NTP Laboratory Network Assessment: Strategic Directions to Improve Access and Quality of TB Diagnostic Services

Assessment Report

Arthur B. Lagos  
Lynette P. Adorio-Arce  
Marlon L. Bayot  

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- The staff of the study laboratories
# ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALABARZON</td>
<td>Cavite, Laguna, Batangas, Rizal and Quezon Provinces (Region 4A)</td>
</tr>
<tr>
<td>CAR</td>
<td>Cordillera Administrative Region</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>DOTS</td>
<td>directly observed treatment, short course</td>
</tr>
<tr>
<td>DR-PTC</td>
<td>presumptive drug-resistant TB case</td>
</tr>
<tr>
<td>DRTB</td>
<td>drug-resistant TB</td>
</tr>
<tr>
<td>DS-PTC</td>
<td>presumptive drug-susceptible TB case</td>
</tr>
<tr>
<td>DSSM</td>
<td>direct sputum smear microscopy</td>
</tr>
<tr>
<td>DST</td>
<td>drug susceptibility testing</td>
</tr>
<tr>
<td>EPTB</td>
<td>extrapulmonary tuberculosis</td>
</tr>
<tr>
<td>EQA</td>
<td>external quality assurance program / external quality assessment</td>
</tr>
<tr>
<td>GX</td>
<td>GeneXpert</td>
</tr>
<tr>
<td>HUCs</td>
<td>highly urbanized cities</td>
</tr>
<tr>
<td>iDOTS</td>
<td>integrated DOTS</td>
</tr>
<tr>
<td>ITIS</td>
<td>Integrated Tuberculosis Information System</td>
</tr>
<tr>
<td>LGU</td>
<td>local government unit</td>
</tr>
<tr>
<td>LNSP</td>
<td>Laboratory Network Strategic Plan</td>
</tr>
<tr>
<td>LPA</td>
<td>line probe assay</td>
</tr>
<tr>
<td>MDR-TB</td>
<td>multidrug-resistant tuberculosis</td>
</tr>
<tr>
<td>MGIT</td>
<td>Mycobacteria growth indicator tube</td>
</tr>
<tr>
<td>MTB</td>
<td>Mycobacterium tuberculosis</td>
</tr>
<tr>
<td>NCR</td>
<td>National Capital Region</td>
</tr>
<tr>
<td>NEQAS</td>
<td>national external quality assurance system</td>
</tr>
<tr>
<td>NTP</td>
<td>National TB Control Program</td>
</tr>
<tr>
<td>NTRL</td>
<td>National TB Reference Laboratory</td>
</tr>
<tr>
<td>OTJ</td>
<td>on-the-job</td>
</tr>
<tr>
<td>PhilPACT</td>
<td>Philippine Plan of Action to Control Tuberculosis</td>
</tr>
<tr>
<td>PhilSTEP-1</td>
<td>Philippine Strategic TB Elimination Plan Phase One</td>
</tr>
<tr>
<td>PMDT</td>
<td>Programmatic Management of Drug-Resistant Tuberculosis</td>
</tr>
<tr>
<td>PTC</td>
<td>presumptive TB case</td>
</tr>
<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
</tr>
<tr>
<td>RHU/HC</td>
<td>rural health unit/health center</td>
</tr>
<tr>
<td>RIT / JATA</td>
<td>Research Institute of Tuberculosis / Japan Anti-TB Association</td>
</tr>
<tr>
<td>RITM</td>
<td>Research Institute for Tropical Medicine</td>
</tr>
<tr>
<td>SOCCSKSARGEN</td>
<td>South Cotabato, Cotabato, Sultan Kudarat, Sarangani, Gen. Santos (Region 12)</td>
</tr>
<tr>
<td>TAT</td>
<td>turnaround time</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TML</td>
<td>TB microscopy laboratory</td>
</tr>
<tr>
<td>USAID</td>
<td>US Agency for International Development</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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EXECUTIVE SUMMARY

Tuberculosis (TB) is still a major public health problem in the Philippines, and the country is one of the world’s high-TB burden countries. The 2016 country profile of the Philippines showed an estimated incidence rate of 554/100,000, which translates to about 573,000 TB cases, and an estimated mortality rate of 21/100,000, which aligns with the approximately 22,000 TB deaths that were reported in 2015. Key findings from the 2016 National TB Prevalence Survey (NTPS) showed that about 1% of the population are afflicted with TB; with a smear+/culture+ prevalence rate of 286/100,000. Moreover, only 13% of the cases were tested with new rapid diagnostic tests (RDTs), and only 37% had bacteriologic confirmation of their disease. Despite the high TB prevalence, the National TB Program (NTP) notification rate showed that only one-third of detected cases were notified.

The NTP has embarked on the new Philippine Strategic TB Elimination Plan Phase One: 2017–2022 (PhilSTEP-1), setting targets and objectives to significantly reduce TB mortality and prevalence by 2022. Among the key activities in the plan is to ensure the access of all priority patients to rapid TB diagnosis along with drug susceptibility testing for rifampicin. This entails the expanded deployment of the new RDTs, exemplified by Xpert, at the primary level of care. The NTP envisions using RDTs as the initial TB diagnostic test within the short term.

This assessment was done to (1) gather information on the laboratory network’s capacity to provide access to diagnostic services, particularly the new rapid TB diagnostics at the primary level of care, (2) identify factors that serve as barriers to ensuring the provision of continuous and reliable laboratory services, and (3) to propose actions to address the identified barriers.

Assessment findings indicate the following:

- The NTP laboratory network capacity to provide access to diagnostic services, especially RDTs, has improved. The deployment of the Xpert/MTB-RIF assay (Xpert) has contributed to the better detection of TB cases, including those with rifampicin resistance. However, improvement in terms of availability, accessibility, and affordability of services is still needed. The availability of RDTs in existing primary care laboratories is still inadequate, and not easily accessible. The specimen referral and transport system is still weak. In addition, elements within the NTP diagnostic protocol serve as barriers to the completion of the diagnostic process. TB microscopy is still the bacteriologic test that is easily available in areas where RDT laboratories are not yet established.

- The capacity of laboratory staff is still limited in terms of the number of staff relative to workload. The workload is high because staff members perform laboratory services for several health programs, many medical technologists have to run several laboratories at various days of the week, and perform other technical tasks, some of which are beyond their mandates.

- The capacity to ensure the continuous delivery of quality service is also limited. A significant number of laboratory downtime days have occurred due to equipment malfunction, human resource issues, and inadequate supplies. Quality management programs are not yet fully organized, except for TB microscopy.
Executive Summary

- Financing of the new and specialized diagnostic technologies is heavily dependent on external funding, a situation that places the laboratory services in a vulnerable position. There is a high likelihood that services will be affected in various ways once funding is reduced or terminated.

- There is a need to improve the use and interpretation of test results. The knowledge and understanding of laboratory staff, program managers, and clinical staff regarding the use of RDTs (i.e., Xpert), and the interpretation of its results, still need to be strengthened.

Recommendations

**Improve Accessibility of Services**

*Strengthen the Specimen Referral and Transport System*

Review, and possibly revise, the current referral or zoning arrangements to develop more feasible and sustainable specimen referral routes. Develop policies and operational guidelines for implementing the specimen referral and transport system. Provide technical, material, and financial support to program managers and field health workers for the implementation of the system.

*Rationalize the Establishment of New RDT Sites for Increased Availability and Better Accessibility*

Provide technical assistance to NTP managers in reviewing and selecting sites for RDT (Xpert) expansion. Consider local TB burden, location of existing diagnostic (e.g., access to X-ray) and treatment facilities, feasibility of specimen referral routes, and availability of transport. Strengthen the pre-assessment capabilities of program managers and provide assistance to local government units (LGUs) to comply with the requirements.

**Ensure Continuous Delivery of Laboratory Services**

*Establish a Program for Equipment and Facility Maintenance*

The NTP and NTRL should begin establishing an equipment and facility maintenance program in order to have the program fully operational by the end of 2018.

*Enhance Staff Management at the Facility Level*

Address issues in staff recruitment, training, retention, and quick turnover. Develop and implement innovative and feasible programs at the local level to enhance staff motivation, productivity, and job satisfaction. Implement immediately the TB screening program for all health workers. Steps must be taken to reduce “unreasonable” multi-tasking among laboratory staff. Strengthen training and supervision for laboratory staff, particularly those working at the peripheral level.
Improve Monitoring of Laboratory Services Implementation and Performance

Develop performance indicators for monitoring of laboratory services improve the program managers’ capacity to perform monitoring tasks, including their ability to address operational problems. Strengthen the laboratory information system, as well as the program managers’ capacity to use information for managing the laboratory network, and for evidence-based decision making and planning.

Explore Alternative Sources to Ensure the Continuous Financing of Laboratory Operations

Advocate to national agencies, LGUs, and barangays for the provision of resources to finance the laboratory services in their respective areas.

Improve Quality and Reliability of Laboratory Services

Strengthen the Training and Supervision of Laboratory Workers

Build the capacity of the subnational level to manage and implement laboratory trainings other than TB microscopy. Enhance the design, management, and implementation of training courses to ensure trainees get sufficient laboratory practice; and address issues regarding the availability of training equipment and supplies, lack of trained trainers, inadequate logistical support, and weak coordination and collaboration. In addition, ensure that gaps in supervision capacity at all levels are addressed.

Strengthen Implementation of Quality Assurance Activities

Build the capacity of regional, provincial/highly urbanized city (HUC) NTP teams to plan and implement quality assurance activities; support quality assurance (QA) organizational strengthening; and ensure the availability of essential equipment, supplies, and adequate logistical support for QA activities. Enhance QA teams’ skills in data collection, management, and use for program monitoring, evaluation, supervision, planning, and problem solving. The NTRL, in collaboration with regional laboratory managers and technical partners, should organize the quality assurance program for new diagnostics (e.g., Xpert assay, culture/drug susceptibility testing [DST], line probe assay [LPA]). NTRL should also begin developing a laboratory accreditation program and relevant quality standards in accordance with the recommendations of the World Health Organization (WHO) and the Global Laboratory Initiative regarding laboratory quality management systems.

Improve Interpretation and Use of Test Results

Strengthen Guidance to Clinical Staff

Build the capacity of regional and provincial/HUC NTP teams in providing technical guidance to clinicians regarding the use of new RDTs, specifically in the interpretation of test results for patient care. Program managers should organize regular activities (e.g., small meetings, panel
discussions, or short training sessions) to provide updated information and knowledge to clinical staff in their jurisdictions in both the public and private sectors. Regional and provincial NTP teams are advised to document field experiences and observations related to problems in Xpert test result interpretation and use.

**Strengthen Capacity to Conduct Researches**

Provide technical support and enhance the skills of laboratory network managers and implementers to perform relevant operational research that will contribute to improvements in laboratory practices and performance. Periodic reviews of the NTP diagnostic algorithm is recommended to identify factors or steps that serve as barriers to the completion of the diagnostic process. Organize activities to share the results of the research to laboratory implementers, clinic staff, program managers, and other stakeholders.
INTRODUCTION

Background Information on the Philippine NTP

The Philippines is one of the world’s high-burden countries for TB and multidrug-resistant TB (MDR-TB). The 2016 country profile of the Philippines showed an estimated incidence rate of 554/100,000, which translates to about 573,000 TB cases, and an estimated mortality rate of 21/100,000; about 22,000 TB deaths were reported in 2015.1 Key findings from the 2016 National TB Prevalence Survey showed that about 1% of the population are afflicted with TB; with a smear +/culture + prevalence rate of 286/100,000.2 The survey further showed that TB is more prevalent among males and in the older age groups (over 65 years), and its occurrence correlates positively among diabetics, smokers, and poor urban dwellers.

Despite the high TB prevalence, the program’s notification rate showed that only one-third of detected cases was notified in the program. Of the more than 345,000 TB cases notified in 2015, 98% are pulmonary TB (PTB) cases. However, only 13% of the cases were tested with new RDTs, and only 37% had bacteriologic confirmation of their disease.1

The country’s National TB Control Program has implemented the Philippine Plan of Action to Control TB (PhilPACT 2010–2016) to enhance its responses to the TB problem. In 2013, the NTP developed the Laboratory Network Strategic Plan (LNSP 2013–2016) as a sub-plan of PhilPACT. The aim of the LNSP is to improve access to quality diagnostic services and strengthen laboratory support systems to ensure the effective and sustainable provision of services. However, the implementation of the LNSP is limited; the 2013 NTP Joint Program Review recommended its urgent implementation.3

With the goal of reducing TB incidence by 90%, and TB mortality by 95% in the country by 2035, the NTP is strengthening its TB program activities through the Philippines Strategic TB Elimination Plan Phase One 2017–2022 (PhilSTEP-1). From a shorter-term perspective, PhilSTEP-1 aims to reduce TB deaths by 50% and TB incidence by 5% by 2022.4

One of the plan’s key activities is to improve access to laboratory services so that all new and relapse presumptive TB patients, presumptive DRTB cases, and patients belonging to high-risk groups are tested with the new RDTs, using Xpert MTB/RIF assay (Xpert) as the initial diagnostic test, and are able to undergo drug susceptibility testing (DST). Improving access to these services entails the wider deployment and sustained implementation of RDTs while ensuring the quality of laboratory services.

Background Information on the Philippines

The Philippines is comprised of 7,641 islands5 but only about 2,000 islands are inhabited. There are three major island groups, including Luzon, Visayas, and Mindanao, with 17 administrative regions, 81 provinces and 145 cities, 1,489 municipalities, and 42,036 barangays.6 The Philippine population reached almost 101 million in 2015: 63.4% belonged to the working-age
population (15–64 years). Children below 15 years of age comprised 31.8% of the population while older persons (65 years and over) accounted for 4.7%. There were more males in the 0–54 age group, but females outnumbered males among those ages 55 years and older.\footnote{7}

The most populous HUCs with populations over 1 million are Quezon City (2.94 million), City of Manila (1.78 million), Davao City (1.63 million), and Caloocan City (1.58 million). Among the regions, Region 4-A (CALABARZON; Cavite, Laguna, Batangas, Rizal and Quezon Provinces) has the biggest population, with 14.41 million, followed by the National Capital Region (NCR), with 12.88 million, and Region 3 (Central Luzon), with 11.22 million residents. More than one-half of the Philippine population reside in Luzon. The Philippines is classified as a lower middle-income country with a poverty incidence of 26.3% and about 9.2% of Filipino families living in extreme poverty in 2015.\footnote{8}

The country’s transport infrastructure is developed but the services are still inadequate. The urban transport system is composed mainly of buses, a mass transport system (e.g., trains in Metro Manila), jeepneys, taxis, tricycles, pedicabs, and motorcycles with extended seats (also known as habal-habal). Modest improvements in the transport services have been made but the road networks are still generally poor. Water transport development was achieved mainly through the upgraded Roll On—Roll Off services (RO-RO); smaller, inter-island boat and ferry services are also available. Air transport capacity remains limited.\footnote{9}

Advancements in Philippine telecommunications have brought an increased use of telephones (landlines) and mobile phones, digital subscriber lines (DSL), cable networks, cellular sites, and other communication devices. The improved availability, affordability, and use of smartphones increased with better Internet access. However, Internet service in the country is expensive and generally slow; faster Internet connections are available only in HUCs.\footnote{10}

**Purpose and Methods of the Assessment**

The main approaches in PhilSTEP-1 are to improve access to TB diagnosis, particularly RDTs (i.e., Xpert); increase the number of laboratories (availability) in primary care level sites; and ensure the sustained delivery of quality and reliable services within the next five years. However, more detailed information regarding the factors that serve as barriers to achieving these objectives are lacking. Obtaining this information will be useful in guiding the program managers at the national, regional, and LGU levels with developing strategies to achieve PhilSTEP’s performance target of “100% of new and relapse TB cases tested with a point of care (POC) molecular test as a primary diagnostic test” and also help address the problem of missing TB cases.

This assessment was done to (1) gather information on the laboratory network’s capacity to provide access to diagnostic services, particularly the new rapid TB diagnostics at the primary care level, (2) identify factors that serve as barriers to ensuring the provision of continuous and reliable laboratory services, and (3) propose actions to address the identified barriers.
Introduction

Information was collected from a sample of laboratories through the review of records and reports, analysis of routinely reported laboratory data, interviews of key laboratory workers and managers (Annex A), field observations, and group discussions. A sample of 33 laboratories was included in this assessment, situated at various levels of the network and located in 12 cities and provinces in 8 administrative regions of the country. These consist of the NTRL, 11 culture laboratories, 3 DST centers (integrated within the culture center), 8 quality assurance centers, 12 microscopy laboratories located in RHU/HCs, and 1 Xpert site at a Programmatic Management of Drug-Resistant Tuberculosis (PMDT) treatment center.
FINDINGS AND ANALYSIS

Capacity to Provide Access to Diagnostic Services

The NTP has established a network of laboratories to provide various tests for patients in the program. The network is a three-tiered structure that provides services at the central, intermediate, and peripheral levels. A laboratory referral system facilitates the transfer of specimens if higher-level testing is required. The services are free of charge for patients under the NTP. Figure 1 shows the services provided at the different levels of the network.

The NTP has been strengthening its laboratory services since the late 1990s with the implementation of DOTS. The improvements in diagnostic services are made to support the enhancements to TB treatment, which includes the adoption of shorter treatment regimens for MDR-TB, the integration of MDR-TB management into the regular DOTS services in primary care facilities (iDOTS), and the use of novel drugs for DRTB treatment.

WHO-recommended RDTs with DST, exemplified by the Xpert MTB/RIF assay (Xpert), was adopted by the NTP in 2011. In 2013, the NTP Laboratory Network Strategic Plan (LNSP) was developed with the aim of improving access to TB diagnosis, ensure quality of services, and strengthen the laboratory systems. However, the implementation of LNSP has been limited.

In accordance with WHO’s policy recommendations on Xpert rollout, new policies, guidelines, and diagnostic algorithms were developed by the NTP to support RDT scale-up and use.\textsuperscript{11,12,13} The policies will enable a broader group of patients (i.e., presumptive DRTB patients, vulnerable groups) to access RDTs, particularly Xpert, as the initial diagnostic procedure instead of smear microscopy.
Availability and Accessibility of NTP Diagnostic Services

One way to improve availability and accessibility is to increase the number of testing sites. The expansion of laboratories has been ongoing for the past several years, in accordance with the implementation of LNSP. In 2016, the diagnostic services that are available in the NTP network included: TB microscopy, provided by more than 2,700 laboratories; Xpert services, in 207 sites; TB culture, available in 24 of 27 laboratories established; DST in three existing culture centers; and LPA in one laboratory (NTRL) of the target three laboratories.

More than 70% of the NTP laboratories were in the public sector as of 2016; over 50% of the existing Xpert sites are situated in intermediate-level facilities such as district, provincial, or tertiary-level hospitals; and in specialized laboratories and tertiary medical centers. These facilities are not easily accessible to most TB patients. Xpert testing is also available in a few private tertiary medical centers; however, the tests are expensive in these facilities and are generally unaffordable for most TB patients. The rest of the Xpert sites are located in primary care facilities such as RHUs and health centers.

The RDT (Xpert) scale-up in recent years did not meet its targets in terms of number and schedule due to a number of factors that served as barriers to the expansion process. The discussions during the 2017 regional laboratory planning workshop revealed barriers to the expansion of RDT-equipped laboratories. These barriers include inadequate infrastructure for power supply, particularly in island municipalities; inadequate space and ventilation requirements in the facility; difficulties in transporting equipment and supplies; and security concerns, especially in conflict or high-crime areas.

Other factors also served as barriers, for example: the reluctance of some LGUs to accept the establishment of Xpert laboratories due to the planned additional workload for already-overloaded laboratory staff, as well as the expected increase in LGU expense to support operations. In addition, some field workers fear infection with MDR-TB strains during the handling of DRTB diagnostic and treatment services. On the other hand, the most frequent barrier in getting the Xpert sites operational are delays in the completion of facility renovations or repairs, delays in the delivery and/or installation of major equipment, and late delivery of essential laboratory supplies.

While the new policies for the expanded use of Xpert have been approved, their implementation remains limited due to shortages in the supply of cartridges, which contributed to the poor availability of services. The limited cartridge supply led to the prioritization of DRTB patients for Xpert testing and the exclusion of other high-risk presumptive TB patients.

The number of available Xpert laboratories relative to their catchment LGUs or facilities is small (table 1). This gap gives rise to a large number of referring facilities from the catchment areas, a situation that will result in demand that exceeds the capacity of the laboratory to test the referred specimens. The distance to the referral laboratories, long travel time, and high transport costs further limit accessibility to testing. Issues regarding the location of some existing Xpert sites were raised by a few program coordinators, as these are now proving to be inaccessible to a large segment of the target population.
Another obstacle to optimal Xpert service availability is the inadequate amount of time given to Xpert testing by some laboratory staff, since most primary care labs are also providing other services, for the other public health programs. Moreover, many primary-level labs are not operating on a daily basis because their Med Tech-in-charge has to run several laboratories on certain days of the week.

**Table 1. Number of Xpert labs and catchment areas by region, 2016**

<table>
<thead>
<tr>
<th>Region</th>
<th>No. labs</th>
<th>No. catchment LGUs or facilities</th>
<th>Ratio of lab to catchment LGUs or facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cagayan valley (R2)</td>
<td>4</td>
<td>23</td>
<td>6 LGUs</td>
</tr>
<tr>
<td>Central Luzon (R3)</td>
<td>19</td>
<td>126</td>
<td>7 LGUs</td>
</tr>
<tr>
<td>CALABARZON (R-4A)</td>
<td>25</td>
<td>109</td>
<td>4 LGUs</td>
</tr>
<tr>
<td>Eastern Visayas (R-8)</td>
<td>7</td>
<td>136</td>
<td>19 LGUs</td>
</tr>
<tr>
<td>Zamboanga Peninsula (R-9)</td>
<td>8</td>
<td>20</td>
<td>3 LGUs</td>
</tr>
<tr>
<td>CARAGA (R-13)</td>
<td>7</td>
<td>94</td>
<td>13 facilities</td>
</tr>
<tr>
<td>SOCCSKSARGEN (R-12)</td>
<td>6</td>
<td>64</td>
<td>11 facilities</td>
</tr>
</tbody>
</table>

**Capacity of the NTP Specimen Referral and Transport System**

The specimen referral route is based on the zoning of laboratories that was put in place by NTRL and NTP coordinators starting in 2011 to facilitate the safe and efficient transport of samples from referring clinics to testing sites. Given the limited accessibility of existing laboratory services, the role of the specimen referral and transport system is crucial.

Discussions during the regional laboratory planning workshops\(^{14}\) showed that the laboratory network’s referral and transport system is still poorly organized and is not adequately supported with funds and logistics. The procedures for coordination of referrals, proper storage, packaging, transport and receipt of specimens, and financing of the system have not been clearly described. Approaches to the implementation of the specimen transport system varied among regions and LGUs, particularly at the primary care level.

Packaging and labeling specimens correctly is essential in order to preserve sample quality and safety, and to prevent administrative mistakes during transport, receipt, and processing of specimens. The system for specimen transport from PMDT sites to referral laboratories is relatively well supported through the Global Fund and Department of Health (DOH) resources, but not so in the case of primary care DOTS facilities, for which specimen transport is financed through barangay or health center funds, or as an out-of-pocket expense of patients or health workers. The lack of proper packaging materials, inadequate knowledge of correct packaging among field health workers, and inadequacy of the cold chain were also mentioned as gaps in the system that have compromised specimen quality, and possibly even test results.

Given the state of the country’s transport system, moving specimens from peripheral health facilities to laboratories is difficult and expensive. As mentioned earlier, the cost of specimen transport is borne to a large extent by the patients or by the health center in primary care facilities, a liability that renders the process unaffordable and is considered a financial burden. In
many instances, the other option is for patients to bring their specimens to the referral laboratory themselves.

In many rural areas, the availability of transport providers that could serve as couriers is limited. Public transport options include small boats, buses, tricycles, and motorcycles (habal-habal). These services are expensive and not ideal for ensuring the integrity of specimens, especially if these are improperly packed.

**Barriers within the NTP Diagnostic Protocol**

TB diagnosis relies on the presumptive TB cases (PTC) undergoing laboratory tests for bacteriologic confirmation. If tests are negative, patients have to undergo other diagnostic procedures, such as tuberculin skin testing, chest X-ray, and clinical evaluation, which may even include medical specialist consultation for difficult cases.

The TB diagnostic algorithm is a complex process and some of its parts can act as barriers to diagnosis. The algorithm presumes that patients, including child PTCs, smear-negative adult PTCs, and extrapulmonary TB cases, move seamlessly (by means of referral) to other diagnostic services for further testing. This is not always the case, however, because most non-laboratory procedures are not easily available, accessible, or free of charge, as these are not part of the NTP’s routine referral diagnostic services.

Under the NTP protocol, patients with negative diagnostic smear examinations must have a chest X-ray, and those with radiologic findings suggestive of TB should undergo Xpert testing. There are little data about the proportion of smear-negative patients who had chest X-ray in the NTP. The limited data from Quezon City showed that only about 18%–22% of the smear-negative patients (PTCs) were able to obtain a chest X-ray in 2014. Many of these patients belong to the urban poor segment of the population and most are not able to have a chest X-ray because of its high cost. Another observation is that the smear-negative PTCs were not adequately followed up for further tests in the diagnostic protocol.

The small proportion of patients tested with RDTs may be partly a result of the small number of smear-negative patients who had chest X-rays. For patients who are unable to have a chest X-ray, the TB diagnostic process usually stops at this point and they are lost from the system as they default from the diagnostic process. The smear-negative PTCs without X-rays, but with the patience and resources to follow-up at the clinic, are usually diagnosed on clinical grounds.

**Processing of Extrapulmonary Specimens**

Extrapulmonary TB (EPTB) cases comprised only 2% of the total notifications in 2015. EPTB detection in the NTP has been low for many years. Several studies have shown that the expected proportion of EPTB cases is higher, and can range from 10% to almost 26% of total TB notifications. Discussions with regional and provincial NTP med tech coordinators and NTRL staff revealed barriers in the diagnosis of EPTB, even with the use of Xpert.

First, the extraction process of extrapulmonary (EP) specimens is not easily performed in primary care facilities (i.e., RHUs, HCs) and patients have to be referred to secondary- or
tertiary-level health facilities. The referral process entails added expense to patients and becomes a barrier. Second, the processing of EP specimens is not easily performed in most Xpert sites; specimens have to be referred to higher-level laboratories where these can be processed correctly and safely. Since most Xpert operators in the country are not trained to process EP specimens, or their laboratories are not equipped for this, all EP specimens from primary and secondary health facilities are sent to the NTRL for processing. This requirement prolongs the turnaround time, causing long delays in the diagnosis and treatment of patients, and increases the cost of the diagnostic process.

**Workload Capacity of Peripheral Laboratories**

The 2014 data from NTRL showed that the average workload of the Xpert labs averages around two tests per day. Data from our study Xpert labs showed an average daily workload of four specimens; workload distribution among the labs showed that 17% had a daily workload of more than 10 specimens per day, another 17% had over six specimens per day; and 33% had less than two specimens per day. The relatively low workload in some labs is due to poor accessibility of Xpert facilities, limited opportunities for specimen referral, lack of information, and the limited supply of cartridges.

However, with the expanded indications for use of RDTs, especially at the primary care facilities, workload can be expected to increase if the barriers are addressed. Using the Xpert four-module machines, a primary-level facility will realistically be able to process at most three batches of four specimens, for a total of 12 tests, per day. Anecdotal reports from program managers described backlogs in testing due to the prolonged waiting time (from the queuing of specimens) in some Xpert sites with high workload due to the limited testing capacity of a single four-module machine. Referral facilities, as well as primary care facilities with high patient load (e.g., more than 12 patients per day), such as those in densely populated urban poor settlements, may require more than one four-module machine and extra staff to test all of its PTCs daily.

The Xpert study labs in primary care centers (RHUs, HCs) provide TB microscopy and an assortment of lab services for infectious disease health programs (e.g., HIV testing) and for other noninfectious health programs (e.g., routine laboratory examinations, blood chemistry). The majority of the labs also serve other health facilities, with the number of referring clinics ranging from 5 to 11, on top of their own catchment areas.

In addition, some laboratory staff are also performing external quality assessment (EQA) functions (i.e., slide rechecking), which are beyond their official mandates; as mentioned previously, some med techs are handling several laboratories in their areas on various days of the week. These multi-tasking arrangements have significantly increased the workload of lab staff, which reduced the time allotted for TB diagnostics and other laboratory tests, and has compromised work quality.

**Acceptability of TB Laboratory Tests**

The proportion of patients tested with smear microscopy is only 0.8% of the population. This is low compared to the high prevalence of TB in the Philippines, where as much as 12% of the population have cough of more than two weeks’ duration. This gap can be viewed as indicating
Findings and Analysis

not only the lack of access to diagnosis, but also the lack of test utilization by clinicians and patients—a common occurrence in the early implementation of DOTS in the 1990s due to their lack of confidence in the test.

TB culture together with DST is a more sensitive way of detecting TB and the presence of drug resistance. However, these tests are not easily accessible for most clinicians and patients, relying to a large extent on a weak referral system to enable testing; test results also take a long time—usually around nine weeks in the study labs.

Anecdotes suggest that generally, there is a favorable view for Xpert among clinicians in the public and private sectors. However, the limited availability and accessibility of Xpert through the NTP process, described previously, tends to diminish their interest. Other factors that contribute to the lack of private sector use of RDTs are the clinicians’ lack of awareness of the test, inability of private sector patients to meet the inclusion criteria for testing, difficulties related to the specimen referral process, and the high cost of testing (when involving private, non-NTP labs).

Currently, the information and guidance for clinicians in both public and private sectors regarding the use and interpretation of Xpert results are still lacking. For example, in some areas, a few clinicians were known to have insisted on using Xpert to follow up patients on treatment or even patients who have finished treatment.

Difficulties in interpreting two or more Xpert test results in the same patient were experienced by clinicians and program managers in some areas. These refer to new presumptive DSTB patients, who were retested due to findings of rifampicin resistance in the initial test. There were instances that led to some confusion when the first and second tests showed markedly different results (e.g., first test result is MTB-positive, with rifampicin resistance; second test result is MTB not detected), causing dilemmas in patient treatment and care. In addition, there were some instances in which clinicians expressed doubts about the accuracy of Xpert test results when these did not match their clinical findings, especially among patients who have completed treatment.

Capacity for Continuous Delivery of Reliable Services

The NTP’s capability to sustain the delivery of reliable services is crucial to its efforts to find and treat all TB cases effectively. The continuous delivery of lab services will depend largely on the support systems that ensure laboratories have minimal disruptions in operations, and on a quality assurance system that helps ensure the accuracy of test results. Laboratories generate test results that are used for patient care and public health management. Inaccurate test results can lead to delayed and/or wrong diagnosis, which can lead in turn to the use of inappropriate treatment. Poor-quality laboratory data can provide misleading information that can lead to poor decisions for public health. Laboratory quality can be defined as accuracy, reliability, and timeliness of reported test results. The laboratory is a complex system involving many people, processes, and procedures that must be performed properly to ensure quality in the laboratory. The complexity of the laboratory system requires the management of many factors to ensure quality in the laboratory. Some of these factors include laboratory environment, quality control.
procedures, communications record keeping, competent and knowledgeable staff, and good-
quality reagents and equipment. A framework for quality assurance in laboratories (figure 2) 
shows the various elements that support the various processes to ensure quality results.

![Figure 2. Laboratory quality assurance framework](image_url)

**Facility Downtime**

Information on laboratory downtime (duration of time that facilities were not functional) was 
gathered from the study laboratories (table 2). A total of 408 days of downtime occurred in 2015 among 
the labs where information was available. Issues related to equipment functionality, staff, 
and availability of supplies are the leading reasons for service interruptions.

The NTP lab network currently does not have a functional maintenance program for both 
equipment and facilities, causing prolonged response times for equipment repair or replacements. 
The waiting time for repairs of major equipment (e.g., biosafety cabinet) is several months. A 
facility maintenance program exists only in three regional TB laboratories; there is no equipment 
maintenance program in place for all culture laboratories. Culture-equipment monitoring is not 
regularly performed in the NTP laboratories.

<table>
<thead>
<tr>
<th>Table 2. Facility downtime in study laboratories, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. days</td>
</tr>
<tr>
<td>Peripheral microscopy lab</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Peripheral Xpert lab</td>
</tr>
<tr>
<td>Culture/DST lab</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>
Findings and Analysis

Power interruptions are quite common in the country, especially in the summer months, and have contributed to facility downtime. Although this was reported by just one study laboratory, the absence of power generators in peripheral and some intermediate laboratories is common; it is surmised that power outages have caused more facility downtime but are not reported.

Staff number in the peripheral laboratories is generally small relative to the number of laboratory procedures and administrative tasks that they perform. Staff shortages have resulted in reduced operations at many laboratories. Issues related to retention and compensation policies, poor work climate, and poor workplace conditions are the common causes of staff shortages.\textsuperscript{23}

Supply management issues also caused interruptions in the delivery of laboratory services at all levels. Table 3 shows the status of laboratory supplies in study laboratories in 2015. Stock-outs of key supplies such as staining reagents, Xpert cartridges, and culture media have caused facility downtime.

Table 3. Laboratory supplies experiencing stock-outs in study labs, 2015

| 1. | Ziehl-Neelsen stain, auramine stain for microscopy |
| 2. | Applicator sticks, immersion oil |
| 3. | Xpert cartridges |
| 4. | Sputum containers, including conical tubes; transfer pipettes |
| 5. | Culture media: Ogawa, mycobacterial growth indicator tube (MGIT) |
| 6. | Lab gowns, nonpowder gloves, N95 respirators |
| 7. | Lab registers, slide boxes |
| 8. | Sodium hydroxide, bleach 10%, alcohol 70%, hand soap, and other disinfectants |
| 9. | Waste disposal bags |

Most of the specialized laboratory services and RDTs are currently financed largely with external funds, particularly from the Global Fund. This renders the laboratory services, particularly RDTs at all levels, highly vulnerable to service disruption once funding is reduced or terminated.

Training and Quality Assurance Programs

Training provides the required skills, knowledge, and attitudes that workers need to perform the lab tests safely, correctly, and efficiently. Well-trained lab workers are necessary in order to produce accurate, reliable, and timely test results.

The lab quality assurance program is a service that helps ensure the accuracy of test results and the development of reliable services over time. The reduction and eventual elimination of laboratory errors is carried out through the systematic identification and analysis of problems and their underlying causes, using regular external rechecking, on-site assessment, supportive supervision, and action taking to correct identified problems.

There is currently no accreditation program for the NTP laboratories. However, an EQA program has been implemented for NTP microscopy laboratories. A separate national EQA system (NEQAS) is being run for hospitals by the Research Institute for Tropical Medicine (RITM), the NTRL’s mother institution.
**Inadequate Training and Supervision of Laboratory Staff**

The demand for training of laboratory network staff has increased significantly in recent years, mainly due to the expansion of laboratory services and the adoption of new RDTs. However, the NTRL is unable to meet the increasing demands for training, leading to a situation in which many lab workers are not formally trained.

There were efforts in the past to decentralize trainings, mainly through training of trainer (TOT) courses. However, the efforts were not sufficient to empower the regional and provincial/city levels to manage and implement laboratory training programs. With the exception of microscopy training, most laboratory trainings remain centralized.

At the peripheral level, program managers resorted to unstructured, one-day on-the-job (OTJ) trainings for newly assigned or recruited Xpert operators; some culture lab staff members were also trained using the OTJ approach. These trainings were not standardized, lacked training materials, and did not allow sufficient practice for trainees. On the other hand, the quality of the formal Xpert trainings also suffered from the lack of training equipment and supplies (e.g., machines and cartridges), trainers, and venues. In addition, many of the laboratory network managers have not been trained in Xpert operations and use; this limited their capacity to train and provide supportive supervision to the peripheral workers.

**Quality of Microscopy Services**

The results of EQA implementation in the study LGUs (figure 3) showed a low level of achievement. In 2014, only 33% of the LGUs, and in 2015, only 42%, achieved high EQA coverage—defined as at least 95% of labs that participated quarterly in EQA activities.

The proportion of LGUs that achieved high performance for microscopy reading—defined as at least 95% of labs in the LGU having less than 5% major errors per quarter out of the total laboratories—was achieved by only 25% in 2014, and 17% of LGUs in 2015. These results indicate that the microscopy services in most of the study areas are still far from reliable.

![Figure 3. Proportion of study LGUs (n=12) with high levels of EQA coverage and performance, 2014 and 2015](image-url)
Findings and Analysis

At the national and regional levels, the reporting of EQA implementation used annual averages to describe coverage and performance. This yields a higher level of achievement compared to the quarterly method used in this study. However, using the annual averages does not allow program managers to see the trends and variations in performance that occur between periods of assessment. Performing the quarterly measurement is aligned with the quarterly activities prescribed in the NTP’s EQA guidelines.

The poor performance in EQA implementation was due to a number of factors that limited the LGUs’ capacity to perform key activities, including on-site assessment, timely collection and blinded rechecking of slides, providing timely and correct feedback, and providing supportive supervision and guidance in addressing problems that cause the microscopy errors (table 4).

Table 4. Barriers to effective EQA implementation in study LGUs, 2015

<table>
<thead>
<tr>
<th>Barrier</th>
<th>No. LGUs</th>
<th>Present in (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of skills and knowledge for program management, data management, on-site lab assessment, and supportive supervision</td>
<td>12</td>
<td>100%</td>
</tr>
<tr>
<td>Transportation problems for field visits and slide collection</td>
<td>10</td>
<td>83%</td>
</tr>
<tr>
<td>Lack of QA controllers (for blinded rechecking of slides)</td>
<td>10</td>
<td>83%</td>
</tr>
<tr>
<td>Inadequate infrastructure and workspace of QA center</td>
<td>5</td>
<td>42%</td>
</tr>
<tr>
<td>Insufficient funds for field visits, including transport expenses</td>
<td>5</td>
<td>42%</td>
</tr>
<tr>
<td>No dedicated plan/budget for QA implementation</td>
<td>3</td>
<td>25%</td>
</tr>
<tr>
<td>Untrained QA team members (doctors, nurses)</td>
<td>2</td>
<td>17%</td>
</tr>
<tr>
<td>Lack of microscopes for slide rechecking</td>
<td>2</td>
<td>17%</td>
</tr>
</tbody>
</table>

Quality of Xpert Tests

There is no organized quality assurance scheme for the NTP Xpert services at this time. While instrument verification is performed after installation of the machines (by a private service provider), other QA activities, such as trainer and user competency assessment, on-site supervision, proficiency testing, and quality improvement, are not regularly performed. Data for quality indicators (performance indicators) are collected but these are not sufficiently analyzed and used to identify problems and improve performance.

Xpert test data showed that almost 36,000 DR-presumptive TB cases (PTCs) were tested in the study labs from 2013 to 2015. The majority of cases tested were the “other retreatment” (46%) and “relapse” (37%) cases; new cases comprised 17% of the total (figure 4). Data for EPTB, child PTCs, DS-PTCs such as “smear-negative patients with chest X-ray findings suggestive of PTB,” and HIV patients tested with GeneXpert (GX) were not available in the study labs.
Data from the study labs showed that the TB detection rate is higher among patients tested with Xpert compared to those with smear microscopy (table 5). Despite the lower number of PTCs tested, more TB cases were found using Xpert, including patients with rifampicin-resistant strains. This illustrates the advantage of Xpert over microscopy in TB case detection.

Table 5. Summary of test results from DSSM* and Xpert in study labs, 2013–2015

<table>
<thead>
<tr>
<th>Year</th>
<th>DSSM</th>
<th>Xpert</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. PTCs</td>
<td>Smear-positive</td>
</tr>
<tr>
<td>2013</td>
<td>21,560</td>
<td>3,334</td>
</tr>
<tr>
<td>2014</td>
<td>24,575</td>
<td>3,321</td>
</tr>
<tr>
<td>2015</td>
<td>23,244</td>
<td>3,418</td>
</tr>
<tr>
<td>Total</td>
<td>69,379</td>
<td>10,073</td>
</tr>
</tbody>
</table>

* Direct sputum smear microscopy

Xpert data from NTRL in 2015 showed MTB detection in 26% of presumptive DR-TB cases, and 26% of the MTB+ cases had rifampicin resistance. Among presumptive DS-TB cases, 32% were MTB+; 3% of whom had rifampicin resistance; “rifampicin resistance indeterminate” was seen in 298 (2%) of presumptive DR-TB cases, and 32 (3%) of presumptive DS-TB cases. DST results from the study labs showed rifampicin resistance in 31% of MTB+ cases in 2015 (figure 5).
Findings and Analysis

The proportion of patients with “MTB not detected” results is higher compared to those who are MTB-positive (figure 6) for all patient types. The results suggest that the current selection process of presumptive DRTB cases captures many patients without active TB, or those who were probably cured of TB from a previous treatment (among retreatment cases) as well as those suffering from post-TB complications and those with other lung disease.

False-negative results must be considered, particularly among cases who were previously treated but had a poor clinical outcome (e.g., treatment default, treatment failure), or among patients coming from areas where mixed infections are common. Technical factors such as poor specimen quality and processing, as well as administrative errors, can also give rise to false-negative results. On the other hand, false-positive results must be considered when dealing with retreatment patients who were bacteriologically cured from their previous episode of TB, and when current chest X-rays and/or clinical findings suggest inactive TB or when the clinical picture suggests the presence of lung disease other than TB. Careful clinical assessment, as well as further diagnostic tests, will be useful to come up with a correct diagnosis and treatment.

A total of 1,667 (5%) error results were recorded from 2013 to 2015 in the study labs. The errors with the highest proportions are invalid results (33%), error codes 5007 (22%) and 5011 (11%),
and no results (11%). The five leading error types accounted for more than 80% of errors annually (table 6).

Table 6. Ten most frequent Xpert errors in study labs, 2013–2015

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th></th>
<th>2014</th>
<th></th>
<th>2015</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Error</td>
<td>%</td>
<td></td>
<td>Error</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5007</td>
<td>49%</td>
<td>5011</td>
<td>23%</td>
<td>INVALID</td>
<td>33%</td>
</tr>
<tr>
<td>2</td>
<td>2008</td>
<td>20%</td>
<td>5007</td>
<td>21%</td>
<td>5007</td>
<td>22%</td>
</tr>
<tr>
<td>3</td>
<td>5011</td>
<td>10%</td>
<td>INVALID</td>
<td>15%</td>
<td>5011</td>
<td>11%</td>
</tr>
<tr>
<td>4</td>
<td>NR</td>
<td>9%</td>
<td>2127</td>
<td>15%</td>
<td>NR</td>
<td>11%</td>
</tr>
<tr>
<td>5</td>
<td>5006</td>
<td>4%</td>
<td>NR</td>
<td>14%</td>
<td>2127</td>
<td>5%</td>
</tr>
<tr>
<td>6</td>
<td>INVALID</td>
<td>3%</td>
<td>5006</td>
<td>4%</td>
<td>5006</td>
<td>5%</td>
</tr>
<tr>
<td>7</td>
<td>2014</td>
<td>3%</td>
<td>2008</td>
<td>3%</td>
<td>1001</td>
<td>5%</td>
</tr>
<tr>
<td>8</td>
<td>2127</td>
<td>2%</td>
<td>1001</td>
<td>2%</td>
<td>1002</td>
<td>4%</td>
</tr>
<tr>
<td>9</td>
<td>1001</td>
<td>1%</td>
<td>1002</td>
<td>2%</td>
<td>2014</td>
<td>3%</td>
</tr>
<tr>
<td>10</td>
<td>1002</td>
<td>1%</td>
<td>2037</td>
<td>2%</td>
<td>2005</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>100%</td>
<td>Total</td>
<td>100%</td>
<td>Total</td>
<td>100%</td>
</tr>
</tbody>
</table>

The occurrence of Xpert errors can be attributed to a number of issues (table 7), which can be related to the following:

- Poor preparation (instruction) of patients for sputum collection, which affects specimen quality. Very often, the field health workers who instruct patients in specimen collection are not trained. There are also issues regarding the timing and convenience of patients during the specimen collection process; many patients prefer to collect samples at home because of the often-poor state of the specimen collection area in most facilities, which are lacking in privacy.

- Improper storage, packaging and transport (e.g., inadequate cold chain) processes that affect specimen integrity.

- Inadequate or lack of effective training and supervision for Xpert operators. This can be attributed to the lack of health services’ capacity to provide effective training and supportive supervision.

- Informal training of many Xpert operators. Most of the informal trainings did/do not have standard content, lacked training materials, and did not assess competencies. The duration of the training is usually, at less than eight hours, not enough to acquire the necessary information and skills to process specimens and operate the machines correctly and safely, and to perform correct recording and reporting.

- Non-availability of detailed work instructions to guide lab workers after training, particularly in peripheral Xpert sites; internal SOPs were available in only 58% of the Xpert sites at the intermediate level study labs.
• Lack of skills for routine troubleshooting and maintenance among operators. This is also related to the inadequate training and supervision in the lab services, lack of supplies for routine maintenance work at the lab, and lack of an organized equipment maintenance program.

• Difficulties in maintaining the quality of cartridges during distribution. In some provinces, the distribution of cartridges to the primary care facilities is through public utility transport (e.g., tricycles), which exposes the supplies to sunlight and other elements.

• Inappropriate storage areas. The storage areas for cartridges in many peripheral facilities are unable to meet temperature requirements, compromising cartridge integrity. Room temperature in many parts of the country can exceed 27 Celsius, especially during the summer months. While air-conditioning has been provided in most Xpert sites, it is usually turned off after office hours, during holidays, and on weekends.

• In some cases, possibly the module failures that were reported.

Table 7. Summary description of causes of GX errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Possible reasons for errors*</th>
<th>Authors’ remarks: possible underlying causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error 5007</td>
<td>Sputum viscosity and/or wrong sample volume, or cartridge reaction tube improperly filled, contains bubbles, or probe integrity issues detected.</td>
<td>Poor sample preparation practices—related to lab worker performance due to gaps in training, inadequate supervision, lack of proper measuring equipment (e.g., graduated measuring cup).</td>
</tr>
<tr>
<td>Error 5011</td>
<td>Loss of tube pressure because the cartridge tube is not airtight, or cartridge valve is not working right.</td>
<td>Poor sample preparation practices—can be due to gaps in training; inadequate supervision. Cartridge quality?</td>
</tr>
<tr>
<td>Error 2127</td>
<td>Power supply issue (main power or unstable power supply fluctuations); ethernet cable between PC and GX instrument; communication cable between gateway and GX module.</td>
<td>Unstable power supply and recurrent power outages; improper machine installation (?).</td>
</tr>
<tr>
<td>Error 2008</td>
<td>Sample is too viscous; The filter is clogged by debris in sample; pressure sensor failed.</td>
<td>Poor sample preparation practices—related to lab worker performance due to gaps in training effectiveness; inadequate supervision.</td>
</tr>
<tr>
<td>Error 5006</td>
<td>An incorrect amount of reagent was inserted into the cartridge; the reagent is bad; fluid transfer failed.</td>
<td>Poor sample preparation practices; lack of proper measuring tools (pipettes, measuring cup); poor quality of reagent can be due to storage issues.</td>
</tr>
<tr>
<td>Error 1001</td>
<td>Environment temperature is too warm; fan failure.</td>
<td>High ambient environment temperature (no air-conditioning); improper machine placement; defective machine (?)</td>
</tr>
<tr>
<td>Error 1002</td>
<td>Difference between the temperatures of the two thermistors has exceeded the acceptable difference of 5°C.</td>
<td></td>
</tr>
<tr>
<td>Error 2014</td>
<td>The heater A/heater B/module’s/optical block thermistor failed.</td>
<td></td>
</tr>
<tr>
<td>Invalid</td>
<td>PCR was blocked due to inhibitors (pus, food particles).</td>
<td>Poor specimen quality—can be due to inadequate instruction to patients on sputum collection; poor training of health workers in sputum collection.</td>
</tr>
<tr>
<td>No Result</td>
<td>Windows or software freeze; power failure; STOP TEST function has been activated (accidentally or deliberately).</td>
<td>Computer-related bugs; power interruption with no backup supply; premature termination of test (e.g., during close of office at 5 pm in some labs).</td>
</tr>
</tbody>
</table>

*Source: Cepheid Xpert Users’ Manual.
Quality of Culture Tests

Culture performance varied widely among the study labs in terms of culture-positive rates, recovery, and contamination rates. Moreover, culture lab performance is not adequately monitored and analyzed; in addition, data management in the culture labs is weak. No baseline levels of performance have been set for the individual labs for reference. DST proficiency testing for intermediate-level culture/DST laboratories is administered by the NTRL, whereas the proficiency testing of NTRL lab staff is handled by the supranational lab of the Research Institute of Tuberculosis / Japan Anti-TB Association (RIT/JATA).

The quarterly recovery rates from eight study culture labs showed variable levels within and between laboratories (table 8). These variations can be due to any of the following: type of population tested (TB suspects versus confirmed TB cases); type of facility performing the tests, such as intermediate (e.g., hospital) versus reference labs; seasonal variations; contamination of specimens during collection; cross-contamination inside the laboratory; problems in performing the lab procedures due to lack of training, lack of work instructions, and supervision; use of suboptimal reagents; and poorly performing equipment (related to lack of maintenance and repair).

<table>
<thead>
<tr>
<th>Facility type</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>NTRL</td>
<td>30%</td>
<td>43%</td>
</tr>
<tr>
<td>LCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BGHMC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RO3</td>
<td>90%</td>
<td>80%</td>
</tr>
<tr>
<td>Bat. MC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTRL</td>
<td>62%</td>
<td>88%</td>
</tr>
<tr>
<td>NMTRL</td>
<td>90%</td>
<td>85%</td>
</tr>
<tr>
<td>DTRL</td>
<td>100%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Table 8. Culture recovery rates in study labs, 2014–2015

Note: Reports not available for shaded cells

The contamination rates also showed variable levels (table 9). The recommended acceptable contamination rates range from 3% to 5% of culture tubes with solid media, and from 3% to 10% for liquid media (APHL).

<table>
<thead>
<tr>
<th>Facility</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>NTRL (liquid culture)</td>
<td>3%</td>
<td>6%</td>
</tr>
<tr>
<td>LCP</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>BGHMC</td>
<td>14%</td>
<td>4%</td>
</tr>
<tr>
<td>DOH-Region 3</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td>Batangas Medical Center</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTRL</td>
<td>1%</td>
<td>11%</td>
</tr>
<tr>
<td>NMTRL</td>
<td>5%</td>
<td>1%</td>
</tr>
<tr>
<td>DTRL</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table 9. Quarterly contamination rates of study labs, 2014–2015

Note: Reports not available for shaded cells
Contamination rates may be influenced by the type of population under study, by specimen collection, and by the laboratory’s level of proficiency in specimen processing. High contamination rates can be attributed to administrative and technical factors related to specimen processing, such as incomplete processing, and the use of contaminated media, reagents, or equipment. Contamination rates below the minimum level indicate harsh decontamination agents, and/or excessive processing times.

**Turnaround Time of Lab Results**

Data for the turnaround times (TATs) for releasing lab results are limited because not all TB microscopy laboratories (TMLs) and Xpert labs are recording and/or monitoring their TATs—no guidance has been issued for its reporting. Table 10 shows the average TAT from the study labs. Health facilities that are referring specimens for testing have longer TATs due to specimen transport issues and queuing of specimens.

**Table 10. Average turnaround times for release of lab results in study labs, 2015**

<table>
<thead>
<tr>
<th>Test</th>
<th>TAT</th>
<th>NTRL target</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSSM (diagnostic)</td>
<td>3 days</td>
<td>3 days</td>
</tr>
<tr>
<td>DSSM (follow-up; 1 LGU data only)</td>
<td>2 days</td>
<td>1 day</td>
</tr>
<tr>
<td>DSSM (diagnostic; referring)</td>
<td>5 days</td>
<td>NA</td>
</tr>
<tr>
<td>Xpert (for own lab)</td>
<td>3 days</td>
<td>2 days</td>
</tr>
<tr>
<td>Culture (solid)</td>
<td>9 weeks</td>
<td>3–8 weeks</td>
</tr>
<tr>
<td>Culture (liquid, NTRL)</td>
<td>6 weeks</td>
<td>2 weeks</td>
</tr>
<tr>
<td>DST (solid)</td>
<td>7 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>DST (liquid, NTRL)</td>
<td>7 weeks</td>
<td>2 weeks</td>
</tr>
<tr>
<td>LPA (NTRL only)</td>
<td>5 days</td>
<td>1–2 days</td>
</tr>
</tbody>
</table>

For 11 Xpert study labs, the following turnaround times were noted: 36% of labs: 1 day; 18% of labs: 2 days; and 46% of labs: 3 days. In general, peripheral-level Xpert facilities had shorter TATs because of the lower workload compared to intermediate- and central-level laboratories that had more referrals. On the other hand, referring facilities reported longer TATs due to the queuing of specimens in the receiving labs, and also due to delays in encoding and transmittal of results.

The TAT for TB culture from the study labs ranged from 8 to 16 weeks (solid culture), with an average of 9 weeks. Some of the study culture labs that exceeded standard TAT attributed this to the following reasons:

- Pooling of specimens before processing
- Delay in encoding results (due to staff shortage)
- Referral to higher-level laboratories for species identification of isolates, leading to longer turnaround times.
The time for recording and reporting, as well as the release and transmittal of culture results, adds another week after eight weeks of incubation (total of nine weeks). A turnaround time of nine weeks seems to be more realistic in the current setting.

**Transmittal of Results**

In primary care facilities, microscopy test results were released to patients, rather than to the clinic staff, in more than 50% of study sites; the rest sent the results to the clinic nurse- or midwife-in-charge. The practice of releasing diagnostic lab results to patients has been observed for many years now; anecdotal reports and field observations showed that some patients were lost in the diagnostic process after the results were handed to them.

Xpert test results were released to the clinic staff in 83% of labs; in specialized clinics, results are transmitted by commercial courier or by a PMDT-assigned transport to PMDT treatment center or satellite treatment centers. Since courier pick-up schedules are not on a daily basis, results are initially transmitted by SMS, email, or phone calls, at the lab staff’s expense, to facilitate the transmittal process. Only one study lab reported using ITIS (Integrated Tuberculosis Information System) offline to send lab results using Internet access through an Internet shop. Of the Xpert labs, 17% released results to patients.

There are certain ethical issues involved when lab tests are signed off by a staff member who has no mandate to perform such tasks. In addition, using test results obtained during Xpert training for clinical diagnosis is an emerging practice described by trainers in some areas. Results obtained during training are not validated; using these lab results for clinical decision making may entail some ethical issues. This practice may cause errors in patient care if the results are incorrect.
RECOMMENDATIONS

The findings show that the NTP has achieved remarkable improvements in increasing access to diagnostic services through the expansion of the laboratory network. WHO-recommended RDTs (i.e., Xpert) are now used in central and intermediate laboratories as well as a number of primary care facilities. These initiatives are supported by revised policies and diagnostic algorithms in accordance with WHO recommendations. Laboratory systems are being strengthened to support the continuous delivery of quality-assured services.

However, more needs to be done to further improve the availability, accessibility, affordability, acceptability, and quality of services, as well as in ensuring the continuous operations of the laboratories. Barriers to access remain; these lead to a situation where only a small proportion of TB patients are diagnosed bacteriologically while the large majority are clinically diagnosed.

The full implementation of the RDTs at the primary level will take time, and will require strong support systems to ensure the sustained delivery of reliable services. This will require more investments and resources in terms of staff, funds, equipment, infrastructure, training, supplies, and development of quality management systems.

The delivery of quality-assured TB microscopy services must be maintained because microscopy will still be the first diagnostic test that is easily available in areas that have no access to RDTs, particularly in geographically isolated areas of the country. In addition, TB microscopy will still be the follow-up test for most patients on treatment. Efforts to maximize the functionality of existing laboratories must be prioritized. The following recommendations are proposed for implementation within the next three to five years, and are directed to the NTP and laboratory network managers at the national, regional, and provincial/city level. Capacity building approaches should address the organizational as well as individual gaps.

Improve Accessibility of Services

Strengthen the Specimen Referral And Transport System

To maximize the utility of existing Xpert labs and address accessibility issues, the specimen referral and transport system must be improved, given the country’s topography, road network, and the state of transport services.

- Review, and possibly revise, the current referral or zoning arrangements in each region to determine more feasible and sustainable specimen referral routes taking into account local terrain, distance of referring facilities to receiving laboratory, availability and cost of local transport, and local security conditions. The ability of the system to function in cases of natural or man-made disasters must be considered.

- Develop clear policies and operational guidelines for implementing the specimen referral and transport system. The policies must include processes for decision making and for the
flow of funds, staff, and materials. This should be a priority and the guidelines should be ready for implementation by mid-2018.

- At the regional and LGU levels, strengthen current specimen transport practices based on the results of the analysis, and in accordance with the new guidelines.

- Provide technical support to regional and/or provincial program managers in organizing, planning, implementing, monitoring, and evaluation of the specimen referral schemes in their respective regions.

- Provide adequate technical, material, and financial support for specimen collection, storage, packaging, and transport, including the cold chain, to preserve sample quality, particularly at the primary care level.

Rationalize the Establishment of New RDT Sites for Increased Availability and Better Accessibility

The majority of the existing Xpert sites are located at secondary or tertiary levels of care and are not yet adequately accessible for many TB patients. Very few private facilities are engaged in the NTP network, especially for the implementation of RDTs and other specialized technologies.

- Provide technical assistance to regional and provincial NTP managers in selecting sites for RDT (Xpert) expansion. Considerations must be given to the local need in terms of TB burden; location of existing diagnostic (e.g., access to X-ray) and treatment facilities, including those for MDRTB treatment; feasibility of specimen referral routes; and availability of transport.

- In the era of changing climatic conditions and the potential for environmental disasters, coordination with other agencies (e.g., Health Facility Development Bureau [HFDB]/DOH, Department of Interior and Local Government) and relevant public and private organizations must be strengthened to obtain technical guidance and support in site selection, and establishment and safe operation of laboratory facilities.

- Improve the assessment of facilities for pre-installation requirements based on the NTRL checklist. The checklist needs to be enhanced, providing more details regarding the requirements for work areas, adequate ventilation (whether through natural or mechanical means), power supply, storage of supplies, and for the proper management of laboratory waste materials. An assessment of staff requirements and LGU commitment must also be performed.

- The capacity of the regional and provincial/HUC NTP teams tasked to perform the assessments must be strengthened. Engaging the participation of technical people specializing in civil, electrical, and mechanical engineering for clinical laboratories is recommended.
**Recommendations**

- Strengthen efforts, including evidence-based advocacy, to engage the LGUs and the private sector in the selection, establishment, and operations of laboratory services, particularly the RDTs. Broader support that will result from these engagements will help manage the cost of services, improve the various aspects of lab operations from the pre-analytical to post-analytical phases of services, and improve access and quality of services.

- Technical assistance should be provided to LGUs so that the requirements for RDT establishment and operations will be met within the shortest possible time.

**Ensure the Continuous Delivery of Laboratory Services**

- Establish a program for equipment and facility maintenance. Facility downtime has been an significant factor in the disruption of laboratory services. Most instances of downtime were caused by weaknesses in the laboratory support systems. Steps must be taken to prevent or reduce these occurrences, or to mitigate the effects of service interruptions.

- In collaboration with DOH Health Facility Development Bureau (HFDB/DOH), DOH Regional Health Offices, relevant private agencies, program technical partners, and donor agencies, the NTP and NTRL should immediately start working on establishing an equipment and facility maintenance program. This should include the development of policies, mandates, procedures, and provisions for staffing, financing, equipping, and management of the program. If possible, this should be approved by the second half of 2018. Organizational and individual capacity building should also start as soon as possible; capacity building plans and budgets must be prepared during 2018.

- To prolong equipment life and ensure optimal performance, especially that of the Xpert machines at primary-level facilities, the NTRL should develop and disseminate SOPs or work instructions to guide lab workers and program managers in implementing facility-level maintenance procedures. These are important, especially in the absence of regular supervision; if possible, they should be available at the facility level by mid-2018.

- Provide support to ensure the continuous operation of facilities during power outages, or to ensure their ability to implement mitigation procedures during prolonged and unexpected power outages (e.g., access to power generators, provision of functional UPS (uninterruptible power supply) units, and implementation of steps to prevent loss of laboratory data).

**Enhance Staff Management at the Facility Level**

Frontline laboratory workers are the most important resource for the health services. Issues related to staff recruitment, training, retention, and quick turnover are causes of service interruption. Short- and long-term interventions are needed to address these issues.
• Develop and implement innovative and feasible programs at the local level to enhance staff motivation, productivity, and satisfaction. Examples of this from some areas include the provision of incentives, which may be non-monetary; provision of adequate and relevant training that addresses real performance gaps; provision of adequate feedback and supportive supervision; provision of clear work instructions; ensuring a safe work environment through the effective implementation of infection control guidelines and procedures; and provision of adequate lab supplies, including those needed for workplace cleaning and maintenance, waste management, and quality control.

• Implement immediately the TB screening program for all health workers and ensure the provision of all legally mandated employee benefits. This would help increase workers’ desire and commitment to work for the public health services.

• Improve management of high laboratory workload through innovative approaches; for example, the use of nontechnical staff to perform clerical functions to reduce workload of technical personnel, and task shifting of existing staff for technical procedures. Steps must be taken to reduce “unreasonable” multi-tasking among lab staff.

• Strengthen the provision and effectiveness of training and supervision for laboratory staff, particularly at the peripheral level, to enhance their capacity to perform lab procedures, particularly RDTs, correctly and safely. Training should utilize other approaches that are appropriate for field workers other than the formal classroom trainings. Training and supervision efforts should be supported with adequate technical, financial, and material support to ensure effectiveness and efficiency.

Improve Monitoring of Laboratory Services Implementation and Performance

Monitoring is an important management function that must be performed effectively to detect problems as they emerge so that health workers can take immediate action to solve the problems and prevent complications that can lead to service interruptions, delays in program activities, or introduce errors in diagnosis.

• Develop the set of performance indicators that will be used to monitor the different aspects of the laboratory services for all technologies currently employed by the program.

• The capacity of lab network managers in monitoring the lab services should be enhanced. This includes improvement of skills in data collection and management, problem identification, analysis, and skills in finding solutions. Capacity building should include logistical and administrative support for the conduct of regular field monitoring (and supervision), action planning, and provision of feedback.

• Strengthen the laboratory information system, particularly the recording and reporting aspects whether in the electronic (ITIS) or manual (paper-based) formats. Address the gaps in the system that contribute to incomplete recording and delayed reporting.
• Establish and implement procedures to ensure that monitoring findings and results are properly disseminated to relevant offices and staff; ensure that these are used in the planning and decision making processes.

**Explore Alternative Sources to Ensure the Continuous Financing of Laboratory Operations**

Advocate to national agencies, LGUs, and barangays for the provision of resources to finance the laboratory services in their respective areas. This should initiate the process of ensuring more stable financing of the lab services in the long term, especially when donor funds are terminated or reduced.

**Improve the Quality and Reliability of Laboratory Services**

• Strengthen training and supervision of laboratory workers. Health workers are the most important resource for the program. Training requires huge investments, but these are necessary to ensure that workers are trained effectively so that they can perform well and contribute to a strong laboratory performance. Training helps ensure that all laboratory staff have acquired the required competencies to correctly and safely perform all relevant laboratory procedures at all stages.

• Build the capacity of the subnational level to manage and implement laboratory trainings beyond TB microscopy—in particular, trainings on Xpert. Capacity building activities should be implemented in accordance to a laboratory network strengthening plan, including a training decentralization strategy.

• Enhance management and implementation of training courses to ensure that trainees have sufficient laboratory practice time. This should address issues in the availability of sufficient quantities of training equipment and supplies. Program managers must also address the lack of trained trainers, inadequate logistical support, and weak coordination and collaboration at various levels of the lab network.

• Address the gaps in supervision capacity at all levels. Proposed actions are to improve the med tech coordinators’ skills in supervision, develop and implementation of a supervisory plan and budget, and provide adequate logistics support for supervisory activities.

**Strengthen Implementation of Quality Assurance Activities**

Quality assurance is a unique service provided by the lab network program managers at different levels. These activities help ensure that services are of good quality and reliable—these are attributes that enhance the confidence and trust of patients and clinicians in the laboratory services.
• Build the capacity of regional and provincial/HUC teams to plan and implement quality assurance activities. This should include support for organizational strengthening, provision of essential equipment and supplies, and adequate logistical support to conduct QA activities. Individual skills should also be enhanced in data gathering, management, and use for program monitoring, evaluation, supervision, planning, and problem solving. Emphasize a systems approach in problem identification and analysis. Subnational leadership practices should also be enhanced.

• The NTRL, in collaboration with the regional lab managers and technical partners, should start organizing QA activities for the new diagnostics (e.g., Xpert assay, culture/DST, LPA). This should be supported by national policies and guidelines, SOPs for the use of lab staff and supervisors, and training for the supervisors and implementers. Technical support for planning and implementation should be provided to the lab staff and lab managers who will perform these procedures.

• The NTRL will start the development of a laboratory accreditation program and quality standards that are aligned with WHO’s and the Global Laboratory Initiative’s laboratory quality management systems.

**Improve Interpretation and Use of Test Results**

• Strengthen guidance to clinical staff. The clinicians, as well as the program managers, surveillance officers, and epidemiologists, are the main users of the data generated by the laboratories. Clinical staff, in particular, are the ones in charge of making and implementing decisions and plans for patient care. Their ability to correctly interpret the laboratory results should be enhanced so that patients’ confidence and trust in the laboratory services will increase. This trust and confidence will eventually be channeled to the patients, who are the ultimate beneficiary of the services.

• Build the capacity of regional and provincial/HUC NTP teams in providing technical guidance to clinicians in the interpretation of traditional and new RDT (i.e., Xpert) test results and its use for patient care. Program managers should organize and implement regular activities to provide updated information and knowledge to clinical staff in their jurisdictions in both public and private sectors. These activities could be in the form of small meetings, panel discussions, or short training sessions. The activities should not require too much of the clinical staff’s time, to avoid taking them away from their patients.

• Regional and provincial NTP teams should exert efforts to document field experiences and observations related to difficulties encountered in test result interpretation and use. These should be analyzed to identify potential sources of error in clinical practice. The results must be shared with the clinical practitioners and program managers through the regular case reviews.
Recommendations

Strengthen Capacity to Conduct Operational Research

As with most new initiatives and technologies, knowledge is often inadequate and research will be a valuable tool to generate new and practical knowledge that can be used to optimize the performance of the new and existing technologies.

- Provide technical support and enhance the skills of lab network managers and implementers to enable the implementation of relevant operational research that will contribute to improvements in lab practices and performance. These research projects could be simple operational studies that can be easily conducted by the lab workers.

- Periodic reviews of the NTP diagnostic algorithm is recommended to identify factors or steps that serve as barriers or deterrents to the full completion of the diagnostic process.

- Activities should be organized to share the results of the operational research with lab implementers, clinic staff, program managers, and other stakeholders.
REFERENCES


ANNEX A. LIST OF LABORATORIES VISITED AND PERSONS MET AND INTERVIEWED

National Capital Region

National TB Reference Laboratory

- Ms. Cristina Villarico—Head, Laboratory Services Unit
- Ms. Catherine Ann Sacopon—Medical Technologist
- Ms. Maria Althea Sabrina Perez—Science Research Specialist
- Mr. Dionisio Cabanela—Laboratory Technician
- Mr. Mar Alrey Jumarang—Laboratory Aide

Lung Center of the Philippines—National Center for Pulmonary Research (LCP-NCPR)

- Mr. Randolf Leppago—Medical Technologist
- Ms. Maria Theresa Remaneses—Medical Technologist
- Mr. Cyryll Castillo—Medical Technologist

Philippine Tuberculosis Society, Inc. —Quezon Institute (PTSI-QI)

- Ms. Emily Datoy—Chief Medical Technologist
- Ms. Lirio Borlongan—Medical Laboratory Technician
- Mr. Ian Paul Resabal—Medical Technologist
- Mr. Jerson Hortillosa—Medical Technologist
- Ms. Rowena Madres—Medical Laboratory Technician

San Lazaro TB Culture Laboratory

- Dr. Arlan Lopez—Laboratory Supervisor
- Ms. Ma. Cecilia Belo—Head, Microbiology Department
- Ms. Mayline Kong—Medical Technologist
- Ms. Ashley Cynna Ong—Medical Technologist
- Ms. Mary Joy Nalangan—Medical Technologist

Quezon City Quality Assurance Center

- Mr. Bernard Yumang—City NTP Medical Technologist Coordinator

Kamuning Super Health Center, Quezon City

- Ms. Ma. Jesusa Chua—Medical Technologist
- Ms. Niña Jamille Guerrero—Microscopist
- Ms. Elena Escoriaga—Laboratory Aide
Cordillera Administrative Region (CAR)

DOH CAR Regional Health Office

- Mr. Clint Ildefonso—Regional NTP Coordinator

Baguio City Health Office QA Center

- Ms. Ruby Magsino—City NTP Controller

Baguio General Hospital and Medical Center (BGHMC)

- Mr. Andrew Sib-aten—Medical Technologist
- Ms. Chris Diane Somera—Medical Technologist

Region 3—Central Luzon

Region 3 TB Culture Laboratory

- Ms. Catherine Toledo—Regional NTP Medical Technologist Coordinator
- Ms. Michelle Bautista—Medical Technologist

Pampanga Provincial Health Office (PHO) QA Center

- Dr. Maria Imelda Labrador-Ignacio—Provincial NTP Medical Coordinator
- Mr. Nickson Manlutac—Provincial NTP Nurse Coordinator
- Ms. Catherine Zapanta—Provincial NTP Med Tech Controller

Lourdes Sur RHU Main (Angeles City QA Center)

- Ms. Femie Pangilanin—Controller
- Ms. Lourdes Pinpin—NTP Nurse Coordinator

Sindalan Rural Health Unit

- Dr. Emerito Mercado—Medical Officer
- Mr. Richard Puno—Medical Technologist
- Ms. Lolita Mabalay—Public Health Nurse

Region 4A—CALABARZON

DOH Regional Office 4A (CALABARZON)

- Ms. Myla Velgado—Regional NTP Medical Technologist Coordinator

Cavite Provincial Health Office (PHO) QA Center

- Ms. Rosemarie Gomez—Provincial Lab Coordinator
- Ms. Minda Lingan—Provincial NTP Nurse Coordinator
Batangas Provincial Health Office (PHO) QA Center

- Ms. Maria Lourdes Soriano—Medical Technologist
- Ms. Viviane Hernandez—Provincial NTP Nurse Coordinator

Batangas Medical Center

- Ms. Dessa Joy Bacay—Medical Technologist
- Ms. Mary Ann Cuartero—Medical Technologist
- Ms. Maria Angelica Castillo—Medical Technologist

Batangas City Health Office (CHO)

- Ms. Catherine Moral—Chief Medical Technologist
- Mr. Edwin Chavez—Medical Technologist
- Ms. Marie Jane Lumanglas—Medical Technologist
- Ms. Vicky Atienza—City NTP Nurse Coordinator

Naic Rural Health Unit (RHU)

- Ms. Jennifer Casamar—Medical Technologist

Region 7—Central Visayas

Cebu TB Reference Laboratory (CTRL)

- Ms. Cresilda Cases—Regional NTP Medical Technologist Coordinator

Cebu City Health Office (CHO) QA Center

- Mr. Norman Capaning—NTP Medical Technologist Coordinator
- Ms. Laurean Jo Cabase—Medical Technologist

Parian Health Center

- Mr. Joselito Manubag—Medical Technologist
- Ms. Loreta Canencia—Laboratory Aide

Mabolo Health Center

- Mr. Owen Joshua Briones—Medical Technologist

Region 8—Eastern Visayas

DOH Regional Office 8

- Mrs. Flor Jimenez—Regional NTP Medical Technologist Coordinator
Annex A. List of Laboratories Visited and Persons Met and Interviewed

Region 8 TB Culture and Xpert Laboratory

- Mr. Brendon Sanilla—Medical Technologist
- Ms. Raquel Espina—Laboratory Aide

Leyte Provincial Health Office (PHO) QA Center

- Ms. Joline Ariza—Provincial NTP Medical Technologist Coordinator
- Ms. Evelyn Pacheco—Controller
- Ms. Karena Cleofe de Veyra—Controller
- Ms. Medly Lou Dimzon—Provincial NTP Nurse Coordinator

Taloban City Health Office (CHO) QA Center

- Dr. Danilo Ecarma—NTP Medical Coordinator
- Ms. Imelda Labarda—NTP Medical Technologist
- Ms. Nilda Cantay—NTP Controller

Eastern Visayas Regional Medical Center (EVRMC)

- Ms. Ma. Merlina Vistal—Head, Microbiology Section
- Ms. Reyna Ann Peques—Medical Technologist

Region 10—Northern Mindanao

Northern Mindanao TB Reference Laboratory

- Ms. Jenny Alabado—Regional NTP Medical Technologist Coordinator
- Ms. Perla Sanchez—Laboratory Supervisor
- Ms. Rene Fleur Clutario—Medical Technologist
- Ms. Irene Abejuela—Medical Technologist
- Ms. Marian Paguidopon—Laboratory Aide

Misamis Oriental Provincial Health Office (PHO) QA Center

- Ms. Maria Carmela Ditona—Controller
- Ms. Stephanie Bolos—Project Associate

Carmen Rural Health Unit (RHU)

- Ms. Leah Yvette Pelaez—Medical Technologist
- Ms. Juvy Madarang—Medical Technologist

Xavier University Community Health Care Center (XU-CHCC) Xpert laboratory

- Ms. Cheerwind Agcito—Medical Technologist
Region 11—Davao Region

Davao TB Reference Laboratory

- Ms. Sonia Dapitanon—Regional NTP Medical Technologist Coordinator
- Mr. Jordan Kintanar—Medical Technologist

Davao City Chest Center (QA Center; TML)

- Ms. Maria Theresa A. Bien—City NTP Medical Technologist Coordinator
- Ms. Melody Maghari—City NTP Controller (Main Laboratory)

Davao del Norte Provincial Health Office (PHO) QA Center

- Ms. Ruby Rosal—Provincial NTP Medical Technologist Coordinator
- Ms. Glomerlina Laag—Provincial NTP Nurse Coordinator
- Ms. Gemma Nadine Eustaquio—Provincial NTP Controller
- Mr. Lougie Depra—Provincial NTP Controller

Davao Regional Hospital (DRH)

- Mr. Jenry Mibato—Medical Technologist