation plan to facilitate the RMDs (GX) training, operation, and scale-up (National TB Control Program, 2018a, 2018b, 2018c, 2018d, 2018e).

The NTP is moving ahead to achieve nationwide coverage of RMD services. This must coincide with the development and implementation of an EQA program with the provisions of proficiency testing, regular on-site supportive supervision, and prompt feedback. Additional resources will be mobilized to develop the SOPs, relevant tools, and mechanisms and support the capacity building of relevant staff to implement EQA.

The NTP introduced the GxAlert system in 38 GX sites. GxAlert is a web-based, open-source data connectivity application that includes a system for data management designed to work with any diagnostic device that can connect to the Internet or a mobile network. This system can capture patient demographic data, interface with various instruments and assays, gain access to individual and aggregate test results, support supply chain management, and monitor device warranty and calibration requirements and records, among other features. Given the benefits and implementation experience of this system, the NTP has planned the expansion of the system (which is now upgraded as Aspect) at all GX sites across the country. A GX focal point will be appointed at the central level for monitoring the performance of the GX sites through the GxAlert system.

The NTP will lead the development and implementation of maintenance and validation plans of GX instruments, supply chain management of GX supplies, and monitoring and supervision. For improved functionality and use of GX, effective coordination is needed with the manufacturer (Cepheid) and its authorized agent to ensure timely installation and troubleshooting.

Although currently GX is predominantly being used as the RDM tool in Bangladesh, the NTP is committed to introducing new technologies and tools that have potential for improving the coverage and quality of TB diagnostic services. Thus, the NTP is considering including other rapid molecular testing options in its diagnostic network that have a similar performance to GX (e.g., Truenat). The NTP intends to support collaboration to pilot Truenat, which can be used as a point-of-care tool for the detection of TB and RR-TB in hard-to-reach remote areas. The 10-color GX for the detection of fluoroquinolone and isoniazid testing will also be introduced in the in the diagnostic algorithm. The NTP will also explore opportunities for introducing e-learning approaches to meet the growing demand for continuous learning for capacity development.

6.1.2 Increase Capacity for First-line and Second-line LPA, Culture, and Phenotypic DST

The NTP plans to upgrade and equip all RTRLs and the 250-bed Shyamoli TB Hospital, Dhaka and develop the capacity of human resources to expand access to first-line and second-line LPA, culture, and phenotypic DST. The infrastructure of the existing laboratories will be assessed, and necessary fit for purpose renovations and upgrades will be made. Phenotypic DST of SLDs, including new drugs such as bedaquiline and delamanid, will be implemented using the liquid culture system to support the current DR-TB shorter treatment regimen. Necessary staff for the new laboratories will be recruited and trained, and existing staff will be re-trained as needed.

6.1.3 Establish and Maintain the Capacity for Maintenance and Validation of the Equipment

The NTP plans to establish a national center for the maintenance and repair of TB laboratory equipment for microscopy, culture testing, and DST (phenotypic and molecular), among others, as appropriate. The center will be equipped with necessary equipment, and two biomedical engineers will be recruited and trained to meet the emerging equipment maintenance needs. A central bank of back-up key laboratory equipment (such as GX, modules, cartridges, uninterrupted power supply, microscopes, centrifuges, balances, etc.) will be created. The annual maintenance contracts will be executed with capable public and private entities for the maintenance of major equipment. Routine and preventive maintenance will be enhanced by the provision of standard procedures, tools, training, monitoring, and supervision functions. The NTP will develop a routine maintenance training curriculum to train the laboratory staff on routine maintenance of the laboratory equipment. The NTP will use outsourcing mechanisms to engage capable local service providers for troubleshooting, annual calibration of Mycobacteria Growth Indicator Tubes, and other key laboratory instruments, and other services.

6.1.4 Enhance the Collection and Transportation of Samples for Culture and DST and GX sites

The specimen transportation system will be scaled up, aligning the expansion of the TB laboratory network. Transportation of specimens for LPA, culture, DST (conventional and molecular), and GX will be performed using triple packaging. Courier services will be provided with cold box to maintain the integrity of the specimen and safe transportation. The SOPs and key performance indicators for sputum collection and transportation will be updated with procedures for EPTB samples and timelines for the collection, transportation, delivery, and testing. Laboratory, clinical, and program staff will be oriented on specimen collection and transportation procedures. Mechanisms will be set up for the routine monitoring of turnaround time (TAT) and delivery conditions and electronic reporting of results.

6.1.5 Enhance Routine Reporting and Surveillance

The NTP has established data flow mechanism from the peripheral level to central level, as illustrated in Figure 3.

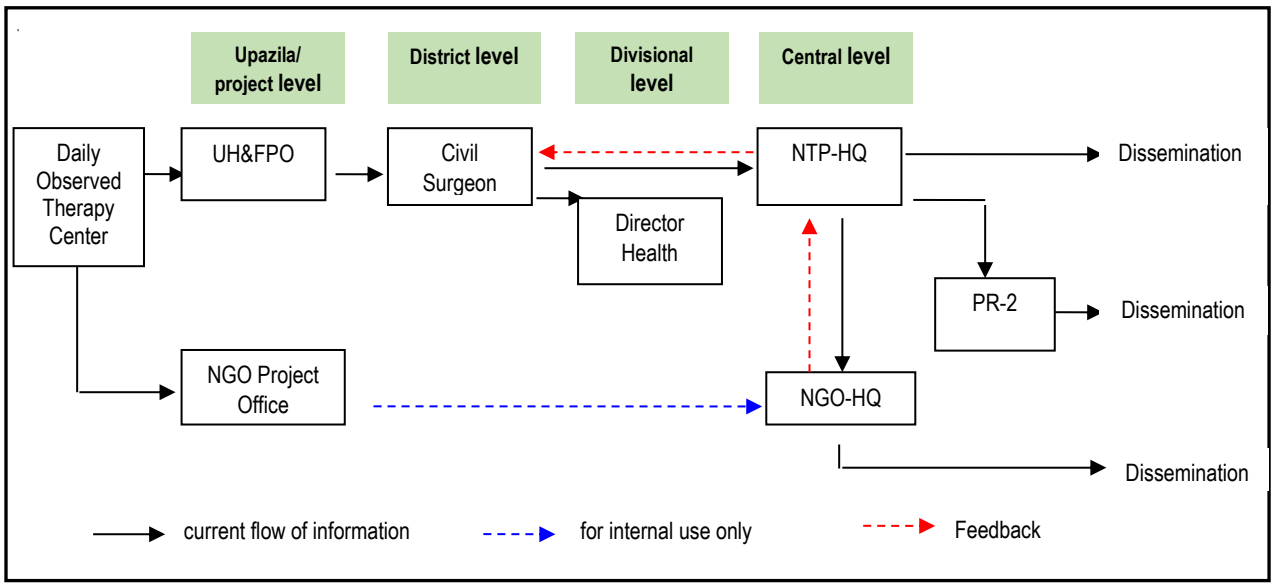

Figure 3: NTP Data Flow for Reporting and Surveillance

UH&FPO=Upazilla Health & Family Planning Officer, NGO=non-governmental organization, PR-2=principal recipient, HQ=headquarters

The NTP receives aggregated TB patient data from 857 reporting centers through TB 10, 11, and 12 reporting forms and laboratory test data from microscopy centers by email on a quarterly basis. Parallel to that, reports are entered directly or pushed from e-TB manager in District Health Information Software, version 2 (DHIS2). E-TB manager is an individualized patient-based recording system that has interoperability with DHIS2. The NTP reports TB patient data to the Ministry of Health through the Bangladesh Country Coordination Mechanism oversite meeting, to WHO through the Operation Management System portal, and to the Global Fund through the Progress Update and Disbursement Request. NTP also provides indicator-based data to the Sustainable Development Goal tracker of Bangladesh (National TB Control Program, 2019)

Routine surveillance will be strengthened through coordination of activities with public and private health care providers. Real-time monitoring of GX and other RMD machines in all existing and planned (1,260) sites through GxAlert or a similar system will be implemented to track the error rates and TAT for module replacement and improve overall maintenance. All existing and newly recruited staff at the RMD sites will be trained for data input and analysis through GxAlert or a similar system.

6.2 Improve the Diagnosis of EPTB, Pediatric TB, and TB in People Living with HIV/AIDS

Key intervention areas are as follows:

6.2.1 Use Molecular Diagnostics for the Detection of Smear-negative TB, Especially EPTB, Pediatric TB, and TB in People Living with HIV/AIDS

The expansion of the RMD network has created opportunities for molecular testing that must be capitalized on for the diagnosis of pulmonary and EPTB among children and immunocompromised individuals. The SOPs for specimen collection of EPTB and childhood TB will be developed, and referral linkages will be set up with the clinics, tertiary-level hospitals, and private practitioners. The NTP has procured EPTB sample processing kits for the NTRL, RTRLs, and other hospitals.

There is a need for training with a focus on building the capacity of clinicians, pediatricians, and health care workers at the primary and secondary level for early diagnosis of childhood TB. Current laboratory practices for the detection of TB in children are the same as for adults. WHO recommends the use of GX MTB/RIF Ultra as the first diagnostic test for all adults and children with the signs and symptoms of TB. HIV testing is not routinely done for TB patients; hence the proportion of TB patients tested for HIV and vice versa is not well recorded. TB tests will be conducted for all HIV-positive clients. Concerted efforts will be made to implement the NTP's policy for the screening of all HIV patients for TB and to enroll all HIV-positive contacts of TB cases in TB preventive therapy.

6.3 Use Quality-assured Microscopy for Treatment Follow-up

Key intervention areas are as follows:

6.3.1 Sustain Microscopy Capacity through Good Maintenance of the Existing Network

The TB microscopy laboratory network will be used only to monitor treatment follow-up of the TB and DR-TB patients as the GX/RMD network expands up to the sub-district level. If the GX or other RMD is not available on-site or by referral, then microscopy may be used. Currently, the EQA program for microscopy is conducted at 40 designated EQA centers. The EQA program will be updated to include components on supervision activities of the EQA centers and of outreach workers and volunteers who prepare smears at outreach centers. The number of smears will be significantly reduced and thus the positivity rates due to the expansion of RMDs, so the EQA program for the smear microscopy will need to be revised. The EQA training curriculum will be revised by adding a supervision module. Efforts will be continued to strengthen the human resources for EQA. Given the expansion of molecular tools (e.g., GX and other RMD testing), existing EQA centers for acid-fast bacilli microscopy will be used to implement EQA for RMD.

6.3.2 Improve the Quality of the Peripheral Laboratories

The performance of the TB microscopy laboratories will be improved through implementing routine quality control in all centers, ensuring the availability of SOPs and job aids, and training and enhancing routine monitoring and supervision. Quality assurance will be strengthened by the implementation of standards needed for an effective TB laboratory network (Global Laboratory Initiative, 2013).

6.3.3 Ensure the Quality of Sputum Collection

The process for sample collection (sputum) will be improved through enhancing the health literacy of individuals to be evaluated for TB through displaying posters, videos, etc. The NTP will develop the job aids relating to the specimen collection, acceptance, and rejection criteria.

6.4 Introduce Laboratory Quality Management Systems in the TB Laboratory Network

Key intervention areas are as follows:

6.4.1 Enhance the Legal Policy and Review and Framework for the TB Laboratory

An inventory of existing regulatory documents (standards, manual/guides, plans, SOPs, etc.) available in the network will be conducted to find gaps and prioritize areas for further actions. The documents that are missing will be developed, and outdated documents will be updated and disseminated. The National TB Laboratory Working Group will organize regular meetings to review the progress and provide management support to the implementation of planned activities.

6.4.2 Strengthen Human Resources for Quality Management Systems

The NTP will develop and update the quality management systems materials for TB laboratory services and train staff. The NTP will take initiative for accreditation of the TB laboratory following the Stepwise Laboratory Quality Improvement Process Towards Accreditation and the Strengthening Laboratory Management Towards Accreditation processes. Quality management systems will be implemented at NTRL and RTRLs, with an aim to fulfill the requirements and be eligible for participation in the accreditation process by 2025. A collaboration platform with the Bangladesh Accreditation Board will be set up to facilitate the accreditation process.

6.4.3 Strengthen Infrastructure of the TB Laboratories

Refer to Sections 6.1–6.3 for more details.

6.4.4 Improve Quality Assurance in the TB Laboratories

The supervision of the NTRL by the SRL will be maintained, including the provision of proficiency testing and supportive visits. The EQA program for the RTRLs will be established. Existing EQA centers for microscopy EQA will be used to strengthen the quality of microscopy centers and RMD established in the districts. The EQA program will be strengthened through monitoring and evaluation, mentorship, and supportive supervision.

6.4.5 Strengthen and Maintain Quality Assurance for All TB Tests

The NTP will work with the NTRL and SRL to develop the guidelines for the quality assurance programs for all the TB diagnostics used in country. A sustainable and stepwise action plan, along with the resources required, will be prepared and implemented at all the levels of the diagnostic network. Standard terms of reference (ToR) of the NTRL and RTRLS have been developed and will be implemented to empower the reference laboratories for effective implementation of the quality assurance programs across the network. The reference laboratories will work closely with the divisional and district health authorities to implement and maintain the quality assurance programs. The NTRL will train all the RTRLs on the stepwise

implementation of internal and external quality assurance programs, and deliver the necessary trainings. The key performance indicators (KPI) for all TB diagnostics based upon Global Laboratory Initiative guidance will be developed and implemented across the network through the cascade training. A mechanism of regular collection, analysis, and reporting of the KPIs following the administrative structure of the laboratory network will be established.

7 Integration with the General Health System

The National TB Laboratory Strategic Plan will be aligned with the National Laboratory Strategic Plan (draft is yet to be finalized by the Institute of Epidemiology, Disease Control, and Research) in the future given the scope and modality. The TB laboratory network, managed by the NTP, is an integral part of the national health system. TB laboratories are nested in the government and non-government health facilities. Additional non-TB tests, such as biochemistry, serology, audiometry, etc., are needed to initiate DR-TB treatment and to address adverse drug reactions are done by the public health services laboratories. The Global Fund to Fight AIDS, Tuberculosis and Malaria and other donors provide major human resources support to the TB laboratories. The NTP will continue discussion with the MOHFW to advocate for increased resource allocation through the Government Operational Plan budget to reduce the donor dependance for the management of human resources. The NTP will establish initiatives to further integrate its laboratory network within the broader health system to meet the growing diagnostic needs for the detection of EPTB and childhood TB and for biochemistry, histopathology, serology, radiology, etc. Specific emphasis will be given to draw on resources available in existing government institutes, universities, and medical colleges, including Bangabandhu Sheikh Mujib Medical University, National Institute of Preventive and Social Medicine, Bangladesh Institute of Tropical and Infectious Diseases, and Infectious Diseases Hospital for diagnostic support and to strengthen collaboration with other programs, such as hospital services, nutrition, non-communicable disease control, maternal and child health, and AIDS/sexually transmitted diseases, to further integrate the TB activities.

8 Linkages with the Private and Non-governmental Organization Sectors

In Bangladesh, the NTP is recognized for its uniqueness as a successful public-private mix (PPM) initiative actively engaging both public and private health care providers (for-profit and non-profit) to expand coverage and ensure equitable access to TB services. Linkages between the private and public health services in rural areas are well established. The national and international NGOs complement the national efforts to increase the coverage of and access to TB diagnostics, including microscopy, RMD, and DST. The NTP will keep expanding partnerships and collaboration with the private for-profit and non-profit sectors to accelerate the detection of all forms of TB through optimum utilization of the laboratory network. The NTP developed a PPM strategy and operational plan to strengthen the linkages between the laboratories in its own network and in the PPM sites. The NTP, along with the NTRL, will implement quality assurance programs for TB diagnostics at all PMM sites (National Tuberculosis Control Program, 2020a).

9 Legal and Political and Compliance Issues

The NTP, MOHFW is the legal body for TB control and endorsement of internationally recommended policies, strategies, guidelines, and technologies. Establishing new TB laboratories requires clearances from the NTP and related government departments (e.g., trade license, pathology registration, laboratory safety

compliance, radiology certification, environmental certification, fire safety certification, drug license). The laboratory technical working group constituted under the NTP is the apex body for making all decisions for strengthening and improving the performance of laboratory network. The NTP follows the International Standards for Tuberculosis Care to provide quality services for TB patients. The rights, confidentiality, and safety of TB patients are protected following the country's laws.

10 ToRs of the NTRL and RTRLs

In 2020, the NTP drafted the standard ToR outlining the roles and responsibilities of NTRL and RTRLs, with support from the United States Agency for International Development. The ToR will be used to improve the capacity and mobilize the resources to perform the reference laboratory functions, such as supervision, quality oversight, and monitoring of the TB diagnostic network and the development of diagnostic policies and guidelines, including the following: (National Tuberculosis Control Program, 2020c)

- Establishing clearly defined supervisory roles of the NTRL and RTRLs over their respective lower tier laboratories
- Incorporating the NTRL and RTRLs within the organogram of the MOHFW of the Government of Bangladesh
- Establishing institutional and regulatory mandate, capacity, and resources to perform their desired roles and responsibilities

After the draft TORs are endorsed, a roadmap will be developed to strengthen and sustain the institutional capacity of the NTRL and RTRLs to achieve the vision and mission of the NTP (refer to the ToRs for details).

11 Human Resources for the TB Laboratory Network

The TB laboratories are managed with staff supported by the government, the Global Fund, and NGOs at all levels. The microscopy centers are entitled to have at least two laboratory technologists according to NTP policy. However, the NTP suffers from an acute shortage of resources, and many laboratories having only on medical technologist. Under the new Global Fund grant, the NTP plans to integrate some of the microscopy centers with nearby RMD laboratories to address the staff shortage. The NTRL and RTRL microbiologist positions will be supported by the NTP and implementing partners. The NTP has plans to incorporate the microbiologist position within the operational plan and the government organogram to achieve the longer-term sustainability. The NTP will recruit 350 medical technologists for laboratories, and 75 medical technologies for radiography for X-ray sites to fill the vacant posts, which are hampering the operations of the RMD and X-ray sites. There is a pool of volunteers who serve at the outreach centers for collection and transportation of the specimens from the persons with possible TB to the RMD sites for testing. The NTP will create more positions under the operational plan and Global Fund grant to ensure that adequate human resources are available to efficiently run the TB diagnostic network. The NTP will continue to train and re-train the staff in collaboration with the development and implementing partners as needed.

12 Management of Laboratory Commodities and Supplies

The reagents, for microscopy, culture, DST (phenotypic), second-line LPA, and RMDs are mainly procured through the Global Drug Facility mechanism. The EQA centers either distribute (ready-to-use) or prepare and distribute the reagents for microscopy on request. A needs-based procurement system is

implemented in implementing partner NGO-supported areas only, not nationwide. The reagents and supplies for the TB laboratories are distributed using the national supplies distribution system supported by the NGOs and the government, although there is no cold chain for distribution and transportation of temperature-sensitive reagents. The private laboratories are not part of the network, and therefore the NTP does not supply any reagents to them, and the quality of their procured reagents is unknown.

The stock management at different levels is done manually. The supply chain management guidelines and SOPs are available for drugs only. There are central and district-level warehouses for the storage of chemicals and drugs. The NTP will develop SOPs for the management of laboratory reagents, RMD cartridges/kits, etc. The NTP will develop electronic supply chain management systems with support from partners. The NTP will also work to ensure that the cold chain for temperature-sensitive reagents throughout the supply and storage cascade as appropriate.

13 Specimen Transport and Referral System

Continued expansion of the RMD and LPA network is improving the coverage and access to the TB diagnostics. Moreover, efforts are being made to develop an effective specimen referral system to increase in the workload of the GX/RMD, LPA, and culture and DST laboratories in terms of testing volumes, data entry, and quality management. The NTP will update the SOP for sputum collection, packaging, and transport. The specimens for culture and DST (including Xpert MTB/RIF) are either transported by couriers, or in many areas, patients are referred to culture and DST laboratories. A mapping exercise about the flow of various specimen types between facilities/areas/regions and referral laboratories will be helpful to integrate the system with other public health programs. The NTP will conduct a mapping exercise that will act as a visual monitoring tool and help strengthen and further expand the specimen referral system. The cost-effectiveness and long-term sustainability of the specimen referral system will be ensured by creating synergy among partners, contracting out the responsibility of the specimen transportation to a courier company, and orienting all field-level staff on the sputum sample transportation system and countrywide scale-up. There are no standard KPIs to monitor the quality and TATs for TB tests available. The NTP will develop the KPIs and implement them at all the levels of laboratory network.

14 Finances for TB Laboratory Services

Finances for TB laboratory services is a part of the NTP budget, which is composed of both government revenue and operational plan fund budget and international funding (Global Fund/United States Agency for International Development). There are budget lines for TB laboratory activities in the National Strategic Plan 2021-2025.

15 Indicators and Targets for TB Laboratory Objectives and Monitoring and Evaluation Framework

Refer to the Annex.

16 Work Plan and Budget

Refer to the costing file for the detailed budget.

Table 1: Yearly Budget Summary by Cost Category (USD)

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5	Total	Percentage of total
Human Resources	3,212,000.00	3,709,630.00	4,160,482.40	5,122,454.18	8,377,295.02	24,581,861.60	15%
Infrastructure Costs	1,511,800.00	604,404.00	622,536.12	969,030.30	2,095,472.30	5,803,242.73	4%
Laboratory Equipment	6,385,540.00	8,005,857.20	7,274,202.00	2,716,086.96	19,076,041.27	43,457,727.44	26%
Laboratory Supplies and Consumables	12,809,525.00	15,268,616.49	16,772,034.39	18,371,633.86	21,237,265.13	84,459,074.86	51%
Monitoring and Evaluation	120,600.00	174,276.00	135,583.02	133,094.15	137,097.90	700,651.07	0%
Other General Costs	174,941.18	319,542.35	470,540.35	632,496.10	803,745.70	2,401,265.69	1%
Overhead	-	-	-	-	-	-	0%
Planning and Administration	10,000.00	10,300.00	19,096.20	1,659,476.41	-	1,698,872.61	1%
Procurement and Supply Management	-	9,270.00	-	-	-	9,270.00	0%
Technical and Management Assistance	43,000.00	108,467.50	142,123.86	83,400.47	78,486.07	455,477.91	0%
Training	142,600.00	134,621.00	180,034.73	101,842.16	231,854.81	790,952.70	0%
Total	$24,410,006.18	$28,344,984.54	$29,776,633.07	$29,789,514.60	$52,037,258.21	$164,358,396.60	100%

Table 2: Summary of Funding Sources and Funding Gap (USD)

Source	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Government: central/national	14,073,588.24	15,355,235.29	14,820,858.82			44,249,682.35
Government: intermediate/provincial						0
Government: local/district						0
Loans						0
Global Fund	21,172,154.41	22,480,891.81	22,484,499.16			66137545.37
Other grants						0
Total	35,245,742.64	37,836,127.1	37,305,357.98	0	0	110,387,227.7
Funding gap	-10,835,736.47	-9,491,142.561	-7,528,724.907	29,789,514.6	52,037,258.21	53,971,168.88

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References

Global Laboratory Initiative. (2013). *TB Microscopy Network Accreditation: An assessment tool.* Stop TB. https://stoptb.org/wg/gli/assets/documents/TBMicroscopy_Network_Accreditation_Web.pdf

National Tuberculosis Control Program. (2018a). *Implementation and scale up plan for GeneXpert network in Bangladesh.*

National Tuberculosis Control Program. (2018b). *SOPs for Xpert MTB/RIF Laboratory.*

National Tuberculosis Control Program. (2018c). *Xpert MTB/RIF Supervision Checklist Package.*

National Tuberculosis Control Program. (2018d). *National TB Prevalence Survey Bangladesh 2015-2016.*

National Tuberculosis Control Program. (2018e). *Assessment report of GeneXpert in Bangladesh.* Global Fund.

National Tuberculosis Control Program. (2020a). *National Strategic Plan for TB Control 2021-2025*. https://www.ntp.gov.bd/wp-content/uploads/2022/03/Clear_FINAL_NSP-Bangladesh-2021-2025.pdf

National Tuberculosis Control Program. (2020b). *National Guidelines and Operational Manual for Programmatic Management of Drug Resistant TB* (3rd ed.).

National Tuberculosis Control Program. (2020c). *Terms of Reference (TOR) for the National TB Reference Laboratory and Regional TB Reference Laboratories – Bangladesh.*

Stop TB. (2014). *A Practical Handbook for National TB Laboratory Strategic Plan Development: Participants Manual* (2nd ed.). https://stoptb.org/wg/gli/assets/documents/Lab_Strategic_Handbook_Participants_Manual.pdf

World Health Organization. (2015). *Implementing Tuberculosis Diagnostics: Policy framework* (p. 13). http://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdfhttp://apps.who.int/iris/bitstream/10665/162712/1/9789241508612_eng.pdf

World Health Organization. (2020). *Global Tuberculosis Report 2020* (p. 208). https://www.who.int/publications-detail-redirect/9789240013131

Annex: Monitoring and Evaluation Indicators

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
NTP Goal	Reduce the prevalence of TB (all forms) by at least 10% by 2020, and by 5% annually after 2020	NTP, partners	Number of TB cases (all forms) notified	268,596 (2018)	154,0782	292,745	298,112	303,259	326,079	320,587
			Number of new bacteriologically confirmed TB cases notified	193,389	107,3170	187,404	202,944	217,224	234,776	230,822
			Incidence of bacteriologically confirmed TB	221/100000 population (WHO 2018)	203	219	215	211	207	203
			MDR-TB patient to be enrolled for treatment	DRS 2017-2018: 1.5% in new cases; 4.9% in re-treat cases	12,997	1,892	2,250	2,598	2,952	3,305
Objective 1	Ensure universal access to rapid molecular diagnostics and gradual phaseout of smear microscopy		# of laboratories performing conventional DST	5 (2020 including BITID Chittagong)	8 (NTRL, 4RTRL, DF, Shyamoli, and BITID)	6	7	8	8	8
	—		Number of laboratories performing molecular DST using GeneXpert tools	272 (2020)	1,260	510	590	650	950	1,260

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
			# (%) of tests for drug resistance performed on previously treated case done using rapid test	20,102	100%	100%	100%	100%	100%	100%
			Number (%) of new TB patients tested for drug resistance	48,167	100%	9,1140 (31%)	11,8440 (40%)	13,4400 (45%)	160,000 (60%)	275,000 (100%)
			% of confirmed cases of MDR-TB with a DST result for fluoroquinolones (LPA) and new drugs		100%	100%	100%	100%	100%	100%
Strategy 1.1 Strengthen laboratory infrastructure, including biosafety										
Activity 1.1.1	Establish new culture and DST laboratories (phenotypic and molecular both)		# of new laboratories constructed/ established during a specified period		4	1	1	1	1	
Activity 1.1.2	Upgrade infrastructure of existing culture and DST laboratories		# (%) laboratories with adequate infrastructure out of planned during a specified period		3	1	1	1		
Strategy 1.2 Improve laboratory human resource development										
Activity 1.2.1	Develop/update materials for culture/DST/LPA laboratories		% of materials, manuals, SOPs developed as per plan during a specified period		100%	100%	100%	100%	100%	100%
Activity 1.2.2	Recruit and train staff for culture/DST/LPA laboratories		# (%) of posts filled according to plan during a specified time		20 (100)	0 (0)	5 (25%)	10 (50%)	15 (75%)	20 (100%)

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
1.2.3	Develop e-Learning materials for continuous learning for capacity development		Number of e-learning materials developed and implemented	0	8 (100%)	3	4	7	8	8
Activity 1.2.4	TPT, screening test of staff in culture/ DST/LPA laboratories		% of lab staff medically examined and provided TPT during a specified period of time	0	100%	0	25%	50%	75%	100%
Strategy 1.3 Enhance management of laboratory commodities and supplies, equipment validation and maintenance										
Activity 1.3.1	Establish national center for maintenance and repair of TB laboratory equipment		# of functional equipment maintenance centers during a specified period of time	0	1	0	0	1		
Activity 1.3.2	Maintain equipment of culture/DST/LPA laboratories		# of laboratories with no delays in equipment maintenance during a specified time period	0	8	6	7	8	8	8
Activity 1.3.3	Procure reagents, commodities, and supplies for culture/DST/LPA laboratories		# of laboratories reporting no stockouts of reagents and supplies during a specified time period	100	100	100	100	100	100	100
Strategy 1.4 Fortify specimen transport and referral mechanisms										
Activity 1.4.1	Optimize collection and transportation of specimens and isolates		% of specimens delivered within established TAT during a specified period of time	..	100%	100%	100%	100%	100%	100%

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 1.4.2 Improve quality of sputum (refer to Objective 3)										
Strategy 1.5 Improve laboratory information and data management systems										
Activity 1.5.1	Establish laboratory information system in culture/DST laboratories		# (%) of laboratories with LIS out of planned during a specified time period		100 % (8)	75	87.5	100%	100%	100%
Activity 1.5.2	Enhance monitoring and evaluation of culture/DST/LPA data		# (%) of laboratories reporting data during a specified time period	….	100 % (8)	100%	100%	100%	100%	100%
Activity 1.5.3	Expansion of data connectivity (Aspect)		Number of Aspect systems connected	38	507	507	507	507	507	507
Strategy 1.6 Develop and maintain laboratory quality management systems										
Activity 1.6.1	Provide EQA services to NTRL and RTRLs		# of laboratories participating in EQA in a specified period of time	…	8	6	7	8	8	8
Activity 1.6.2	Provide proficiency testing to NTRL and RTRLs		# of laboratories received panel testing out of planned during a specified time period		8	6	7	8	8	8
Activity 1.6.3	Conduct re-checking of isolates from RTRLs		# of laboratories participating in EQA in a specified period of time		8	6	7	8	8	8
Strategy 1.7 Develop operational research capacity										
Activity 1.7.1	Conduct drugs resistance survey (for costing refer to DRS 2010-11)		Drug resistance surveys achieved per national strategies		1	0	1	0	0	0

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 1.7.2	Enhance routine surveillance		# of laboratories linked to clinical database during a specified time period		8	6	7	8	8	8
Activity 1.7.3 Increase capacity for operation research at NTRL and RTRLs (refer to Objective 4)										
Strategy 1.8 Establish a laboratory policy framework										
Activity 1.8.1 Develop/update policy documentation (refer to Objective 4)										
Objective 2	Improve the diagnosis of EPTB, pediatric TB, and TB in people living with HIV/AIDS		# of laboratories performing culture other than sputum sample	4 (2020) only NTRL	8	4	5	6	7	8
			Number of laboratories performing rapid molecular diagnosis for EP and other TB	1 (NTRL)	81 (80 GX, 5 LPA for both first-line and second-line DST)	47	55	63	71	81
			Number (%) of newly notified TB cases diagnosed using culture or molecular-based tests for EP and child TB	107,438 (2018) for EPTB, child TB	578,416	117,498	116,372	115,595	114,851	114,100
Strategy 2.1 Strengthen laboratory infrastructure, including biosafety										
Activity 2.1.1	Establish new and upgrade the existing GeneXpert laboratories s		# laboratories with adequate infrastructure out of planed during a specified time period	272 (2020)	1,260	510	590	650	690	1,260
Strategy 2.2 Improve laboratory human resource development										
Activity 2.2.1	Update Xpert MTB/RIF training materials using international		% of materials, manuals, SOPs available during a specified time period		100%	100%	100%	100%	100%	100%

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
	packages, develop SOPs and job aids									
Activity 2.2.2	Recruit and train staff for Xpert MTB/RIF		%) of health facilities (laboratories) with at least one worker trained/re-trained out of all staff during specified period	273	100%	100%	100%	100%	100%	100%
Strategy 2.3 Enhance management of laboratory commodities and supplies, equipment validation and maintenance										
Activity 2.3.1	Develop plans for management of supplies and equipment maintenance for Xpert		# of materials, manuals, SOPs available during a specified time period	3	4	4	4	4	4	4
Activity 2.3.2	Procure commodities and supplies for Xpert laboratories		% of laboratories reporting no stockouts of reagents and supplies during a specified time period		100%	100%	100%	100%	100%	100%
Strategy 2.4 Improve laboratory information and data management systems										
Activity 2.4.1	Update M&E plan for Xpert MTB/RIF		Xpert M&E plan available during a specified period of time	1	1	1	1	1	1	1
Activity 2.4.2	Monitor and evaluate performance of Xpert laboratories		# (%) of laboratories reporting data during a specified period	272 (2020)	1260	510	590	650	690	1,260
Strategy 2.5 Fortify specimen transport and referral mechanisms										
Activity 2.5.1	Collect and transport specimens for Xpert MTB/RIF		% of specimens delivered within established TAT during a specified period of time	…	100%	100%	100%	100%	100%	100%

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 2.5.2	Develop/update SOPs for sputum collection and transportation procedures with EPTB, child TB samples		Number of SOPs to be developed or updated	1	2	1	2	2	2	2
Activity 2.5.2 Improve quality of sputum (refer to Objective 3)										
Strategy 2.6 Develop and maintain laboratory quality management systems										
Activity 2.6.1	Develop and implement EQA program for Xpert sites		Xpert EQA program available during a specified period	0	100%	20%	40%	60%	80%	100%
Activity 2.6.2	Conduct proficiency testing for Xpert sites		# (%) of laboratories received panel testing out of planned during a specified period	0	100%	10%	40%	60%	80%	100%
Activity 2.6.3	Supervise Xpert laboratories		% of laboratories received supportive supervision visit by NTRL and RTRLs during a specified period	…..	100%	100%	100%	100%	100%	100%
Strategy 2.7 Establish a laboratory policy framework (ToR) (refer to Objective 1 4)										
Activity 2.7.1	Govt approved organogram/ToR of NTRL and RTRLs			0	100%	0	100%	100%	100%	100%
Strategy 2.8 Develop operational research capacity (Refer to Objective 4)										
Activity 2.8.1	Sentinel surveillance		NTRL and RTRL linked with clinical data	0	TBD	TBD	TBD	TBD	TBD	TBD
Objective 3	Use quality assured microscopy to		# (%)of AFB microscopy laboratories that are quality assured	1,145 (100)	1,145 (100)	1,145 (100)	1,145 (100)	1,145 (100)	1,145 (100)	1,145 (100)

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
	perform treatment follow-up									
	—		# (%)of AFB microscopy laboratories that are using LED microscopy	782 (68)	1,145 (100)	907 (80)	1,032 (90)	1,067 (93)	1,102 (96)	1,145 (100)
Strategy 3.1 Strengthen laboratory infrastructure, including biosafety										
Activity 3.1.1	Minor renovations of existing laboratories, including water and power supply and security frames; this includes 40 EQA centers (average cost per lab)		# (%)of laboratories to be renovated during a specified period		355 (100%)	71 (20%)	71 (20%)	71 (20%)	71 (20%)	71 (20%)
Strategy 3.2 Improve laboratory human resource development										
Activity 3.2.1	Revise/update/ develop training materials and guiding document for the lab (all)		# of materials, manuals, SOPs available during a specified period	4	12	6	8	10	11	12
Activity 3.2.2	Recruit, train, and mentor staff		# (%) of health facilities (laboratories) with at least one worker trained/re-trained out of all staff during a specified period	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)
Strategy 3.3 Enhance management of laboratory commodities and supplies, equipment validation and maintenance										
Activity 3.3.1	Procure equipment		# laboratories need to repair equipment during a specified period		250	50	50	50	50	50

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 3.3.2	Procure supplies, commodities, and reagents		# (%) of laboratories reporting no stock out of reagents and supplies during a specified period	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)
Strategy 3.4 Fortify specimen transport and referral mechanisms										
Activity 3.4.1	Enhance specimen referral for AFB microscopy		% of laboratories receiving specimens within an established TAT during a specified period	1,145 (100%)	1,145 (100%)	1,145 (100%)	1,145 (100%)	1,145 (100%)	1,145 (100%)	1,145 (100%)
Activity 3.4.2	Develop/update poster, video to educate on better sputum production		Number of health literacy materials developed	NA	5	1	2	3	4	5
Activity 3.4.3	Improve quality of sputum specimens		% of good quality sputum specimens produced		100%	80%	90%	90%	95%	100%
Strategy 3.5 Improve laboratory information and data management systems										
Activity 3.5.1	Develop monitoring and evaluation system for AFB microscopy network and EQA program		# (%) of laboratories with LIS out of planned during a specified period	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)
Strategy 3.6 Develop and maintain laboratory quality management systems										
Activity 3.6.1	Conduct supervision and mentorship of AFB microscopy and EQA centers		# (%) of laboratories received documented support at least one visit from upper level out of planned during a specified period	1,185	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 3.6.2	Enhance internal quality control, quality assurance, and quality improvement processes		# (%) of laboratories with documented quality practices during a specified period	1,185	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)	1,185 (100%)
Strategy 3.7 Establish a laboratory policy framework (refer to Objectives 2 and 4)										
Strategy 3.8 Develop operational research capacity (refer to Objective 4)										
Objective 4	Establish Laboratory Quality Management Systems (QMS) in the TB laboratory network	NTP, partners	Number of national and regional laboratories implementing a quality management system according to international standards and national strategies	0	8	1	4	5	6	8
			Number of TB reference laboratories accredited	0	1 (RTRL Sylhet applies for accredit-ation)	0	0	0	1	RTRL Sylhet applies for accredit -ation
			% of TB laboratories with appropriate biosafety measures in place		100%	80%	90%	90%	100%	100%
Strategy 4.1 Establish a laboratory policy framework										
Activity 4.1.1	Develop and disseminate national standards for TB laboratory (infrastructure, equipment and supplies)		# of materials, manuals, SOPs available during a specified period	0	3	2	3	3	3	3

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Activity 4.1.2	Complete policy framework for TB laboratories		% of materials, manuals, SOPs available during a specified period	0	100%	100%	100%	100%	100%	100%
Strategy 4.2 Improve laboratory human resource development										
Activity 4.2.1	Recruit and train staff		# (%) of laboratories implementing QMS out of planned during a specified period		11	3	4	9	10	11
Activity 4.2.2	Exchange experiences in building QMS		# of meetings conducted during a specified period		15	3	6	9	12	12
Strategy 4.3 Strengthen laboratory infrastructure, including biosafety (refer to Objectives 1–3)										
Strategy 4.4 Develop and maintain laboratory quality management systems										
Activity 4.4.1	Implement QMS in culture/DST laboratories		# (%) of laboratories implementing QMS out of planned during a specified period	0	8	1	4	6	7	8
Activity 4.4.2	Conduct assessments of implementation of requirements for accreditation of network (culture and DST)		# of assessment reports available during a specified period		5	1	1	1	1	1
Strategy 4.5 Enhance management of laboratory commodities and supplies, equipment validation and maintenance										
Activity 4.5.1 Provide laboratories implementing QMS and EQA centers with equipment, commodities and supplies (refer to Objectives 1 and 3)										
Strategy 4.6 Develop operational research capacity										
Activity 4.6.1	Conduct TB laboratory OR (Truenat, Xpert XDR TB cartridges, etc.)		# of TB-specific laboratory operational research projects completed per national strategies		5	1	1	1	1	1
Activity 4.6.2	Disseminate results of OR		# of conferences during a specified period		4	0	1	1	1	1

Title	Description	Implementers	Indicator	Current	5 y. target	2021	2022	2023	2024	2025
Strategy 4.7 Improve laboratory information and data management systems										
Activity 4.7.1	Increase laboratory data analysis capacity at NTRL and RTRLs		# (%) of referral laboratories with at least one laboratory officer trained in laboratory data analysis		8	0	2	2	2	2
Strategy 4.8 Fortify specimen transport and referral mechanisms (refer to Objectives 1–3)										