



Philippines TB LABORATORY NETWORK STRATEGIC PLAN 2018-2022 *A Sub-Plan of PhilSTEP1*



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Foreword

The Philippines is third to India and China in leading the count of the accounted 87% new tuberculosis (TB) cases in the top 30 high-burden countries, with multidrug-resistant TB remaining a serious public health threat. The 2016 National TB Prevalence Survey showed that the prevalence of bacteriologically confirmed pulmonary TB in the country is 1,159 per 100,000. This presents around one million Filipinos having the disease, but many of them do not know it.

The Department of Health, working with all stakeholders, has developed the 2017-2022 Philippine Strategic TB Elimination Plan Phase 1 (PhilSTEP1) to address this serious national problem. PhilSTEP1 envisions a “TB-Free Philippines” and serves as the road map for activities geared towards the elimination of TB in the country, with the long-term goal of reducing the TB burden by decreasing TB mortality by 95% and TB incidence by 90% by 2035. To achieve this, we need to reduce TB deaths by 50% (from 22,000 to 11,000) and to reduce TB incidence by 23% (from 554 per 100,000 to 427 per 100,000) in 2022. These medium-term goals can only be achieved if we actively find TB cases in the country, treat them effectively, and cure them to break the chain of TB transmission.

TB case finding requires a robust network of laboratories that are accessible and we able to provide continuous quality-assured services. The Laboratory Network Strategic Plan (LNSP) 2018-2022 has been created to guide the efforts of the National TB Control Program (NTP) and its partners to build laboratory services capacities to find all TB cases.

Strengthening the laboratory network is an enormous undertaking that requires close collaboration between all stakeholders, including those in the communities. In order for us to do this, we need to harness innovative ideas, resources, and dedication to achieve our LNSP objectives. Efforts must be focused on providing high-quality services through a resilient network of laboratories, supported by robust laboratory systems that will bring effectiveness, efficiency, and sustainability.

We hope that the LNSP will provide strategic direction, promote stewardship and accountability among all stakeholders, and ensure that our services address the needs of our citizens afflicted with TB - a true manifestation of the NTP's patient-centered services. Let us all unite in strengthening our TB laboratory network. Together, we can end TB in our country.



Francisco T. Duque III, MD, MSc
Secretary of Health
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Abbreviations and Acronyms

| | | | |
|-----------------------------|--|------------------|---|
| ACCESS TB Project/GF | Advancing Client-centered Care and Expanding Sustainable Services for TB Project/Global Fund | PBSP | Philippine Business for Social Progress |
| CHD | Center for Health Development | PhilSTEP1 | Philippine Strategic Tuberculosis Elimination Plan, Phase 1 |
| DPCB-DOH | Disease Prevention and Control Bureau - Department of Health | PCHRD | Philippine Council for Health Research and Development |
| DOH | Department of Health | POC | Point of Care |
| DR-TB | Drug-Resistant TB | PTB | Pulmonary TB |
| DST | Drug Susceptibility Test | QA | Quality assurance |
| EQA | External Quality Assessment | QMS | Quality Management System |
| FIND | Foundation for Innovative New Diagnostics | RIT | Research Institute of Tuberculosis |
| GLI | Global Laboratory Initiative | RITM | Research Institute for Tropical Medicine |
| GX | GeneXpert | RR-TB | Rifampicin-Resistant TB |
| HFEP | Health Facilities Enhancement Program | RTDL | Rapid TB Diagnostic Laboratory |
| HPDPB | Health Policy Development and Planning Bureau | SIAPS | Systems for Improved Access to Pharmaceuticals and Services |
| ITIS | Integrated TB Information System | SLD | Second-line anti-TB drugs |
| KMITS | Knowledge Management and Information Technology Service | SLIPTA | Stepwise Laboratory quality Improvement Process Towards Accreditation |
| LGU | Local Government Unit | TASC | Technical Assistance Support to Country |
| LNSP | Laboratory Network Strategic Plan | TB | Tuberculosis |
| LPA | Line Probe Assay | TEV | Travel Expense Voucher |
| M&E | Monitoring and evaluation | TML | TB Microscopy Laboratory |
| MTaPS | Medicines, Technologies, and Pharmaceutical Services | UHC | Universal Health Care |
| MDR-TB | Multidrug-Resistant TB | USAID | United States Agency for International Development |
| NTP | National Tuberculosis Control Program | USAID | United States Agency for International Development TB Innovations Health System Strengthening Project |
| NTPMO/GFATM | National TB Control Program Management Office - Global Fund to Fight AIDS, TB and Malaria | TBIHSS | |
| NTRL | National Tuberculosis Reference Laboratory | WHO | World Health Organization |
| NTRL-RITM | National TB Reference Laboratory - Research Institute for Tropical Medicine | WRD | WHO-recommended Rapid Diagnostic |
| | | XDR-TB | Extensively Drug-Resistant TB |

Executive Summary

The Philippines' policy and strategic direction for tuberculosis (TB) control and elimination are prescribed in Republic Act (RA) No. 10767: Comprehensive TB Elimination Plan Act of 2016, or the TB Law. The law mandates the Department of Health (DOH) to develop, and lead the implementation of the 2017-2022 Philippine Strategic TB Elimination Plan Phase 1 (PhilSTEP1), the first in a series of national strategic plans that aim to move the country towards its vision of a TB-free Philippines. The attainment of this vision entails the achievement of impact targets by 2022 which include the reduction of TB deaths by 50%, reduction of TB incidence by 23%, the reduction of TB-affected families suffering from the catastrophic costs TB to 0%; with at least 90% of patients satisfied with National TB Control Program (NTP) services. The 2019 passage of the Universal Health Care (UHC) Act (RA No. 11223) provides policy direction to the DOH to rationalize and integrate the financing and delivery of critical health services within an organized healthcare provider network.

NTP Laboratory Network

The NTP organized its laboratory network to provide essential, effective, accessible, quality assured, accurate, equitable, and affordable TB diagnostic services to find TB cases in the country so that they can be treated and cured. The NTP laboratory network is comprised of the National Tuberculosis Reference Laboratory (NTRL), which is at the apex of the network and plays the leadership role, and other laboratories at national, regional, provincial and city, municipal, and barangay level.

The diagnostic tools currently employed by the NTP include smear microscopy, molecular tests with drug susceptibility testing (DST), culture, and culture-based DST deployed at various levels of the network. The tools complement one another to get an accurate diagnosis, which guides clinical staff in providing the most appropriate treatment and patient care based on NTP guidelines. The laboratory test results provide data that can be used as information for evidence-based policy development, research, and improvements in program management, program implementation, and clinical practices.

The LNSP 2018-2022 defines the key areas for laboratory strengthening. It provides strategic focus and direction for the laboratory network based on challenges examined from 2016 to 2018. The LNSP provides an outline of the strategies and activities that will be implemented from 2018 to 2022. Furthermore, it aligns stakeholders to the country's laboratory network goals, objectives, and results and shows the funding required for its implementation.

The LNSP aim to improve cooperation among stakeholders, prevent overlap or duplication of activities, and increase the effective use of resources. The LNSP promotes accountability among stakeholders and will serve as a template for the regional and LGU level health plans to address laboratory network challenges in their localities.

The NTP laboratory network has achieved notable improvements over the years. The range of diagnostic technologies has expanded with the adoption and scale-up of the World Health Organization (WHO)-recommended rapid diagnostic (WRD) tests that allow the simultaneous detection of TB and the presence of rifampicin resistance from sputum within two hours, significantly reducing diagnostic time from months to hours. The program also expanded the availability of TB culture, drug susceptibility testing (DST), and the line probe assay (LPA) capable of detecting a broader range of drug-resistance patterns that can indicate the presence of multi-drug or extensively-drug resistant TB.

However, important challenges remain which limit the optimal performance of the laboratory network. These include the existence of barriers that limit access to services, the presence of factors that hinder timely and continuous service delivery, gaps in laboratory service quality, and the limited utilization of laboratory information which can support decision making and program management.

On the other hand, opportunities are also present that can increase the NTP's capability to address challenges. Financing and technical opportunities are available from the passage of the UHC Act, as well as new tax initiatives that can increase allotments for health. The health priorities of the Philippines are aligned with global priorities, increasing opportunities for technical cooperation and assistance. The development of new technologies for communication have improved the ways people access information to learn or adopt new program directions and approaches.

Program managers must be proactive to make use of the available opportunities. This is particularly important for financing, as laboratory services heavily rely on foreign funds and long-term sustainability would be threatened if foreign financing ends.

Strategic Directions

The NTP defined four priority objectives to address identified challenges.

1. To improve access to quality-assured TB diagnostic services
2. To ensure the continuous availability of TB diagnostic services
3. To strengthen quality management systems (QMS) for TB laboratories
4. To improve utilization of TB laboratory information and conduct of TB research

Objectives 1 and 2 are clear manifestations of the NTP's patient-centered approach as it endeavors to improve access to services, reduce or eliminate out-of-pocket expenses and other opportunity costs, and ensure timely TB diagnosis so that treatment can be started immediately. Objectives 3 and 4 focus on improving the quality of results, decision making, and knowledge generation through research, which will collectively improve the management and delivery of services.

The strategies and activities in Objective 1 aim to increase the availability and accessibility of WRDs, LPA, and culture/DST so that all presumptive TB cases, including patients with rifampicin resistance, will be tested using new technologies. Rapid detection of drug-resistant TB will enable earlier treatment. The specimen referral system will be strengthened to ensure that specimens are collected, transported to the laboratory, and tested within the standard turnaround time (TAT) to eliminate diagnostic delay. The participation of private sector providers will also be strengthened.

Objective 2 activities will address the problem of repeated, and sometimes prolonged, unplanned laboratory downtime that causes interruption to services. Strategies focus on improving laboratory supply chain management to prevent stock-outs of supplies, making laboratory services sustainable through interventions that address human resource shortages, and the improvement of laboratory equipment and facility maintenance.

The activities in Objective 3 aim to strengthen laboratory QMS so that laboratories will be able to produce highly accurate, reliable, and timely results by establishing and reinforcing quality assurance management systems for all laboratories.

Objective 4 activities will further develop the NTP information system capacity for laboratories and treatment facilities via the Integrated TB Information System (ITIS). This aims to improve the collection and analysis of data and increase operational research. The results and knowledge gained from activities will help improve program management and service delivery.

Estimated annual financing for LNSP 2018-2022 implementation allocates the largest amounts for activities under Objective 2, followed by Objective 1. The implementation of LNSP 2018-2022 will involve the creation of multi-year operational plans at all levels. Additionally, monitoring and evaluation plans at all levels of the network will ensure monitoring and evaluation activities are conducted regularly and results are reported to stakeholders.

Chapter 1

Introduction

Background

The 2016 Philippines National Tuberculosis (TB) Prevalence Survey estimated that one million Filipinos have tuberculosis, including an estimated 760,000 Filipinos over 15 years of age with pulmonary tuberculosis (PTB). The prevalence of bacteriologically confirmed TB was 1,159 per 100,000 population. The prevalence of TB increased with age and was higher among males.¹

The Philippines' policy and strategic direction for TB control and elimination are prescribed in RA 10767: Comprehensive TB Elimination Plan Act of 2016, or the TB Law.² The law mandates the DOH to develop and lead the implementation of the Philippine Strategic TB Elimination Plan (PhilSTEP). PhilSTEP is the first in a series of national strategic plans that aim to move the country towards its vision of a TB-free Philippines.³ The attainment of this vision entails the achievement of PhilSTEP impact targets by 2022 which include the reduction of TB deaths by 50%, reduction of TB incidence rate by 23%, the reduction of TB-affected families suffering from the catastrophic costs of TB to 0%; with at least 90% of patients satisfied with NTP services.

TB is reiterated to be one of the diseases of action in the national health plan of FOURmula One Plus of the Department of Health in 2017-2022. The FOURmula One plus is a medium-term strategic framework and plan for the health sector in response to the challenges identified in improving health outcomes and the health system. The 2018-2022 LNSP is anchored under the service delivery pillar of FOURmula One plus whose objectives are: increase access to quality essential health products and services; ensure equitable access to quality health facilities; and ensure equitable distribution of manpower.

The passage of RA 11223, or the UHC Law in 2019 provides policy direction to the Department of Health to rationalize and integrate the financing and delivery of critical health services within an organized health care provider networks.⁴ The policy directions of the UHC Law will serve as the framework for the adjustments and enhancements in the organization of TB diagnostic, treatment, and preventive services to make TB care more accessible, effective, and sustainable.

The TB Laboratory Network

The TB Laboratory Network is essential to the NTP and the Philippine health system goal of eliminating TB, thereby improving the population's health status. The elimination of TB will rely strongly on cutting the chain of transmission by finding all TB cases, preferably with bacteriological confirmation whether by smear microscopy, Xpert MTB/RIF assay, or culture; providing them with effective treatment; and curing them as soon as possible.

The NTP organized the laboratory network to provide essential TB diagnostic services that are accessible, quality assured, accurate, equitable, affordable, and effective in finding TB cases in the country so that they will be provided with treatment and cured. The NTP laboratory network is comprised of the National TB Reference Laboratory (NTRL), which is at the apex of the network and plays a leadership role, and other laboratories at national, regional, provincial and city, municipal, and barangay level. The laboratories are situated in hospitals, clinics, stand-alone laboratories, and community health stations. The majority of NTP laboratories are in public facilities, while a smaller number are managed by private organizations, either non-profit or for-profit. Laboratory services are free of charge for patients if utilized within the NTP's service delivery network.

The NTP’s laboratory services utilize a mix of old and new technologies with varied capabilities and levels of operational difficulty. The laboratory-based diagnostic tools currently employed by the NTP include smear microscopy, molecular tests with DST, culture, and culture-based DST. These tools are deployed at various levels of the network and complement each other in order to get an accurate diagnosis which guides clinical staff to provide the most appropriate treatment and patient care based on NTP guidelines. The laboratory test results also provide data for disease and drug resistance surveillance that can be used as information to support evidence-based policy development; research; and improvements in program management, program implementation, and clinical practices.

Strategic Plan for the TB Laboratory Network

The LNSP 2018-2022 is a sub-plan of PhilSTEP1. LNSP defines the key areas of laboratory strengthening based on PhilSTEP1 strategies 3, 4, 5, and 6 (Table 1). The LNSP provides strategic focus and direction for the laboratory network. It is based on challenges identified by local studies completed between 2016 and 2018 and guided by recommendations from the World Health Organization (WHO)⁵, the Global Laboratory Initiative (GLI)⁶, and the 2016 NTP Joint Program Review (JPR) Report⁷. LNSP provides an outline of the strategies and activities that will be implemented within the specified period. Furthermore, it aligns stakeholders to the country’s laboratory network goals, objectives, and results; and shows the funding required for its implementation. LNSP is a tool that improves cooperation among stakeholders, prevents overlap or duplication of activities, increases the effective use of resources, and ensures leadership at all levels.

LNSP also helps promote accountability among stakeholders and ensures that their contributions to LNSP achievements will be recognized. Moreover, LNSP will serve as a template for regional and local government unit (LGU)-level health plans to address lab network challenges in their localities.

| Table 1. TB Laboratory Network Components in PhilSTEP1 Strategies | | |
|---|---|---|
| PhilSTEP1 Strategies | | TB Laboratory Network Components |
| Strategy 3 | Galvanize local and national efforts to ensure adequate and competent human resources | Human resources, training, laboratory protocols |
| Strategy 4 | Advance the generation of TB information and utilization for decision making | Electronic and mobile technology; monitoring and supervision; research; program review, program internal review; data quality control |
| Strategy 5 | Guarantee compliance to national standards of TB care and prevention and availability of quality TB products and services | Supply management system; quality assurance system (QAS); biosafety and biosecurity; equipment and facility maintenance; quality of commodities |
| Strategy 6 | Expand the provision of integrated patient-centered TB services | Expansion of new diagnostics; private laboratory engagement; specimen referral systems; laboratory infrastructure |

LNSP Development Process

The LNSP development process employed a stepwise approach utilizing information gathering, consultations, and consensus-building among stakeholders at all levels of care. The planning activities were organized by the core teams from NTRL and the United States Agency for International Development-funded TB Innovations and Health System Strengthening Project (USAID’s TBIHSS). A series of consultation meetings were conducted among NTP, NTRL, international and local partners, and other key stakeholders from July to August 2018. A three-day workshop was held September 5-7, 2018 which produced the first draft of the LNSP 2018-2022 document. Inputs to the next drafts came from meetings and workshop discussions. The planning process provided opportunities for decision makers, managers, partners, and implementers to extensively discuss and reflect on the laboratory network’s challenges; to agree on the priority objectives, strategies, and activities; and to determine the required resources.

Chapter 2

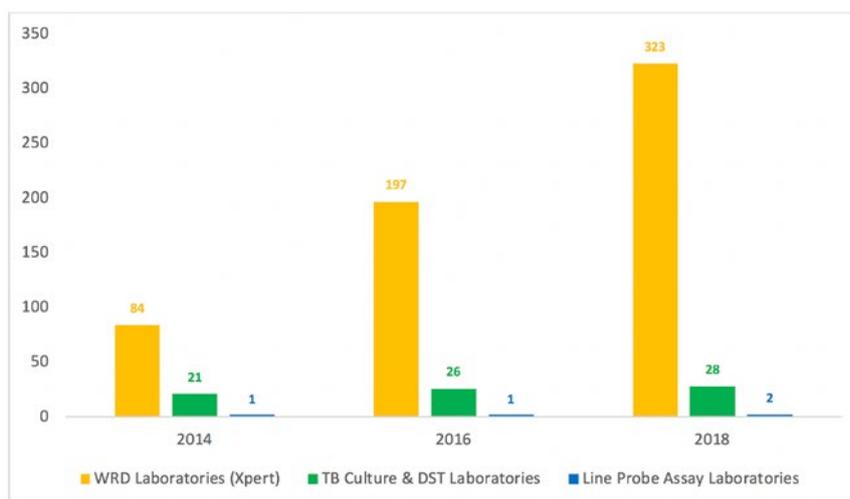
Situational Analysis

The situational analysis was conducted using national studies, particularly the 2016 NTP Joint Program Review, 2016 National TB Prevalence Survey, and the 2016 TB Catastrophic Cost Study. The findings of the studies; a review of PhilSTEP1, the WHO END TB Strategy, the GLI Framework of Indicators for Laboratory Strengthening and other relevant documents; as well as insights from laboratory teams, consultation meetings, workshops, local and international partners contributed to an analysis of the strengths, weaknesses, opportunities, and threats that informed in the development of the LNSP.

Achievements

The NTP has been improving access to diagnostic and treatment services over the past two decades which have contributed to an increase in the number of notified cases to the NTP.⁸ The expansion of the TB laboratory network saw the adaptation of the WRD test that is able to detect TB in sputum specimens within two hours. WRD, in the current Philippine context, refers to the Xpert MTB/RIF[®] assay, a nucleic acid amplification test that can simultaneously detect TB and the presence of rifampicin resistance in sputum within two hours. The test sites for WRDs were established in locations where high TB prevalence is expected, local political support is strong, infrastructure is available, and referral networks are available for complementary tests including X-rays.

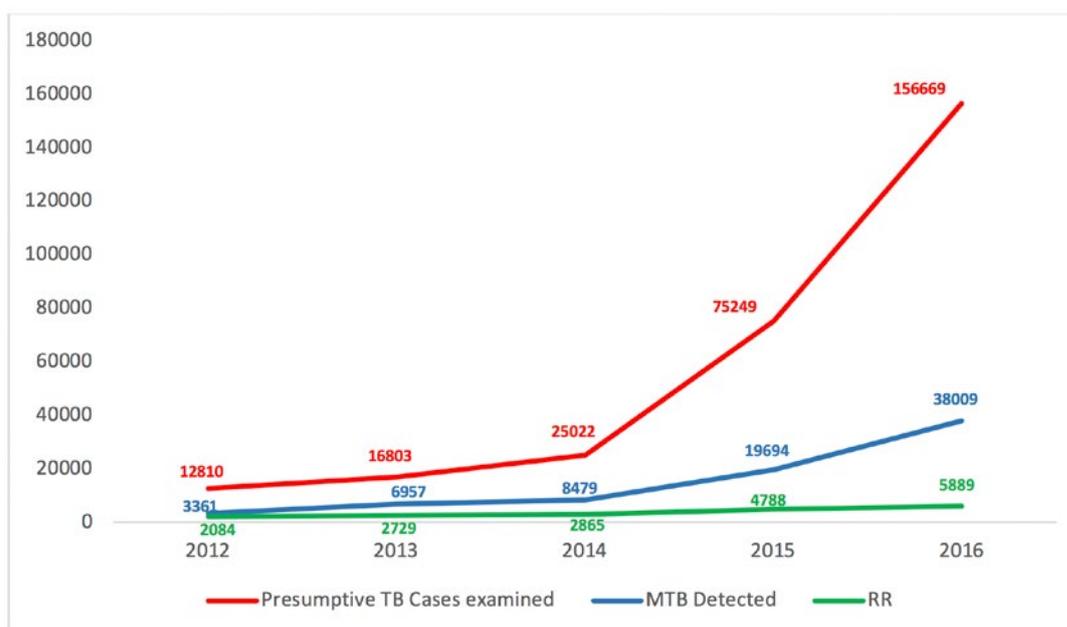
Figure 1. Expansion Trend of Specialized TB Diagnostics in NTP, 2014-2018



In addition, the NTP also expanded the availability and indications for the use of specialized tests such as culture/DST and LPA. Figure 1 shows the trend in the number of laboratories providing specialized diagnostics in the NTP network.

The NTP's adoption and scale-up of new technologies to complement the traditional smear microscopy has dramatically transformed the ability of the program to find TB cases. To further optimize the yield from new technologies, TB diagnostic algorithms were redesigned, tested, and modified. By prioritizing vulnerable groups, the NTP was able to promote equitable access to diagnosis. Data from the NTP shows that the number of presumptive TB cases tested with WRDs, as well as the number of TB cases found, including those with rifampicin resistance, showed an upward trend from 2012 to 2016 (Figure 2) as a result of the adoption of WRD tests.

Figure 2. Number of Presumptive TB Cases Examined and Diagnosed with TB and Rifampicin Resistance with WRD, 2012-2016



The coordination of NTP stakeholders, partners, and providers was also strengthened to ensure that stakeholders' priorities and resources are aligned with national objectives. More funds were mobilized from domestic sources (e.g. taxes, LGUs) and donors (e.g. The Global Fund to Fight AIDS, Tuberculosis, and Malaria) which enabled the scale-up of new technologies; and the expansion, improvement and sustaining of existing services. Supply chain and logistics, governance, and management capacity building is under way at the national level and in selected regions to address supply issues that hamper service delivery.

Health worker deployment schemes by the DOH, supported by manpower from donor-funded projects, enabled the deployment of additional nurses and medical technologists to areas with serious workforce shortages. On the other hand, regional NTP managers implemented task-shifting schemes wherein non-professional community health workers and volunteers were trained to perform selected laboratory-related tasks (e.g. sputum collection, smear preparation) correctly and safely.

NTP and NTRL launched initiatives for regional capacity building to allow decentralized laboratory training management and implementation aimed at addressing training delays and backlogs. The initiatives include the development of a training decentralization strategy; the implementation of enhanced training-of-trainers courses; and the establishment of new, and the upgrading of existing, regional laboratory training facilities that will meet international standards.

Improved processes in laboratory planning, monitoring, and evaluation were also instituted at the national and regional level. The implementation of quality assurance schemes, biosafety, and waste management practices at all levels are also undergoing enhancements. Efforts to develop or update tools and standard operating procedures, and conduct trainings are already building capacity for laboratory information management and utilization.

Combined efforts to strengthen the NTP's laboratory systems have contributed to increased access to TB diagnosis, improved capacity, and better overall laboratory performance. Table 2 shows the NTP's case finding results from 2015 to 2017. The figures show an increase in the number of notified cases, illustrating improvements in access to diagnosis and drug susceptibility testing, at least for rifampicin resistance, from 1% to 19%.^{9,10}

The improved diagnostic capacity of the laboratory network is further demonstrated by the increased proportion of bacteriologically confirmed TB cases, including those with multi-drug resistant (MDR-TB) and extensively drug-resistant (XDR-TB) bacteria; and by the increased proportion of patients who were tested with WRDs at the time of diagnosis.

| Table 2. TB Case Notifications, Philippines 2015 and 2017 9,10 | | |
|--|---------|---------|
| | 2015 | 2017 |
| Total cases notified | 286,544 | 328,773 |
| Total new and relapse | 276,672 | 317,266 |
| % tested with rapid diagnostics at time of diagnosis | 20% | 26% |
| % with known HIV status | 13% | 24% |
| % pulmonary TB | 97% | 98% |
| % bacteriologically confirmed pulmonary TB | 36% | 39% |
| TB treatment coverage | 85% | 55% |
| % of notified tested for rifampicin resistance | 1% | 19% |
| Laboratory-confirmed MDR/RR-TB cases | 3,788 | 6,438 |
| Laboratory confirmed XDR-TB cases | 2 | 15 |

Challenges

The analysis of the laboratory network situation showed that in spite of its achievements, there are still improvements needed to realize TB elimination targets. For example, the figures in Table 2 also indicate that access to services still needs improvement. The proportion of cases tested with WRDs at time of diagnosis, while improved, is still far from the desired level. Moreover, the proportion of patients tested for rifampicin resistance is still very low.

From the analysis of the laboratory network's performance, four priority challenges were identified that serve as barriers to the laboratory network's optimal performance.

1. Existence of barriers that limit access to services
2. Presence of factors that hinder timely and continuous service delivery
3. Gaps in laboratory service quality
4. Limited utilization of laboratory information

Existence of barriers that limit access to services

Barriers to access include availability, accessibility, affordability, and acceptability. TB diagnostic services (i.e. TB microscopy laboratories) are now widely available in the country. However, access to WRDs, particularly the Xpert MTB/RIF and LPA testing sites, is still inadequate.

Most TB patients are poor and reside in marginalized communities with inadequate basic services. Poor road infrastructure, an expensive and unreliable transport system, and long distances to laboratories inhibit access for indigenous patients.¹¹ The limited number of WRD sites, plus problems in the laboratory systems that limit the laboratories' functionality, have prevented its wider use as the NTP's primary diagnostic test, leaving a number of health facilities no choice but to revert to TB smear microscopy as the initial TB bacteriology test.

The specimen referral system remains weak. This contributes to limited service access for the poor, as it imposes high financial and opportunity costs to have their specimens transported to the laboratory. The costs for the specimen packaging and transport are often borne by patients, and by their families, or by the inadequately compensated peripheral field health workers, who are also poor.

Inadequate engagement of private care providers has also limited patient referrals and their access to WRDs. Anecdotal evidence suggests that many private sector physicians still prefer X-rays over bacteriology tests for TB diagnosis because they believe X-rays are sufficient to diagnose TB. The engagement of private and other public-sector non-NTP laboratories in NTP laboratory activities is still inadequate, particularly in terms of quality and affordable service delivery, reporting, and participation in quality assurance programs.

Presence of factors that hinder timely and continuous service delivery

Most of the factors that hinder the delivery of timely and continuous services are related to laboratory system capacity. Workforce recruitment and retention issues lead to staff shortages, causing disruptions in services as medical technologists, as well as non-professional laboratory workers, have to attend to several laboratories. In some places, the TB laboratory is non-functional because there is no medical technologist or a suitable alternate worker.

In some WRD sites, the workload caused by the high volume of specimen referrals has led to long specimen queues, delaying testing. This prolongs TATs, thereby delaying diagnosis and treatment. Power supply is unstable in many areas, and air-conditioning, which is important for Xpert machines and cartridges, is usually available only for limited periods of time. This has potential implications in machine durability and cartridge integrity.

Supply management issues such as poorly coordinated procurement planning, storage problems, and issues regarding distribution and quality assurance have led to stock-outs of essential supplies particularly specimen containers, culture media, reagents, and Xpert cartridges.

The systems for equipment and facility maintenance remain poorly organized and inadequately funded. This, together with a weak LGU infrastructure, has caused breakdowns in either equipment or facilities, or both; causing unplanned laboratory downtimes and the interruption of services. Additionally, the current financing policies of DOH prevent the use of its funds for capital outlay, equipment upgrades or replacements, which serves as a barrier to ensuring sustainable services.

Gaps in the quality of laboratory services

A formal TB laboratory QMS is being implemented at the NTRL but is not yet in place for the rest of the NTP laboratory network. The TB microscopy quality assurance program is ongoing, anchored on the external quality assessment (EQA) of peripheral microscopy laboratories performed by the provincial and city NTP-QA teams. However, its implementation remains inadequate due to gaps in the systemic capacities of the QA teams. A similar system of EQA designed for the other tests such as Xpert, culture, DST, and LPA has not yet been established by the NTP.

Systematic monitoring and assessment of laboratory performance is not performed on a regular basis. Observations during field monitoring visits showed that laboratory workers are using outdated or inappropriate protocols, or no protocols, for the procedures being performed. Even the conduct of internal quality control procedures particularly at the peripheral level has been variable. These are indications of a fragmented system that prescribes the standards, approaches, and required capacities for ensuring high-quality laboratory performance. This also shows a lack of prioritization and capacity to perform specific laboratory monitoring.

Policy guidance on biosafety, biosecurity, and waste management is lacking. A process for the certification of laboratory equipment and infrastructure is implemented by the Research Institute for Tropical Medicine (RITM)'s Biomed Department across all culture and DST laboratories before they start operations. However, this is a temporary mechanism courtesy of RITM; and this will likely be discontinued in the near future because of constraints to their own capacity. In addition, problems regarding laboratory supplies that do not meet quality standards or specifications have not been resolved.

Waste management practices are also far from ideal due to unclear guidelines, weak policies and systems, lack of supplies, and inadequate training and supervision. This is an important issue because of the potential implications to the safety of health workers, the physical environment, the community, and its residents.

Training of laboratory staff also needs improvement to ensure the safe and correct conduct of procedures from pre-analytic to post-analytic stages. The NTP's laboratory training technologies, policies, and management approaches need to be updated and streamlined to ensure all laboratory workers receive timely, effective training. It is also necessary to strengthen the employee support system that will nurture, motivate, and incentivize public health care workers.

Information system gaps that limit utilization of laboratory information

The creation of the ITIS provided improvements to the NTP information system, particularly in reporting and data gathering. This has enhanced data collection and retrieval in terms of time and convenience. However, the ITIS laboratory module is not yet completely

developed which limits its usefulness to laboratory services. Currently, there is no laboratory connectivity system that can be used for recording, reporting, and monitoring.

Reporting forms are integral to the information system. TB culture laboratories are not using standard reporting forms, and computation of indicator-based performance is not standardized across all TB culture laboratories. Program implementation reviews and data quality check activities are periodically conducted but the methodologies employed are variable and of inconsistent quality. The overall effectiveness of these activities to ensure good data quality has not yet been determined.

The increased capacity to gather laboratory-related data has not been translated to better management and use of information to support research, policy development, decision making, planning, and knowledge generation at all levels. Even EQA data that has accumulated over the years has remained largely unused for analysis, interpretation, and reporting of results. Findings from past assessments and discussions indicate that this gap is due to inadequate policy guidance, and to the lack of skills and tools to perform critical appraisal of data that will enable the optimal use of laboratory information.

Opportunities and Threats

Better health cooperation and resources provide opportunities to strengthen the laboratory network's performance. The passage of the UHC Act opens up new avenues for obtaining needed resources since a major thrust of the law is health system strengthening, to which the laboratory network can easily belong to and be one of its priorities. Additional funds for health care are also forthcoming from "sin taxes" on alcohol and tobacco sales. Current local health concerns and priorities align with the global health community, creating more opportunities for technical cooperation, partnerships, and technical assistance.

Arrangements for technical assistance or cooperation with technical and development organizations are still in place; however, local managers and decision makers must innovate or be creative to maximize technical assistance benefits. These opportunities can be used to obtain support for laboratory strengthening, including local innovations to health and laboratory systems. Strengthening laboratory systems is a long-

term process that requires substantial resources and the political will to institute cultural shifts. Gathering support for systems strengthening should be a high priority to make the laboratory network resilient - able to address new challenges, sustain its gains, and institute further development.

Program managers need to be proactive in taking new initiatives or actions (e.g. research) that exploits the existing or emerging funding opportunities to improve the operations and performance of laboratory networks. However, competition for resources will be considerable.

Technical partnerships with the private health sector, academe, and the business community may provide opportunities to build capacity to address the identified barriers in human resources, equipment maintenance, supply chain management, training, and supervision.

Modern and inexpensive technologies are available and can be utilized to provide remote learning for public health workers. In addition, these new technologies can be easily used to enhance communications to support monitoring, supervision, consultation for problem solving, and information sharing for advocacy to enhance political and financial support.

Materials, including technical guides that indicate policy trends and updates, are freely available online. These can be used to help understand programmatic trends; improve knowledge and skills in laboratory techniques, monitoring, and assessment of laboratory systems performance; and guide planning and management.

Current reliance on donor funding and support threatens laboratory service sustainability. If donor funding is reduced or terminated, existing laboratory systems would be severely under resourced. The current funding situation should provide the impetus for the TB laboratory network managers and decision makers to explore the integration of TB laboratories into the National Health Laboratory Network. This may lead to the development of a stronger and more resilient national laboratory network and systems.

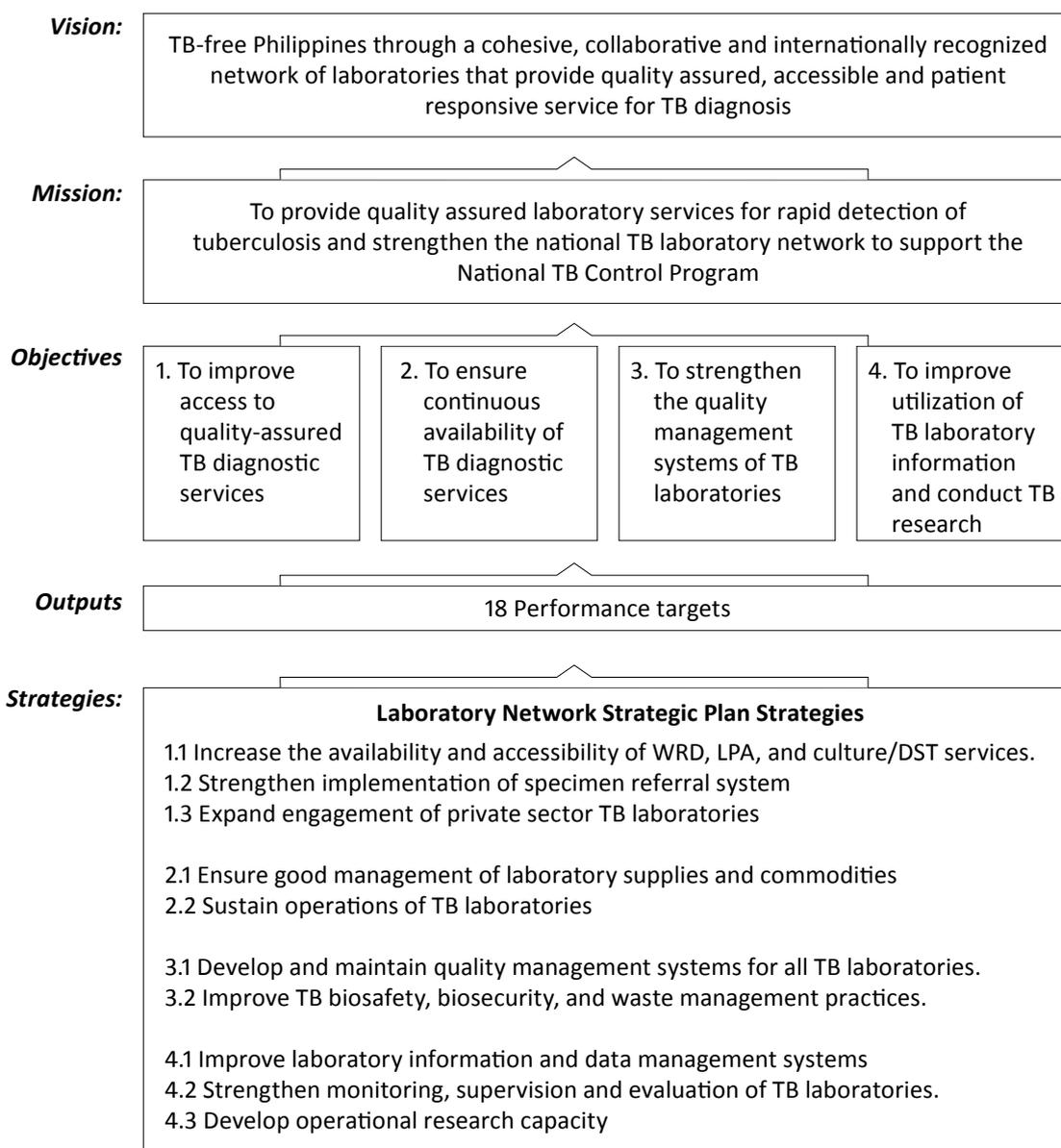
Chapter 3

Strategic Directions

Framework of the 2018-2022 Laboratory Network Strategic Plan

The logical framework below shows how the country will accomplish the vision and milestones related to TB diagnostic Network in support to the goal of the National TB Control Program “TB Free Philippines”.

Figure 1. Logical framework of 2018-2022 LNSP



The LNSP, as a sub-plan of PhilSTEP1, has adopted its vision. The planning group, however, has formulated the laboratory network's own vision and mission statements that align to PhilSTEP1 (Box 1).

Box 1: LNSP Vision and Mission Statement

NTP Vision: TB-free Philippines

Laboratory Network Vision: A TB-free Philippines through a cohesive, collaborative, and internationally-recognized network of laboratories that provide quality-assured, accessible, and patient-responsive services for TB diagnosis.

Laboratory Network Mission: To provide quality-assured laboratory services for rapid detection of tuberculosis and strengthen the national TB laboratory network to support the NTP.

This chapter describes the LNSP objectives (Box 2) that will address the priority challenges identified in the situational analysis. The corresponding strategies, activities, and performance targets for each objective are further described to provide context and guidance to national, regional, provincial, and city level planners when they create their respective operational plans to implement the LNSP. The LNSP objectives, activities, and targets reflect the laboratory activities and targets of PhilSTEP1 and are informed by WHO's framework of indicators and targets for laboratory strengthening.¹²

To enable the implementation of the strategies, the relevant NTP policies, guidelines, and algorithms will be updated; appropriate operational plans and budgets will be developed, and resources will be provided. Strengthening the laboratory systems will be a priority in order to improve access, support the establishment and maintenance of new laboratories, and sustain the delivery of quality-assured services.

Box 2: Objectives of LNSP 2018-2022

1. To improve access to quality-assured TB diagnostic services
2. To ensure continuous availability of TB diagnostic services
3. To strengthen quality management services for TB laboratories
4. To improve utilization of TB laboratory information and conduct of TB research

Objective 1: To improve access to quality-assured TB diagnostic services

Improving access to laboratory services is a manifestation of the NTP's patient-centered approach as it addresses important issues such as high out-of-pocket expenses and related opportunity costs, delayed or missed TB diagnosis, inaccessible treatment, and missed opportunities to be cured. In this objective, access to services will be improved by strategies and activities that will:

- Increase the availability and accessibility of WRDs, LPA, and culture/DST in the public sector;
- Strengthen the specimen referral and transport system; and
- Expand the engagement of private sector TB laboratories.

Strategy 1.1: Increase availability and accessibility of WRD, LPA, and culture/DST services

Performance targets and outputs:

1.1.1 95% of presumptive TB cases are tested using WRD

1.1.2 100% of RR-TB cases are tested using second line LPA and phenotypic DST

The major activity in this strategy is to increase the number of testing sites for Xpert MTB/RIF, LPA with second-line anti-TB drug-DST capability, and liquid culture/DST, especially in the public sector. The use of new generation technologies (e.g. Xpert MTB/RIF Ultra) that are proven to be more effective from a program perspective will be considered. The establishment and operational planning for new test sites will be done with the participation of key local stakeholders using NTP/NTRL's criteria and checklists.

The expansion of laboratories will take into consideration the opportunities that will be available through the implementation of the UHC Law; mechanisms for the future integration of the TB laboratories into the National Health Laboratory Network will be explored. Program managers will ensure that intensified and active case finding strategies appropriate to the local context are implemented to optimize results and performance against targets.

Strategy 1.2: Strengthen implementation of the specimen referral and transport system

Performance targets and outputs:

- 1.2.1** Policy on specimen referral and transport system approved and implemented
- 1.2.2** 100% of specimens referred to laboratories are tested
- 1.2.3** 90% of referred specimens are tested within standard laboratory turnaround time
- 1.2.4** 95% of referring facilities have sustainable specimen referral mechanism

The expanding network of laboratories improves accessibility of laboratories. However, this will not completely address the need for an effective and efficient way of transporting specimens. Given the geography of the Philippines, an effective specimen referral system is critical to improve access to services and achieve the NTP's case finding targets and the performance targets in Strategy 1.1.

The specimen referral and transport system will ensure that the required specimens are collected, packed, and transported correctly and safely, and ensures the specimen integrity throughout the transport process. Additionally, it ensures that all specimens referred are analyzed and that test results are communicated immediately to the clinic staff within the standard laboratory TAT. The standard NTP laboratory TATs are: three to five days for smear microscopy; three days for Xpert MTB/RIF Assay, and nine weeks for solid culture.

To achieve this, the organization of the specimen referral system will be strengthened through the implementation of a comprehensive policy describing leadership structure, mandates, governance, and management. Mandates will cover monitoring and evaluation, staff roles and functions, training, procurement of services for transporting specimens, and financing.

Local level plans and budgets will be developed to sustain the effective operation of the system. Detailed and updated procedures and protocols for specimen collection, storage, packaging, transport, and disposal of laboratory waste materials will be developed and used as training aids and standard work instructions at all levels.

The NTP managers will work to ensure uninterrupted supply and quantities of standard and quality-assured materials for specimen collection, packaging, and transport (including the cold chain), as well as the supplies for managing laboratory waste.

All health workers involved in the specimen collection and transport process, including non-laboratory personnel, will be trained to ensure processes are performed correctly and safely. Training of health workers will contribute to the overall goals of laboratory quality assurance.

Strategy 1.3: Expand engagement of private sector TB laboratories

Performance targets and outputs:

- 1.3.1** 100% of private TB laboratories in the locality are engaged with the NTP laboratory network
- 1.3.2** 100% of engaged private TB laboratories are reporting

The participation of the private sector, whether for profit or not, is important to the country's TB elimination initiatives. The NTP's achievements engaging private hospitals and individual providers are commendable. However, the engagement of private laboratories needs to be strengthened further to harness their potential contribution to the goal of making quality assured services more available, accessible, and affordable.

The engagement of private sector TB laboratories needs to be more organized; with clear, updated terms of reference that describe the coordinating structure, roles, functions, and expectations of private laboratories and the NTP. The policy will be developed through the leadership of the NTRL in collaboration with technical partners and key stakeholders.

Training for private sector laboratory staff will be done to enable their effective participation in the delivery of services. Training-related activities will be coordinated by the NTRL. Implementation training will be done in collaboration with regional and provincial NTP teams and private sector partners. The progress and results of private sector engagement efforts will be monitored and assessed regularly.

| Table 3: Objective 1 strategies and performance targets | | |
|--|--|---|
| Objective | Strategy | Performance Targets |
| To improve access to quality-assured TB diagnostic services | 1.1 Increase the availability and accessibility of WRD, LPA, and culture/DST services | 1.1.1 95% of presumptive TB cases are tested using WRD 1.1.2 100% of RR-TB cases are tested using second line LPA and phenotypic DST |
| | 1.2 Strengthen implementation of specimen referral system | 1.2.1 Policy issuance on specimen referral system implemented 1.2.2 100% of specimens referred to laboratories are tested 1.2.3 90% of referred specimen are tested within laboratory TAT 1.2.4 95% of referring facilities have sustainable specimen referral mechanism |
| | 1.3 Expand engagement of private sector TB laboratories | 1.3.1 100% of private TB laboratories in the locality are engaged with the NTP lab network 1.3.2 100% of engaged private TB laboratories are reporting |

Objective 2: To ensure continuous availability of TB diagnostic services

Interruptions in diagnostic services are usually due to problems related to infrastructure or laboratory systems, or both. Problems related to facility or equipment breakdown, unstable power supply, staff recruitment and retention, and stock-outs of essential laboratory supplies are the leading causes of service interruptions. This objective aims to address the gaps in laboratory systems to reduce or prevent interruptions secondary to laboratory downtime by:

- Improving supply management, and
- Ensuring sustainable laboratory operations.

Human resource is a vital element in the continuous operations of TB laboratories. Measures to retain medical technologists across local, regional, and national laboratories must be implemented to ensure the continuous operations of TB laboratories.

Strategy 2.1: Ensure good management of laboratory supplies and commodities

Performance targets and outputs:

- 2.1.1** No stock-outs of laboratory supplies and commodities at all laboratories

The strategy and activities aim to improve the laboratory supply chain management system through an improved procurement process, quality assurance, storage, distribution, information management, and monitoring to ensure the continuous supply of quality-assured commodities. A national and localized procurement plan will be developed, guided by forecasting and quantification data. It will take into consideration variations in procurement practices at the national and local level, and by donor-assisted projects. The coordination of supply chain management activities at all levels will be strengthened.

Strategy 2.2: Sustain operations of TB laboratories

Performance targets and outputs:

- 2.2.1** Human resource plan and program for TB laboratory services implemented
- 2.2.2** 100% of TB laboratories have uninterrupted services

This strategy aims to address the gaps in human resources and laboratory maintenance to ensure continuous operations. A considerable proportion of human resource funding to operate TB laboratories is secured through foreign-assisted projects. LGU-funded staff in peripheral diagnostic facilities are facing various challenges in managing TB case finding efforts against other tasks.

An analysis of the current and future human resource needs will be done, including the identification of performance gaps and training needs. The findings will be used to inform the development of a human resource program and plan. Advocacy will be conducted to national agencies including the DOH and Department of Budget and Management, and to the LGUs to implement the human resource program. Previous workforce enhancement initiatives implemented by government may have to be sustained as stop-gap measures while more permanent solutions are developed.

Capacity building for laboratory workers, in both public and private sector, must be strengthened and implemented on a continuous basis so that workers will become capable to perform various TB tests. A system for the effective supervision of laboratory workers will be implemented.

To enable the timely and effective implementation of trainings, some of the managerial roles and responsibilities of the laboratory training program will be delegated to sub-national levels. This decentralization will reduce the heavy training workload of NRTL and will prevent training delays. The policies, plans, and capacity building activities will be created and implemented to enable the regional and provincial NTP Teams to perform the delegated tasks. In addition, continuous training of trainers will be done for regional and LGU staff. This set of activities and interventions will ensure that all newly hired or assigned lab workers are given timely and effective training and supervision.

A comprehensive facility and equipment maintenance policy, program, and plan will be designed in collaboration with government and private stakeholders, donors, and technical partners. The policy will provide options to implement laboratory equipment and facility maintenance work effectively and efficiently appropriate to various levels of the laboratories network. More importantly, the policy will describe the governing structure with clearly defined roles and functions. It will also guide the creation of plans and budgets and the provision of other resources including staff, infrastructure, training, and equipment.

| Table 4: Objective 2 strategies and performance targets | | |
|---|--|---|
| Objective | Strategy | Performance targets |
| To ensure continuous availability of TB diagnostic services | 2.1 Ensure good management of laboratory supplies and commodities | 2.1.1 No stock-outs of laboratory supplies and commodities at all laboratories |
| | 2.2 Sustain operations of TB laboratories | 2.2.1 Human resource plan and program for TB laboratory services implemented 2.2.2 100% of TB laboratories have uninterrupted services |

Objective 3: To strengthen QMS of TB laboratories

TB laboratories should function within standards to deliver high-quality services with accurate and timely results. This objective focuses on the development and implementation of a QMS for TB laboratories based on the model endorsed by WHO and GLI. The model focuses on broad system strengthening approaches rather than just test quality assurance methods.¹³ Additionally, the activities will strengthen laboratory EQA implementation, biosafety, biosecurity, and waste management.

| Strategy 3.1: Develop and maintain QMS for all TB laboratories |
|--|
| <i>Performance targets and outputs:</i> |
| 3.1.1 95% of all TB laboratories are under a well-functioning QAS |
| 3.1.2 At least 50% of TB laboratories performing culture, LPA, and phenotypic DST are implementing a formal QMS |

The key activities aim to enhance current policies and guidelines on quality assurance for smear microscopy, and to build the implementers' capacity to perform EQA functions. A similar system for the other diagnostic technologies that have been adopted by the NTP will be developed and implemented. Plans and budgets for EQA activities will be developed to strengthen organizational capacity of the LGUs' quality assurance teams. These teams will be trained and given tools to improve their capacity to perform their technical supervisory and problem-solving functions, and improve their skills in data analysis, interpretation, and use of information for making laboratory-related decisions.

To ensure that operations are within standards, a formal QMS model will be developed by the NTRL and instituted in all NTP facilities performing TB culture, LPA, and phenotypic DST. This model will be patterned on the QMS model developed by the WHO, the United States Centers for Disease Control and Prevention, and the Clinical Laboratory Standards Institute. The model, which is fully compatible with International Organization for Standardization standards, organizes all laboratory activities into 12 quality system essentials that serve as building blocks for quality management. Each block must be addressed if overall laboratory quality improvement is to be achieved. Under the coordination and leadership of NTRL, national and regional program managers will develop their respective quality assurance and QMS plans and budgets to ensure implementation.

Strategy 3.2: Improve TB biosafety, biosecurity, and waste management practices

Performance targets and outputs:

3.2.1 100% of TB laboratories meet biosafety, biosecurity, and waste management standards

Laboratory biosafety, biosecurity, and waste management are a combination of measures aimed at reducing TB transmission risks in laboratories. It is crucial that laboratories, at all levels, implement and adhere to proper practices to minimize TB laboratory-associated infections and prevent the unwanted spread of TB. Health care facilities, including laboratories, contribute a substantial amount to all health care waste materials nationally, many of which are considered hazardous.

Policies, guidelines, and plans for biosafety and biosecurity will be updated and implemented at all levels. Standardized biosafety protocols appropriate for the various laboratory levels will be developed and disseminated for implementation. Laboratory workers at all levels will undergo training on biosafety and biosecurity practices. Strict monitoring of adherence to standard biosafety and biosecurity practices will be implemented.

Findings regarding laboratory waste management practices showed many variations in peripheral health facilities and laboratories in both rural and urban areas. These variable practices are due to factors including inadequate supplies for correct waste management, weak or irregular waste collection schedules especially in LGUs that are utilizing private hauling contractors, and a lack of clear protocols for laboratory waste management. Many health workers and managers are not fully aware of the waste management practices, especially final disposal and potential hazards for health workers and the community generated at facilities.

The comprehensive policies, guidelines, and procedures for laboratory waste management will be developed and implemented in collaboration with relevant government agencies, LGUs, private organizations, and stakeholders. Collaboration activities will include the DOH, Department of Environment and Natural Resources, Department of Interior and Local Government, technical partners, and environment protection advocates. The policies will prescribe the mandates, organization, financing, leadership, and management of the laboratory waste management system.

The coordinating mechanisms for the implementation and monitoring of laboratory waste policies will be strengthened and updated to ensure the compliance of all concerned agencies and facilities particularly the clinics, hospitals, and laboratories in both the public and private sector. Trainings, orientations, and supportive supervision will be done to ensure that laboratory workers are able to perform the procedures correctly. Work aids and standard operating procedures will serve as ongoing reference tools for laboratory personnel. For this measure to succeed, it is crucial that laboratory supplies of good quality and adequate quantity are always available in laboratories, including basic laboratory personal protective equipment, spill kits, disinfectant solutions, and hand soaps.

Table 5: Objective 3 strategies and performance targets

| Objective | Strategy | Performance targets |
|---|--|---|
| To strengthen the quality management systems of TB laboratories | 3.1 Develop and maintain quality management systems for all TB laboratories | 3.1.1 95% of all TB laboratories are under a well-functioning QAS 3.1.2 At least 50% of TB laboratories performing culture, LPA, and phenotypic DST or combination implementing formal QMS |
| | 3.2 Improve TB biosafety, biosecurity, and waste management practices | 3.2.1 100% of TB laboratories meet biosafety, biosecurity, and waste management standards |

Objective 4: To improve utilization of TB laboratory information and conduct TB research

Laboratories generate data which, when analyzed and interpreted, become sources of valuable information that can support research, generate knowledge, provide evidence for policy and guidelines development, guide program management, and enable disease surveillance. Under this objective, the LNSP aims to address the inadequate utilization of information by improving laboratory information and data management systems:

- By strengthening laboratory performance monitoring and evaluation;
- Through supportive supervision; and
- By developing capacity to perform operational research.

Strategy 4.1: Improve laboratory information and data management systems

Performance targets and outputs:

- 4.1.1** 100% of laboratory reports are generated on time using case-based electronic data
- 4.1.2** 100% of TB laboratories participating in data quality check and data reviews

Activities in this strategy aim to address the need for generating accurate and timely reports from the laboratory network. Policies, guidelines, and strategies to promote data quality and management will be developed and implemented. The policy will assign mandates; define responsibilities for data governance and leadership; define the purpose of data collection; determine data ownership; and describe the intended use of data. Furthermore, the guidelines will outline clinical data standards and the requirements for a national minimum data set that will be identified by a group comprised of national program managers, policy makers, and stakeholders. The strategies, on the other hand, will outline the approaches to ensure data integrity at all stages from data entry, collection, verification, validation, aggregation, storage, analysis, and data sharing.

ITIS will be strengthened and updated for laboratory use. The growing number of Xpert MTB/RIF machines and other diagnostics require a data connectivity solution, to be addressed by this strategy. These technologies will improve data gathering capacity which will feed data to the ITIS database and build case-based reporting capability. This will provide the regional and LGU TB teams needed access to real-time data which they can quickly analyze to assess local case finding efforts.

Strategy 4.2: Strengthen monitoring, supervision, and evaluation of TB laboratories

Performance targets and outputs:

- 4.2.1** All priority TB laboratories are monitored and supervised on-site at least once within a year and periodically/quarterly via remote monitoring by the regional and/or provincial/city health office

The activities within this strategy aim to address the need for more frequent and targeted monitoring (on-site and remotely) of the TB laboratory network especially for priority TB laboratories identified by the national, regional, and local laboratory network managers. The activities will involve the development of practical policies, guidelines, and strategies that regions and provinces can follow. Annual monitoring and evaluation (M&E) plans and budgets for laboratory services will be developed and implemented by the regional, provincial, and city laboratory network managers. This will help ensure that activities are supported by funds, logistics, and other required resources. In addition, current test-specific monitoring tools will be updated.

Training on the monitoring of TB laboratories will be provided to NTP coordinators at the regional, provincial, city, and municipal level through the NTP’s Integrated Program Management Course. This training complements NTRL’s training on laboratory performance monitoring and assessment for staff of culture laboratories.

Regional, provincial, and city NTP managers will create supervisory plans to be implemented with the external quality assessment and laboratory field monitoring activities to maximize on-site visits. NTP regional and provincial/city coordinators will also be trained to enhance their skills in performing competency assessments and supportive supervision. Selected medical technologists and other professionals will be trained as trainers.

Strategy 4.3: Develop operational research capacity

Performance targets and outputs:

4.3.1 100% of CHDs conducting or participating in operational research

Research is integral to the End TB Strategy but is usually conducted at the national level. This strategy addresses the lack of regional or local operational studies that can generate knowledge and information to provide evidence for improvements in policies, program management, planning, service delivery, and patient care practices. Activities in this objective focus on improving capacity to conduct operational research.

The Center for Health Development Offices (CHDs) will craft research agendas so that studies will focus on priority research questions or topics appropriate to the regional context and situation. Plans and budgets will be created and implemented by CHDs to ensure that planned research activities are conducted with supportive funds. Once research is complete, CHDs will ensure results are shared, reported, published, and used to support decision making and policy development. The CHD and LGU health staff will be trained to conduct operational research including the development of research agendas, managing research, reporting, and publishing study results, and generating and applying knowledge from research studies.

Table 6: Objective 4 Strategies and performance targets per laboratory network strategy

| Objective | Strategy | Performance targets |
|--|--|---|
| To improve the utilization of TB laboratory information and conduct of TB research | 4.1 Improve laboratory information and data management systems | 4.1.1 All laboratory reports are generated on time using case-based electronic data 4.1.2 All TB laboratories are participating in data quality check and data reviews |
| | 4.2 Strengthen monitoring, supervision, and evaluation of TB laboratories | 4.2.1 All priority TB laboratories are monitored and supervised on-site at least once within a year and quarterly via remote monitoring by the CHD or provincial health office (or both) |
| | 4.3 Develop operational research capacity | 4.3.1 100% of CHDs conducting or participating in operational research |

Chapter 4

Implementation Process

The most important aspect of LNSP 2018-2022 is its implementation. The implementation process will start at the national level, rolling out to the regional and LGU level including provinces, cities, municipalities, and communities. The LNSP roll-out process will involve the creation of operational, or implementation, plans and budgets from the national to the LGU level. Operational plans will describe details on prioritized activities for that year. The process will also adhere to principles practiced in the development of the LNSP including broad stakeholder consultation, consensus building, evidence-based decision making, and prioritization of problems, objectives, strategies, activities, and targets to ensure focus in the plans.

National Level

NTRL will lead, coordinate, and monitor the implementation process at the national level with the support of regional NTP coordinators. Implementation planning will be guided by the framework developed for the LNSP (Annex 1). NTRL will organize the dissemination of the approved LNSP to CHDs and facilities, preferably in 2019. The process will include an orientation of program managers and partners who will lead LNSP implementation at sub-national levels. NTRL will lead national level annual operating plan development, stakeholder coordination, and mobilization of resources (financial, human, technical, and material). NTRL will report on implementation progress to national NTP managers and stakeholders.

Regional Level

The cascade of LNSP implementation activities to the LGU level will be led by regional NTP staff with technical assistance from the NTP, NTRL, technical partners, and stakeholders. CHDs will develop regional laboratory strengthening plans that are aligned with the national LNSP and integrated into the regional PhilSTEP1 plans. Regional laboratory strengthening plans will be informed by the regional situation, NTP results, and local health priorities. Regional planning will ensure broad stakeholder participation involving LGUs, technical partners, private sector, implementers; and the Regional Coordinating Committee (where committees exist). Prioritization of activities and other decisions will be based on evidence. DOH regional NTP teams will lead and coordinate orientation and advocacy activities at the LGU level, providing guidance to the provincial and city level planners.

Provincial and City Level

Provincial and city health offices will create their respective multi-year and annual laboratory strengthening plans using the regional LNSP as a reference and include these in provincial and city health investment plans and budgets. The identification of priority activities for provinces, cities and municipalities will be informed by the local context, while being guided by the regional LNSP and annual operating plans. Provincial and city health offices will help mobilize human, technical, and material resources and logistical support from LGUs and barangays to complement the national and regional resources for LNSP implementation. Provincial and city health offices will monitor, evaluate, and report the implementation of their respective laboratory strengthening plans.

Chapter 5

Monitoring and Evaluation

Monitoring is the systematic and continuous collection of indicator-based data that will show the progress of plan implementation, the extent to which the objectives are achieved, and progress in the use of allocated funds. Evaluation refers to the objective assessment of implementation and the results that were achieved. Instituting monitoring and evaluation promotes stewardship and accountability for the implementation and results of the LNSP.¹⁴

Leadership and Coordination of M&E Activities

The NTRL will assume the leading role for LNSP M&E, including the coordination of national and regional M&E activities. The NTRL will ensure that M&E reports are generated and shared with stakeholders.

Development of M&E Plans

M&E plans and budgets for LNSP will be created at national, regional, and provincial and city level. The M&E plan will include the framework of indicators, data collection approaches, schedules, terms of reference for those involved in M&E activities, budget, and other resources needed. The M&E plans will guide the collection, analysis and interpretation of data, as well as reporting, and the use of results (e.g. for additional planning). The regional NTP coordinators will provide guidance to sub-national levels to develop their M&E plans. Implementation of M&E plans will be monitored by NTRL and regional NTP teams.

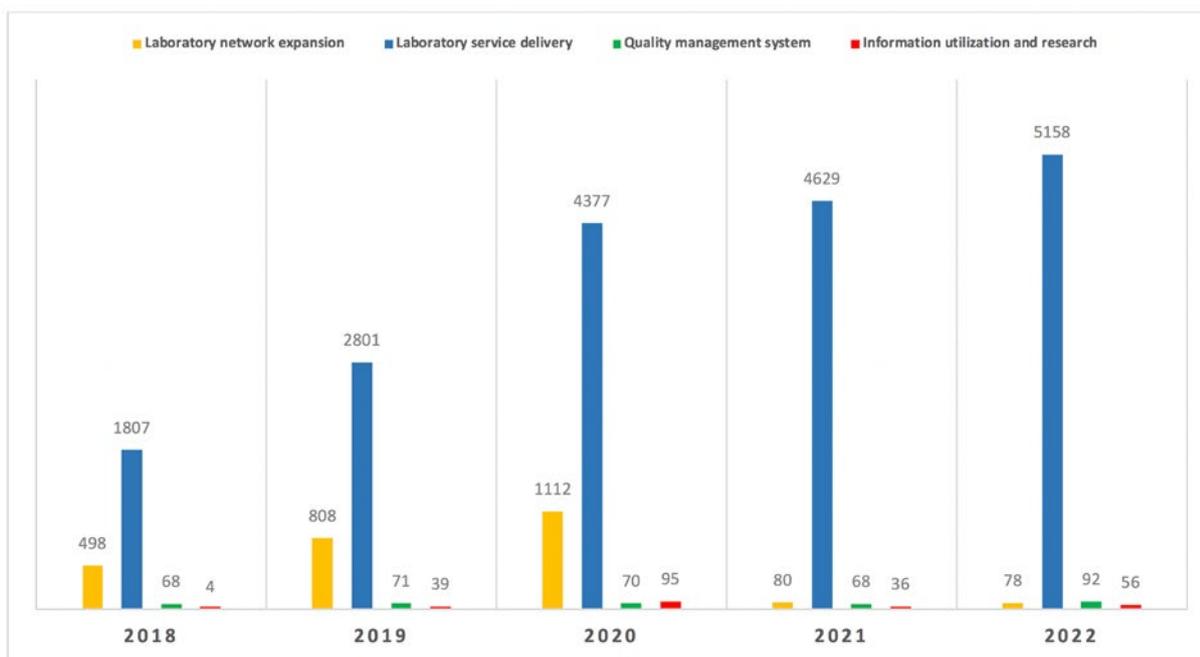
The LNSP national document will provide the minimum set of indicators (M&E Framework, Annex 2) which all levels must refer to. In certain instances, the regional, provincial, and city managers can expand their framework by creating additional performance indicators to enable the collection of specific data useful for local program management. The collection of additional data can be part of routine M&E planned activities or can be designed in a research context. Any information and knowledge gained from the additional data should be shared with all stakeholders.

Chapter 6

LNSP Fund Requirements

The fund requirements (budget estimates) were calculated using a modified WHO costing template utilized to develop the PhilSTEP1 budget. The assumptions used to develop the estimated budget were based on the strategies and activities planned in this strategic plan. In addition, the cost items were guided by current costs and estimates, the Global Drug Facility catalogue 2019, as well as PhilSTEP1 cost estimates. Figure 3 shows the annual financial requirements (in millions of pesos) to implement the planned LNSP activities for each objective from 2018 to 2022.

Figure 3. LNSP Annual Estimated Budget by Objective (2018-2022)



The highest estimated funding requirements are for ensuring the continuous provision of diagnostic services under Objective 2 (laboratory service delivery) which highlight the laboratories' critical role in the timely detection of TB patients so that they can be put on treatment. Objective 1 (laboratory network expansion) comes next in terms of the required funds reflecting the high, but necessary, costs of expanding the laboratory network to make services more accessible, particularly for poor patients.

The funding requirements for Objective 3 (quality management systems) are lower than for Objectives 1 and 2 but are equally important in order to ensure that laboratories provide accurate results. Objective 4 (information utilization and research) requirements are the lowest; the activities to be funded in this group will strengthen program management as it provides crucial information and knowledge that will inform the decision-making process.

Detailed annual budgets, as well as fund sources, will be described in annual operational plans.

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Annex 1. LNSP Implementation Matrix 2018-2022

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|---|--|--|--------------------------------------|---------------------|---------------|---------------|---------------|---------------|---|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| OBJECTIVE 1: TO IMPROVE ACCESS TO QUALITY-ASSURED TB DIAGNOSTIC SERVICES | | | | | | | | | | |
| Strategy 1.1 Increase availability and accessibility of WRD, LPA, and culture/DST services | | | | | | | | | | |
| 1.1.1 95% presumptive TB cases are tested using WRD 1.1.2 100% of RR-TB cases are tested using second line LPA and phenotypic DST | 1.1.1.1 Develop national, regional, provincial, local expansion plans | | # of Expansion plans (national, regional, provincial, local) | Approved written plans | | 100% | 100% | 100% | 100% | NTP, NTRL, and development partners (USAID's TBIHSS, TB Platforms, TASC, and FIND, WHO) |
| | 1.1.1.1.1 | Expansion plans issued, released, and implemented across all regions | | | | | | | | |
| | 1.1.1.2 Implement diagnostic algorithm with WRD as initial test for presumptive TB | | # of regions implementing WRD as initial diagnostic test for presumptive TB | | 3/17 regions | 10/17 regions | 17/17 regions | 17/17 regions | 17/17 regions | NTP and NTRL |
| | 1.1.1.2.1 | Policy issued, released, and implemented across all regions | | | | | | | | |
| | 1.1.1.3 Timely procurement and distribution of commodities and supplies | | Availability and implementation of procurement plan | Approved procurement plan | | x | | | | NTP, NTRL and development partners (USAID's TBIHSS, TB Platforms, MTaPS, and Global Fund) |
| | | | 100% of WRD tests and LPA sites with no stock-outs of commodities and supplies | Monitoring reports (stock cards) | | | 100% | 100% | 100% | |
| | 1.1.1.4 Ensure adequate, competent, and committed manpower in TB laboratory services | | 100% of WRD test sites with LGU/DOH-hired staff | Human Resources for Health Directory | | | 50% | 75% | 100% | DOH, NTP, NTRL, and development partner (USAID's Human Resources for Health 2030) |
| | 1.1.1.4.1 | Ensure LGU/DOH counterpart | | | | | | | | |
| 1.1.1.4.2 | Decentralized training from national to regional level | % of regions capacitated via decentralized training programs | NTRL Training Report | 6/17 regions | 17/17 regions | 17/17 regions | 17/17 regions | 17/17 regions | NTRL | |

| Performance Target | Main Activities and Sub-activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--------------------|---|---|---|---------------------|--|--|--|--|---|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| | 1.1.1.5 Facility improvement and enhancement through LGU, DOH HFEP, and donors | 100% of facilities based on expansion plan targets are upgraded | <ul style="list-style-type: none"> Assessment reports On-site readiness checklist | | | | | | |
| | 1.1.1.6 Procurement and distribution of machines/ equipment | # of targeted machines to be procured and distributed/laboratories (functional) (PhilSTEP1) <ul style="list-style-type: none"> POC molecular test (e.g. Xpert) – 1100 LPA – 5 (NTRL, CTRL, LCP, R10, R11) Culture - 29 | <ul style="list-style-type: none"> Purchase order request Payment Delivery receipt Bill of lading | | POC mol. test - 490 LPA - 3 Culture-29 | POC mol. test - 700 LPA - 4 Culture-29 | POC mol. test – 1,100 LPA - 5 Culture-29 | POC mol. test – 1,100 LPA - 5 Culture-29 | NTP, NTRL, and development partners (USAID’s TBIHSS and TASC, and WHO,FIND) |

| Performance Target | Main Activities and Sub-activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|---|---|--|--|---------------------|------|------|------|------|---|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| Strategy 1.2 Strengthen implementation of the specimen referral system | | | | | | | | | |
| <p>1.2.1 Policy on specimen referral approved and implemented</p> <p>1.2.2 100% specimens referred to laboratories are tested</p> <p>1.2.3 90% of referred specimen are tested within standard laboratory TAT</p> <p>1.2.4 95% of referring facilities have sustainable specimen referral mechanism</p> | <p>1.2.1.1 Develop national guidelines on specimen transport and referral system</p> | <ul style="list-style-type: none"> National and localized guidelines on referral and specimen transport developed Increase in the number of laboratory examinations done | <ul style="list-style-type: none"> Approved national and local guidelines on referral and specimen transport NTP laboratory report Monitoring and evaluation report | | X | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS, TASC, and FIND, WHO) |

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--------------------|------------------------------------|---|--|---|---------------------|--------------|--------------|--------------|--------------|---|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| | 1.2.1.1.1 | Consultation with stakeholders (public and private) regarding specimen referral and transport mechanism | | | | | | | | |
| | 1.2.1.1.2 | Development of guidelines for referral and specimen transport mechanism | | | | | | | | |
| | 1.2.1.1.3 | Dissemination of guidelines for specimen referral mechanism | | | | | | | | |
| | 1.2.1.1.4 | Capacity building of staff on specimen packaging and transport system | | | | | | | | |
| | 1.2.1.1.5 | Implementation of specimen referral mechanism | | | | | | | | |
| | 1.2.1.1.6 | Monitoring and evaluation of specimen referral mechanism | | | | | | | | |
| | 1.2.1.2 | Develop localized implementation plan on specimen referral mechanism | Implementation plan on specimen referral mechanism | Approved implementation plan on specimen referral mechanism | | 100% of LGUs | 100% of LGUs | 100% of LGUs | 100% of LGUs | NTRL and development partners (USAID's TBIHSS, TB Platforms, and ACCESS TB) |

| Performance Target | Main Activities and Sub-activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|---|--|---|---------------------|------|------|------|------|--|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| Strategy 1.3 Expand engagement of private sector TB laboratories | | | | | | | | | |
| 1.3.1 100% of private TB laboratories in the locality are engaged with the NTP laboratory network | 1.3.1.1 Mapping of private TB laboratories | Directory of private TB laboratories | Mapping tool | X | X | | | | USAID's TBIHSS |
| | 1.3.1.2 Development of guidelines/ mechanism for engagement of private TB laboratories | Guidelines on mechanism of engagement of private TB laboratories | Approved guidelines on the mechanism of engagement of private TB laboratories | | X | | | | NTRL and development partners (USAID's TBIHSS, TASC) |
| | 1.3.1.3 Advocacy, training, and memorandum of understanding | % of private TB laboratories engaged | MOU | | 5% | 25% | 50% | 100% | NTRL and USAID's TBIHSS |
| 1.3.2 100% of engaged private TB laboratories are reporting | 1.3.2.1 Monitoring of performance of the private TB laboratories | % of private TB laboratories submit notification reports | Monitoring reports | | 100% | 100% | 100% | 100% | |

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|--|--|--|---|---------------------|------|------|------|------|--|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| OBJECTIVE 2: TO ENSURE CONTINUOUS AVAILABILITY OF TB DIAGNOSTIC SERVICES | | | | | | | | | | |
| Strategy 2.1 Ensure good management of laboratory supplies and commodities | | | | | | | | | | |
| 2.1.1 No stockouts of laboratory supplies and commodities at all laboratories | 2.1.1.1 Systematize the procurement, storage, distribution, and monitoring of laboratory supplies and commodities | | | | | X | X | X | X | NTP, NTRL, development partners (USAID's TBIHSS, ACCESS TB, MTaPS, TB Platforms) |
| | 2.1.1.1.1 | Assessment of supply chain management | | | | | | | | |
| | 2.1.1.1.2 | Development of national and localized plan for selection, procurement, storage distribution, and monitoring of laboratory supplies and commodities | Procurement, storage, and distribution plan developed | Approved national and localized supply management plan | | | | | | |
| | 2.1.1.1.3 | Capacity building of staff | | | | | | | | |
| | 2.1.1.1.4 | Implementation of plan | Implemented Guidelines on Laboratory supply management | <ul style="list-style-type: none"> • Periodic forecasting and inventory of laboratory supply • Supply Evaluation Report | | | | | | |
| | 2.1.1.1.5 | Monitoring of implementation plan | % of procured laboratory supply are delivered on time | <ul style="list-style-type: none"> • Monitoring Reports • Inventory reports | | | | | | |
| | 2.1.1.2 Establish and sustain quality management system of laboratory supplies and commodities | | | | | | | | | |

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|---|---|-------------------------|------------------------|---------------------|------|------|------|------|--|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| Strategy 2.2 Sustain operations of TB laboratories | | | | | | | | | | |
| 2.2.1 Human resource plan and program for TB laboratory services implemented. | 2.2.1.1 Ensure continuous operation of TB culture and DST laboratories | | | | | X | X | X | X | DOH, NTP, NTRL, and development partners (USAID's TBIHSS and ACCESS TB) |
| | 2.2.1.1.1 | Assessment of culture and DST laboratory staffing, equipment, facility, and operation | Assessment done | Assessment report | | | | | | |
| | 2.2.1.1.2 | Review and consolidate TB Culture and DST Center data – staffing, equipment, facility, and operations | | | | | | | | |
| | 2.2.1.1.3 | Conduct assessment of TB Culture and DST Center data – staffing, equipment, facility, and operations | | | | X | X | X | X | NTRL and development partners (USAID's TBIHSS and ACCESS TB) |
| | 2.2.1.1.4 | Finalization of assessment findings and presentation to involved laboratories | | | | X | X | X | X | NTRL and development partners (USAID's TBIHSS, TB Platforms and ACCESS TB) |
| | 2.2.1.1.5 | Advocacy | Advocacy plan developed | Approved advocacy plan | | X | | | | NTRL and development partners (USAID's TBIHSS and ACCESS TB) |
| | 2.2.1.1.6 | Identify stakeholders (chiefs of hospitals, administrators, central and regional directors, etc.) | | | | | | | | |
| | 2.2.1.1.7 | Formulate advocacy plan | | | | X | X | | | NTP, NTRL, and development partners (USAID's TBIHSS and ACCESS TB) |

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|---|---|---|--|---|---------------------|------|------|------|------|--|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| | 2.2.1.1.8 | Conduct advocacy | | | | | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS and ACCESS TB) |
| | 2.2.1.1.9 | Continuous capacity building of TB culture and DST laboratories | Capacity building plan implemented and monitored | <ul style="list-style-type: none"> • Approved capacity building plan • Training reports • Directory of trained staff • Monitoring reports | X | X | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS and ACCESS TB) |
| 2.2.2 100% of TB laboratories have uninterrupted services. | 2.2.2.1 Conduct Human resources for health inventory in all TB laboratory network facilities | | Inventory developed | Inventory report | X | X | X | | | DOH and development partner (USAID's Human Resources for Health 2030) |
| | 2.2.2.2 Continuous capacity building of TMLs, training needs assessment, conduct trainings/mentoring/coaching and post-training monitoring and evaluation | | Capacity building plan implemented and monitored | <ul style="list-style-type: none"> • Approved capacity building plan • Training reports • Directory of trained staff • Monitoring reports | X | X | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS and ACCESS TB) |
| | 2.2.2.3 Continuous provision of supplies, commodities, and equipment - Inclusion of needed supplies, commodities, equipment, and maintenance into regional office and LGU budget planning -Procurement and distribution of Auramine staining kits by regional office | | Decentralized procurement and distribution | Annual Operational Plan/WFP/APP | X | X | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS, MtaPS, and ACCESS TB) |

| Performance Target | Main Activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|---|---|--|--------------------------|----------------------------------|-------------------------------|------|------|--|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| OBJECTIVE 3: TO STRENGTHEN THE QMS OF TB LABORATORIES | | | | | | | | | |
| Strategy 3.1 Develop and maintain QMS for all TB laboratories | | | | | | | | | |
| 3.1.1 95% of all TB laboratories are under a well-functioning QAS | 3.1.1.1 Submission of application of NTRL for accreditation to ISO 17043 as Proficiency Testing provider | <ul style="list-style-type: none"> 50% of action plan completed Submitted documents to Philippine Accreditation Bureau | <ul style="list-style-type: none"> Accomplishment reports Receiving copy signed by Philippine Accreditation Bureau | | X (Preparation) | X (Submission) | | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.1.2 Development of quality assurance guidelines | QA guidelines for Xpert MTB/RIF Assay, Culture and LPA developed; Smear Microscopy amended | Approved QA guidelines for Smear Microscopy, Xpert MTB/RIF Assay, Culture and LPA | DSSM | Xpert MTB/RIF Assay, TBC and LPA | | | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.1.3 Development of training programs for laboratory quality assurance | Training programs and modules developed for Xpert MTB/RIF Assay, Culture, DST | Training programs and modules developed for Xpert MTB/RIF Assay, Culture, DST training reports | | | | | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.1.4 Provision of EQA services to all levels of the laboratory network | # and % of TB laboratories trained in QMS % of TB laboratories implementing EQA Baseline: TML = ~75% RTDL = none TBC = none DST = 89% LPA = 100% | EQA Reports | X DSSM, TBC, DST, LPA | X | X Xpert; TBC Panel Testing | X | X | NTP, NTRL, and development partners (USAID's TBIHSS and RIT Japan) |

| Performance Target | Main Activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|---|--|--|---|---------------------|------|------|------|--------|--|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| | 3.1.1.5 Implementation of QA guidelines | % of TML, RTDL, Culture, DST and LPA laboratories implementing QA guidelines | Monitoring Reports | X | X | X | X | X | None |
| 3.1.2 At least 50% of TB laboratories performing culture, LPA and phenotypic DST are implementing a formal QMS | 3.1.2.1 Development of national and regional laboratory QMS Plans | Developed national and regional laboratories QMS Plans | Approved national and regional laboratories QMS Plans | | X | X | | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.2.2 Assessment of quality management systems of TB Culture, DST, and LPA laboratories | 100% of TB Culture, DST and LPA laboratories are assessed (only NTRL) | SLIPTA Checklist (WHO GLI) | | X | X | X | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.2.3 Establish QMS in TB Culture, DST and LPA laboratories | 50% of TB Culture, DST and LPA laboratories implementing QMS (only NTRL) | SLIPTA Checklist (WHO GLI) | | | X | X | X (15) | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.1.2.4 Accreditation of TB Culture, DST and LPA laboratories (ISO 15189) | 35% of TB Culture, DST and LPA laboratories accredited (only NTRL) | Accreditation certificate | | | | | 10 | NTP, NTRL, and development partners (USAID's TBIHSS) |

| Performance Target | Main Activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|--|---|--|---------------------|------|------|------|------|---|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| Strategy 3.2 Improve TB laboratory biosafety, biosecurity, and waste management practices | | | | | | | | | |
| 3.2.1 100% of TB laboratories meet biosafety, biosecurity and waste management standards | 3.2.1.1 Update guidelines and plans on infection prevention & control (IPC), biosafety, biosecurity, and waste management. (national, regional, provincial, city level) | Updated guidelines, policy and plans on IPC, biosafety, biosecurity and waste management. | Approved guidelines, policy and plans on IPC, biosafety, biosecurity and waste management. | | X | X | | | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | 3.2.1.2 Implement guidelines and plans on IPC, biosafety, biosecurity, and waste management | Incidence rate among TB health workers lower than national incidence rate | Special ITIS report | | X | X | X | X | NTP, NTRL, and development partner (USAID's TBIHSS) |
| | | All laboratories meet IPC and biosafety standards | Monitoring reports | X | X | X | X | X | NTP, NTRL, and development partners (USAID's TBIHSS and TB Platforms) |

| Performance Target | Main Activities and Sub-activities | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|---|---|--|-----------------------|---------------------|------|------|------|------|---|
| | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| OBJECTIVE 4: TO IMPROVE UTILIZATION OF TB LABORATORY INFORMATION AND CONDUCT TB RESEARCH | | | | | | | | | |
| Strategy 4.1 Improve laboratory information and data management systems | | | | | | | | | |
| 4.1.1 100% laboratory reports are generated on time using case-based electronic data | 4.1.1.1 Establish data connectivity solution to WRD facilities | 100% of WRD facilities have data connectivity solution | ITIS Report | | 10% | 80% | 100% | | NTP, KMTIS, ITIS NTRL and development partners (USAID's TBIHSS and ACCESS TB) |
| | 4.1.1.1.1 Pilot available data connectivity solutions | | | | | | | | |
| | 4.1.1.1.2 Roll-out of recommended data connectivity solutions | | | | | | | | |
| | 4.1.1.1.3 Integrate data connectivity solution to ITIS | | | | | | | | |
| | 4.1.1.1.4 Monitor the implementation of data connectivity solution | | | | | | | | |
| | 4.1.1.1.5 Evaluation of implementation (i.e. joint/dedicated evaluation) | | | | | | | | |
| | 4.1.1.2 Develop and implement case-based ITIS laboratory module and link ITIS to other information systems | Existence of improved ITIS laboratory module | ITIS Report | | | | | | NTP, KMTIS, ITIS NTRL and development partners (USAID's TBIHSS and ACCESS TB) |
| | 4.1.1.2.1 Assess current information system (ITIS-laboratory module) | | | | | | | | |
| | 4.1.1.2.2 Improve and/or develop comprehensive Laboratory Information System (LIS) | | | X | X | X | X | | |
| | 4.1.1.2.3 Utilize laboratory information system | | | | | | | | |
| 4.1.1.2.4 Monitor laboratory information system | | | | | | | | | |

| Performance Target | Main Activities and Sub-activities | | Indicator | Means of Verification | Gantt Chart/Targets | | | | | Responsible |
|--|--|--|---|--|---------------------|------|------|------|------|---|
| | | | | | 2018 | 2019 | 2020 | 2021 | 2022 | |
| | 4.1.2.2.2 | Implement performance assessment and improvement planning activity | | | | | | | | |
| Strategy 4.2 Strengthen monitoring, supervision, and evaluation of TB laboratories | | | | | | | | | | |
| 4.2.1 All priority TB laboratories are monitored and supervised on-site at least once within a year and periodically/quarterly via remote monitoring by the regional and/or provincial/city health offices | 4.2.1.1 Conduct of monitoring and supervision activities | | 100% of priority TB laboratories are monitored and supervised by regional and/or provincial/city office | Post-monitoring report and/or signed feedback report | | 80% | 100% | 100% | 100% | DOH, NTP, NTRL, LGU, and development partners (USAID's TBIHSS and TB Platforms) |
| | 4.2.1.1.1 | Develop guideline and tool for monitoring and supervision activities | | | | | | | | |
| | 4.2.1.1.2 | Harmonization of laboratory monitoring guidelines and tools | | | | | | | | |
| | 4.2.1.1.3 | Disseminate guideline and tool to regional and/or provincial/city health offices | | | | | | | | |
| | 4.2.1.1.4 | Implement guideline and utilize tool | | | | | | | | |
| Strategy 4.3 Develop operational research capacity | | | | | | | | | | |
| 4.3.1 100% of CHDs conducting or participating operational research | 4.3.1.1 Conduct of operational research | | At least 80% of regional offices have conducted operational research | Research proposal and/or published research | | 30% | 50% | 70% | 100% | DOH, NTP, HPDTB, PCHRD, NTRL, LGU, and development partner (USAID's TBIHSS) |
| | 4.3.1.1.1 | Develop guideline and plan on the capacity building | | | | | | | | |
| | 4.3.1.1.2 | Capacitate identified participants | | | | | | | | USAID's TBIHSS and TB Platforms |
| | 4.3.1.1.3 | Submit research proposal(s) and request for funding | | | | | | | | |
| | 4.3.1.1.4 | Implement research proposal(s) | | | | | | | | |
| | 4.3.1.1.5 | Publish and disseminate results to other forums | | | | | | | | |

Annex 2. M&E Framework of Indicators

| Indicator | Calculation | Baseline | Target in 2022 | Frequency | Responsible Unit/Agency | Level/s of Reporting | Source document | Means of Verification |
|---|---|-------------------------|---------------------------------|----------------------------------|-------------------------|--|--|-------------------------------|
| OBJECTIVE 1: IMPROVE ACCESS TO QUALITY -ASSURED TB DIAGNOSTIC SERVICES | | | | | | | | |
| Population Testing Rate | Numerator: Number of people with signs and symptoms of TB who underwent initial diagnostic test Denominator: Population expressed as percentage | 1.1% (2018) | 2.0% | Quarterly cumulative Annually | NTP | Facility/ LGU, Province/ HUC, Regional, National | NTP Report (Report 1) and DOH Population Estimates | TB Laboratory Register |
| Percentage of notified new and relapse TB cases tested with WRD as the initial diagnostic test. | Numerator: Number of notified new and relapse TB cases tested with a WRD as the initial diagnostic test Denominator: Total number of notified new and relapse TB cases | 20% | 100% | Quarterly cumulative Annually | NTP | Facility/ LGU, Province/ HUC, Regional, National | NTP Report (Report 3a + 3b) | TB Register and DRTB Register |
| Percentage of RRTB tested using second-line line probe assay (SI-LPA) and phenotypic DST | Numerator: Number of RRTB cases tested for SI-LPA Denominator: Number of RRTB cases identified/ notified | No available data (NAD) | 100% | Annually | NTRL | Facility/ LGU, Province/ HUC, Regional, National | NTP Report DST/LPA | TB Laboratory Register |
| Policy issuance on specimen referral and transport system | Specimen referral system guidelines/ policy developed and implemented | No existing policy | Specimen referral system policy | At least one policy issued | NTRL | National | Policy on specimen referral system | Approved policy |
| Proportion of referred specimens tested in laboratory facilities | Numerator: Number of referred specimens tested Denominator: Total number of referred specimens to laboratory | NAD | 100% | Quarterly cumulative Annually | CHD/NTRL | Facility/ LGU, Province/ HUC, Regional, National | Specimen Receiving and Results Releasing Form | TB Laboratory Register |
| Proportion of referred specimen tested within standard laboratory TAT | Numerator: Number of referred specimens within standard laboratory TAT Denominator: Total number of referred specimens to laboratory | NAD | 90% | Quarterly cumulative Annually | CHD/NTRL | Facility/ LGU, Province/ HUC, Regional, National | Specimen Receiving and Results Releasing Form | TB Laboratory Register |

| Indicator | Calculation | Baseline | Target in 2022 | Frequency | Responsible Unit/Agency | Level/s of Reporting | Source document | Means of Verification |
|---|--|----------|----------------|--------------------------------------|---|--|--------------------------------|---|
| Proportion of referring facilities with sustainable specimen referral system | Numerator: Number of referring facilities that have sustainable referral system Denominator: Total number of referring facilities with specimen referral system | NAD | 95% | Annually | CHD/NTRL | Facility/ LGU, Province/ HUC, Regional, National | Annual work and financial plan | Facilities with local policy on specimen referral (e.g. specimen referral activities included in local investment plan for health/ annual budget/work and financial plan) |
| Proportion of private TB laboratories in the locality engaged with the NTP lab network. | Numerator: Number of private TB laboratories engaged Denominator: Total number of identified private TB laboratories in the locality | NAD | 100% | Annually | CHD/NTRL | Facility/ LGU, Province/ HUC, Regional, National | Annual Reports | ITIS |
| Proportion of engaged private TB laboratories in the locality who are reporting | Numerator: Number of engaged private TB laboratories who are reporting Denominator: Total number engaged private TB laboratories in the locality | NAD | 100% | Annually | CHD/NTRL | Facility/ LGU, Province/ HUC, Regional, National | Annual Reports | ITIS |
| OBJECTIVE 2: ENSURE CONTINUOUS AVAILABILITY OF TB DIAGNOSTIC SERVICES | | | | | | | | |
| Proportion of WRD and LPA sites with no stock-outs of commodities and supplies | Numerator: Number of WRD and LPA sites reported no stock-outs Denominator: Number of WRD and LPA sites | NAD | 100% | Quarterly not cumulative Annually | Facility, Province/ HUC, Regional, National | NTRL/ NTP | Quarterly/ Annually | Supply management report/record |
| Percentage of TB laboratories with uninterrupted services | Numerator: Number of TB laboratories with uninterrupted services Denominator: Total number of TB laboratories | NAD | 100% | Quarterly not cumulative Annually | Facility, Province/ HUC, Regional, National | NTRL/ NTP | Quarterly/ Annually | Monitoring report/ record |

| Indicator | Calculation | Baseline | Target in 2022 | Frequency | Responsible Unit/Agency | Level/s of Reporting | Source document | Means of Verification |
|---|--|--|----------------|-----------|-------------------------|----------------------|-----------------------------|--|
| OBJECTIVE 3: STRENGTHEN QUALITY MANAGEMENT SYSTEM OF TB LABORATORIES | | | | | | | | |
| Percentage of TB laboratories that monitor performance indicators and enrolled in an EQA system for all diagnostic methods performed (Smear Microscopy, Xpert MTB/RIF Assay, Culture, DST and LPA). | Numerator: Number of TB laboratories (stratified by type of diagnostic testing) that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed. Denominator: Number of TB laboratories (stratified by type of diagnostic testing) | TML: NAD RDT: NAD Culture: NAD DST: NAD LPA: NAD | 100% | Quarterly | Regional/ National | NTRL | NTP Report on EQA | EQA Feedback Sheet |
| Percentage of TB laboratories performing culture, and/or LPA and phenotypic DST (or combination) with formal QMS that aims to achieve accreditation according to international standards | Numerator: Number of laboratories performing culture, and/or LPA and phenotypic DST (or combination), with formal QMS implemented Denominator: Number of laboratories performing culture, and/or LPA or phenotypic DST (or combination) | 4% (NTRL) | 50% | Annually | Regional/ National | NTRL | ISO 15189:2012 Audit report | ISO 15189:2012 Audit report |
| Percentage of TB laboratories meet biosafety, biosecurity and waste management standards | Numerator: Number of TB culture and DST laboratories meeting biosafety standard Denominator: Total number of functional TB culture and DST laboratories | NAD | 100% | Annually | Regional, National | NTRL | NTP Report (Report 2b) | Biosafety Checklist; Assessment report |
| OBJECTIVE 4: IMPROVE UTILIZATION OF TB LABORATORY INFORMATION AND CONDUCT TB RESEARCH | | | | | | | | |
| Percentage of WRD facilities at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system | Numerator: Number of WRD facilities using a WRD at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system Denominator: Number of WRD laboratories | To be determined | 100% | Annually | Regional/ National | NTRL | Annual Report | ITIS; laboratory connectivity performance report |

| Indicator | Calculation | Baseline | Target in 2022 | Frequency | Responsible Unit/Agency | Level/s of Reporting | Source document | Means of Verification |
|--|--|--|----------------|---------------------|---------------------------|----------------------|-----------------|--|
| Percentage of laboratory are generated report on time using case-based electronic data | Numerator: Number of TB laboratories generated on time case-based electronic data Denominator: Number of TB laboratories | TML: NAD RDT: NAD Culture: NAD DST: NAD LPA: NAD | 100% | Quarterly/ annually | Regional/ National | NTRL | Annual Report | IT IS; laboratory connectivity performance report |
| Percentage of TB laboratories participating in data quality check and data review activities | Numerator: Number of TB laboratories participating data quality checks and data reviews Denominator: Number of TB laboratories | TML:NAD RDT:100% Culture: NAD DST: NAD LPA: NAD | 100% | Quarterly/ annually | Regional/ National | NTRL | Annual Report | ITIS; data quality check activities attendance sheet |
| Percentage of priority TB laboratories are monitored and supervised on-site at least once within a year and periodically/quarterly via remote monitoring by the regional and/or provincial/city health office. | Numerator: Number of TB laboratories monitored and supervised on site at least once within a year and periodically/ quarterly via remote monitoring by the regional and /or provincial/city health office Denominator: Number of priority TB laboratories | NAD | 100% | Annually | Provincial/ City/Regional | Province/ City/CHD | Annual Report | Supervisory Report |
| All center for health development offices conducting or participating operational researches | Numerator: Number of CHDs conducted or participated operational researches Denominator: Total number of CHD Offices | NAD | 100% | Annually | Regional | CHD/NTRL/ NTP | Annual Report | Research papers |