Laboratory Network Monitoring Guide

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Recommended Citation

Lagos AB, Adorio-Arce LP. 2017. *Laboratory Network Monitoring Guide*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

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ACRONYMS AND ABBREVIATIONS

Acc.	accomplishment
AO	administrative order
DR	drug resistant
DR-PTC	drug-resistant presumptive TB case
DST	drug susceptibility test
EQA	external quality assurance
ITIS	Integrated Tuberculosis Information System
LNSP	laboratory network strategic plan
LNW	laboratory network
M&E	monitoring and evaluation
MDR	multidrug resistant
MDR-TB	multidrug-resistant TB
MTB	Mycobacterium tuberculosis
NTP	National TB Program
PTC	presumptive TB case
QA	quality assurance
QAP	quality assurance program
RR	rifampicin resistant TB
Sm (-)	smear negative
Sm (+)	smear positive
T	drug-susceptible TB
TAT	turnaround time
TI	tuberculosis indeterminate
TML	TB microscopy laboratory
XDR-TB	extensively drug-resistant TB
Xpert MTB/RIF	GeneXpert Mycobacterium tuberculosis/rifampicin assay

PREFACE

The Philippines National TB Program's (NTP) laboratory network strategic plan (LNSP) aims to improve access to quality laboratory services, including establishing new facilities (especially in remote areas), adopting new diagnostic technologies, and strengthening the laboratory systems.

The implementation of laboratory network (LNW) strengthening plans and the performance of the LNW require a comprehensive monitoring of activities to detect problems, document results (performance), and gather lessons from the process. However, many program managers find monitoring difficult to implement because of the lack of knowledge, skills, and operational support, especially for field visits. A contributing factor is management's weak appreciation of the value of monitoring for program management and improvement.

This document aims to provide guidance to health workers who are tasked with monitoring the LNW's status and performance. In this document, we provide the readers with practical tips on how to monitor—from preparation, data collection, data management, and reporting to a list of indicators to guide data collection.

The intended users of this guide are NTP coordinators (physicians, nurses, and medical technologists). They will benefit from the information gathered through the monitoring process by using it for planning and decision making to improve program performance.

This guide is a small contribution to the NTP's efforts to improve delivery of diagnostic services. It is not an exhaustive reference that will answer all of the problems found in monitoring activities or in the TB control program itself. Rather, it attempts to put monitoring in its proper perspective so that practitioners will find it useful, productive, meaningful, and enjoyable.

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Systems for Improved Access to Pharmaceuticals and Services
Philippines, June 2017

INTRODUCTION

The LNW plays an important role in the NTP because it provides the means for diagnosis and paves the way to treatment. Laboratories provide the data that serve as evidence of patients' response to treatment and cure at the end of the treatment. This role increases in significance with the onset of multidrug-resistant TB (MDR-TB) cases as the LNW now has an even greater role in differentiating the types of patients, which will guide clinicians in selecting treatment regimens. In addition, the laboratories provide data for TB surveillance.

In order for the LNW to support attainment of the country's TB strategic objectives in terms of providing effective, reliable, and sustainable services, the NTP is working within a framework that aims to strengthen TB diagnostic services and ensure that these are fully functional.

The framework includes the following elements: (a) national policies and standards that form the legal regulatory framework; (b) human, financial, and material inputs to enable the effective and sustainable delivery of services; and (c) the systems and processes that support the staff in providing the services (figure 1).

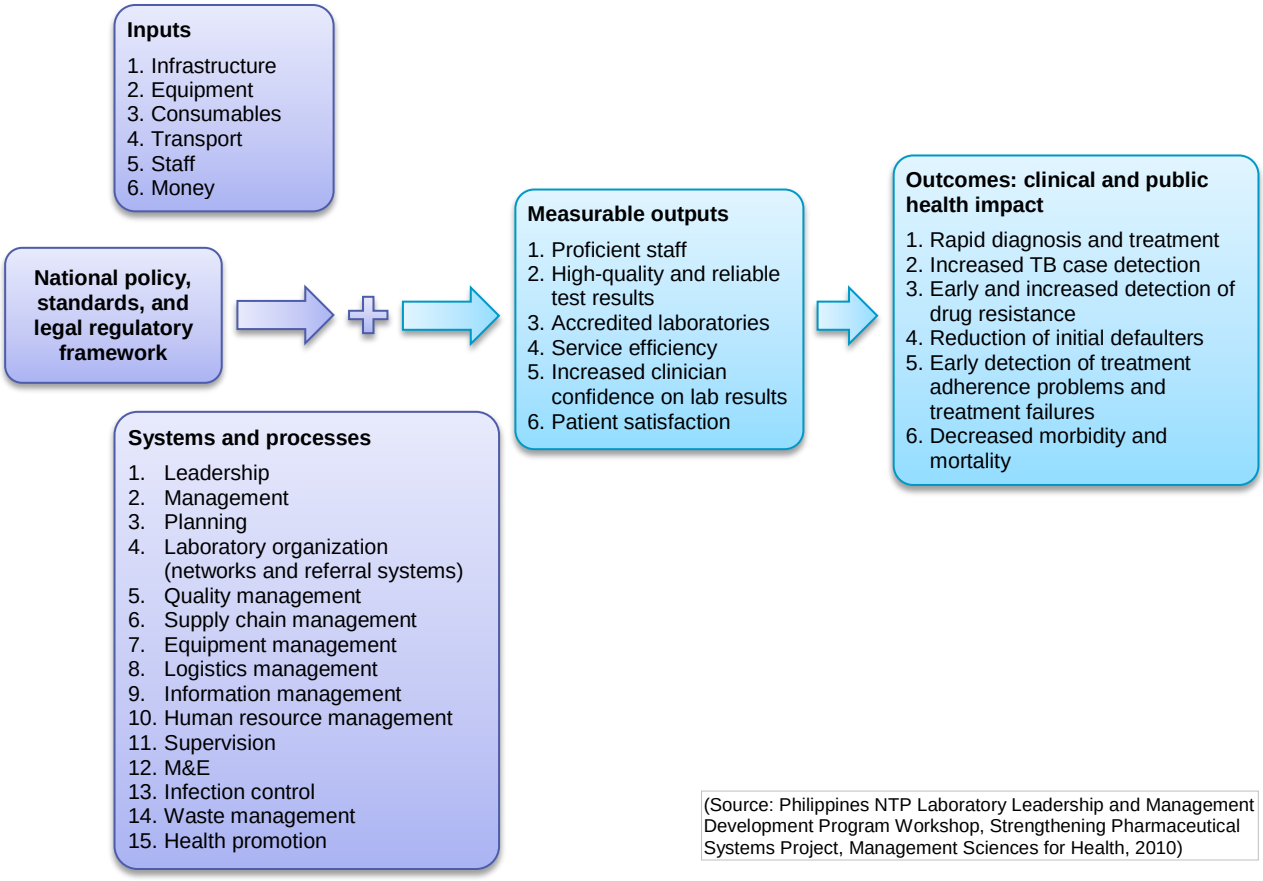

Figure 1. Framework for fully functional TB diagnostic services in the NTP

Working together, these elements will generate measurable outputs, such as proficient staff, high-quality and reliable test results, accredited laboratories, service efficiency, increased clinician confidence in lab results, and patient satisfaction. Although some program managers may feel that "patient satisfaction" is not important for this guide, we believe that it is high time that this be given the attention that it truly deserves. Patient-centeredness should be exercised, even at the start of the diagnostic process.

The fully functional LNW is expected to contribute to program outcomes that have clinical and public health impact including shorter turnaround times (TATs) to diagnosis and treatment; increased TB case detection; early and increased detection of drug resistance; reduced initial defaulters; early detection of treatment adherence problems and treatment failures; and decreased TB morbidity and mortality.

Laboratory Quality Assurance Framework

The quality assurance (QA) framework shown in figure 2 demonstrates the interrelationship of various activities in the performance of laboratory tests that start even outside the laboratory. The process starts at the "pre-analytical stage" when patients are prepared prior to diagnostic tests. This includes the orientation and education of patients and how they can cooperate for a successful testing process, up to the time when the specimens are produced and brought to the laboratory.

The framework also covers the analytical stage (the point where the sample or specimens are tested in the laboratory) and the post-analytical stage where results are handed over to the requesting clinical staff. It is important to constantly look at (monitor) these steps in the process because they can provide important clues to the interpretation of laboratory results. In each of these stages, one must be aware of the elements of the systems and processes that may contribute to the quality of the laboratory results.

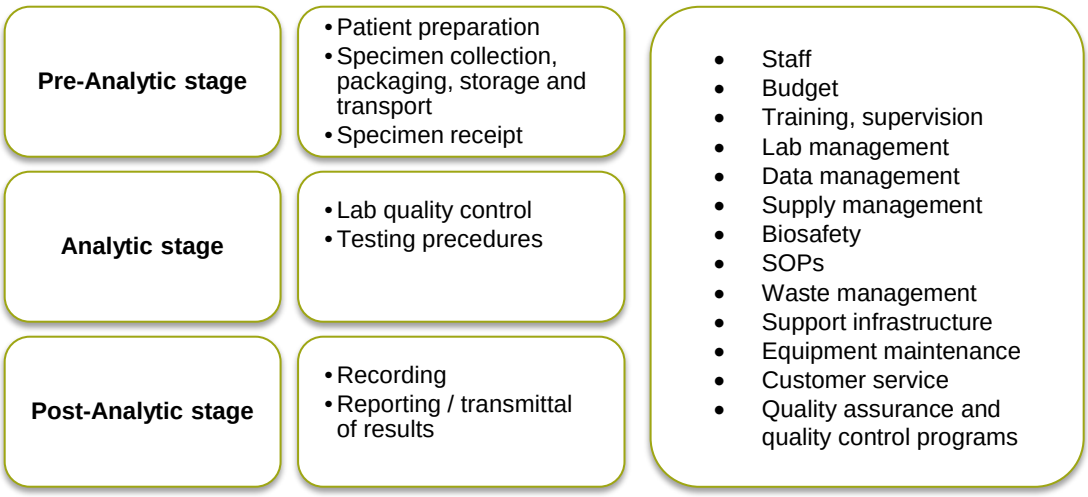

Figure 2. Laboratory QA framework

HOW TO MONITOR

Monitoring is the regular, systematic, and purposeful observation of program performance. It is a process of routinely gathering information on all aspects of the program that will be used for decision making to improve performance. The main purpose of monitoring is to identify and resolve operational problems as soon as they emerge. Monitoring involves giving feedback to implementers, program managers, donors, and program beneficiaries–the stakeholders!

For practical reasons, managers should focus on monitoring **major** program activities only. Select the activities to monitor based on level of priority or importance and your capacity to monitor. Selecting too many activities will detract from problem identification and resolving, which can make the entire process counterproductive.

What should be monitored?

1) Laboratory leadership and governance

- Strategic directions (e.g., strategic plan) aligned with national strategies and responsive to local needs
- Policies and guidelines aligned with national policies/guidelines
- Organization of LNW based on local needs and priorities

2) LNW management

- Planning/budgeting; implementation of program activities based on plans
- Laboratory human resources
- Number, location of laboratories (province/city, regional, national)
- Specimen referral and transport system (province/city, regional, national)
- Supply management
- Equipment and facility maintenance
- Trainings and results (regional, national)
- Information system (province/city, regional, national)
- Monitoring and evaluation (M&E)

3) Laboratory service delivery and results

- Quantity (i.e., numbers tested)
- Quality (based on external quality assurance [EQA] program results)
- TAT
- Contribution to case finding and case holding: outputs, outcomes

How can monitoring be done?

- At the office through the review of reports and other sources of information

    - Relies heavily on the quality of reports/information
    - Useful, especially when time and resources are limited
    - Usually generates more questions that can only be answered by on-site activities
    - Interviews of health workers through mobile phones or other technologies (e.g., Skype calls, however, these can be expensive)

- By direct contact with health workers through field visits

    - Most popular monitoring method used
    - Requires more time and resources
    - Involves careful planning and good coordination of field activities
    - Activities during field visits include:

        - Review of records and reports
        - Direct observation of facility, staff performance, environment
        - Interviews of health workers, patients, etc.

The field visit allows more activities to be performed and provides opportunities to establish direct contact with health workers and patients; conduct face-to-face interviews; observe staff performance, the facility, and environment; analyze records, reports, and results at the source; collect routine and/or non-routine data or information; and validate submitted data/reports.

In addition, the field visit provides opportunities to teach, supervise, and encourage health workers; it allows interaction with the local health staff to jointly identify and analyze problems and find solutions. It provides opportunities to discuss with local decision makers; this is useful for advocacy, information dissemination, and securing commitments from local officials.

Examples of records for review are:

- Presumptive TB case master list
- Laboratory registers/TB registers
- Lab request forms, treatment cards
- Stock inventory cards and records
- Equipment maintenance records

Examples of reports to review are:

- Case finding and treatment outcome reports
- Laboratory EQA reports
- Biosafety reports
- Supply management reports
- Equipment/facility maintenance reports

Examples of what to observe during laboratory field visits:

- Laboratory processes, such as collection, submission, and storage of specimens; performance of testing procedures; recording; quality control
- Supply management, storage, inventory management
- Infection control practices
- Waste management practices
- Equipment
- Infrastructure

Interviews of health workers and patients are done during field visits among health workers (all categories) and patients. Interviews can be done either individually or in groups. Examples of information to collect from health workers and patients:

- Health workers' views about the NTP's and laboratories' performance and activities; implementation problems, and knowledge of TB and TB control activities
- Patients' views on TB causation, transmission, and treatment; stigma; TB control services; and the steps in the diagnostic processes

How should sites be selected for field visits?

It is difficult to visit all of the laboratories in the local network within a given period (e.g., a year). It is practical to select the laboratories to be visited based on some criteria. For example, those laboratories that:

- Have poor performance (to identify the problems)
- Showed dramatic changes in performance (to find the reasons for the change)
- Are newly organized
- Have newly hired or trained staff (to provide supportive supervision)
- Are implementing new initiatives, policies, or technologies

How should NTP coordinators prepare for monitoring?

1) Planning for the visit

- Officially communicate with the local staff regarding the monitoring visit
- Prepare logistics
- Prepare materials for monitoring: previous reports, checklists, etc.

- What to monitor: select aspects of the lab services that will be monitored
- How those places will be monitored

2) Coordination, communication, scheduling

3) Securing funds for travel

4) Obtaining travel orders

5) Setting up logistical support

What should be done during field visits?

1) Courtesy call to the head of office
2) Conduct the monitoring visit at the facility
3) Collect the data (quantitative and qualitative)
4) Give feedback to lab staff
5) Discuss problems with the staff
6) Jointly develop and plan interventions
7) Write short report for lab staff
8) Agree on schedule of next visit

DATA COLLECTION

Data collection can be done within the office by reviewing submitted reports (passive data collection). These data are analyzed and become the basis for identifying problems and writing a feedback report. The findings can be used to decide whether to conduct a field monitoring visit for active data collection. Data can be collected through review of records/registries/reports, interviews, or direct observation of the environment, procedure, staff behavior, and practices.

Observations may be recorded in writing or by audio, scanning, or taking pictures.

1) Tools for field data collection

- Checklist (based on program indicators, custom indicators)
- Counting sheets (for quantitative data)
- Interview questionnaires
- Pencil, calculator

2) How to collect data (process or methods of data collection)

- During office monitoring:
    - Review the reports
    - Identify the problems and facilities that require field visits
- During field visits:
    - Collect quantitative data based on program indicators
    - Review the laboratory operations
    - Review the laboratory systems
    - Conduct interviews with staff, patients and other stakeholders
- After the field visit:
    - Manage the data from the field visit
    - Identify problems, root causes, interventions based on the analysis of field data
    - Discuss findings with the lab staff and jointly identify interventions
    - Jointly plan and develop evaluation indicators with the staff for the implementation of interventions

3) List of indicators to guide data collection

Annex 1 shows the list of indicators for laboratory strengthening under the End TB Strategy.

Regional Level

1) Describe the status of implementation of national policies, guidelines, and strategic initiatives by province/cities:

Status of Implementation of National Strategic Initiatives

Implementation of	Description
ITIS	
LNW expansion activities	
LNSP	
AO on GeneXpert	

2) Number of provinces/cities with annual lab network work plan including M&E plan. Secure a copy of the annual lab network work and M&E plans. Progress in the implementation of the plans must be monitored and discussed. Identify the reasons behind the accomplishment of targets or delay, if there is any.

3) Level of accomplishment (Acc.) expressed as a percentage of planned establishment of new laboratory facilities by type by province/city. This will provide information on the status of the laboratory expansion in the area by technology per province/city.

Number of New Functional Laboratories Established by Technology and Year versus Targets

Name of province/city	Number of newly established laboratories (year_____)							
	TMLs		Xpert MTB/RIF		Culture		DST	
	Target	Acc.	Target	Acc.	Target	Acc.	Target	Acc.

4) Laboratory procedures performed: This gives information on the services provided by the LNW in the province/city and its contribution to case finding.

TB microscopy: Number Examined, Number and % (+); Number and % (-); Number of PTCs with 2 Specimens

TBML performance by LGU region _____ Quarter _____ Year _____

Name of province/city	No. of PTCs examined	No. of PTCs examined with 2 diagnostic specimens	Sm (+)		Sm (-)	
	No.	No.	No.	%	No.	%
Total						

Xpert MTB/RIF: Number of Cases Tested by Type

Regional Summary Table for Xpert MTB/RIF

Number and proportion of tests by type of patients in Xpert laboratories by province/city
Quarter _____ Year_____

Province/city	No. PTCs tested	PTC type							
		New		Relapse		Other ret.		Unknown	
		No.	%	No.	%	No.	%	No.	%
Total									

Xpert MTB/RIF Test Results for New Cases

Xpert MTB/RIF test results of new DR-PTCs by province/city **Quarter ____ Year ____**

Name of province/city	No. tested	MTB (+)		RR		T		TI		MTB (-)		No. of errors
		No.	%	No.	%	No.	%	No.	%	No.	%	
Total												

Xpert MTB/RIF Test Results for Relapse Cases

Xpert test results of relapse DR-PTCs by province/city **Quarter_____ Year _____**

Name of province/city	No. tested	MTB (+)		RR		T		TI		MTB (-)		No. of errors
		No.	%	No.	%	No.	%	No.	%	No.	%	
Total												

Xpert MTB/RIF Test Results for Other Retreatment Cases

Xpert MTB/RIF test results of other retreatment DR-PTCs by province/city
Quarter_____ Year _____

Province/city	No. tested	MTB (+)		RR		T		TI		MTB (-)		No. of errors
		No.	%	No.	%	No.	%	No.	%	No.	%	
Total												

TB Culture

TB Culture Contamination Rate

Culture positivity rates by laboratory_____	**Quarter ____ Year _____**			
Culture lab	Q1	Q2	Q3	Q4

TB Culture Recovery Rate

Culture recovery rates by laboratory_____	**Quarter ____ Year _____**			
Culture lab	Q1	Q2	Q3	Q4

DST

First-Line DST

Results of first-line DST by laboratory	**Quarter_____**	**Year_____**							
Lab	No. of pts	DR		MDR		Other resistance		T	
	No.	No.	%	No.	%	No.	%	No.	%
Lab 1									
Lab 2									
Total									

Second-Line DST

Second-line DST performance by laboratory	**Quarter _____**	**Year _____**							
	No. pts	DR		XDR		Other resistance		T	
Lab	No.	No.	%	No.	%	No.	%	No.	%
Lab 1									
Lab 2									
Lab 3									
Total									

EQA

Data Collection Tool for Quality Assurance Program (QAP) Participation, Regional Level

Region _____. Trend of quarterly EQA participation (coverage) by province/city						**Year _____**
		Year 1				
		Q1	Q2	Q3	Q4	Participation level
Name of province/city	No. TMLs	%	%	%	%	high/low
1						
2						
3						

Note: High EQA participation (coverage) means that at least 95% of TMLs in a province/city LNW participated in the QAP quarterly.

Proportion of Microscopy Laboratories that Achieved Acceptable Performance

Region _____. Proportion of microscopy laboratories that achieved acceptable performance by quarter ____ Province/city						
		Year 1				
		Q1	Q2	Q3	Q4	Performance level
Name of province/city	No. TMLs	%	%	%	%	high/low
1						
2						
3						

High EQA performance (reading proficiency) means that at least 95% of the total TMLs in a province/city LNW have less than 5% major errors per quarter.

Summary of Quarterly Participation

Trend of EQA performance by quarter by					
	Year _____				Performance level
	Q1	Q2	Q3	Q4	for the year
Name of province/city	%	%	%	%	high/low
1					
2					
3					

Note: High EQA performance (reading proficiency) means that at least 95% of the total TMLs in a province/city LNW have less than 5% major errors per quarter.

Provincial/City Level

1) **Laboratory outputs:** These data provide information on the contribution of the LNW in case detection; it implies functionality of the laboratories, availability of the staff to perform the procedure, quality of laboratory service, and hints on the quality of recording and reporting by the laboratory

TB Microscopy–Number Examined, Number, and % (+); Number and % (-); Number of PTC with Two Specimens

TBML performance by facility	**Province/city** _____ **Quarter** _____ **Year** _____				
	No. of PTCs examined	Sm (+)		Sm (-)	
TMLs	No.	No.	%	No.	%
TML 1					
TML 2					
TML 3					
Total					

Xpert MTB/RIF–Number of Cases Tested by Type

Provincial Summary Table for Xpert MTB/RIF

Number and proportion of tests by type of patient in GeneXpert labs by facility **Province/city: _____Quarter _____ Year_____**									
		PTC type							
		New		Relapse		Other treatment		Unknown	
Facility	No. PTCs tested	No.	%	No.	%	No.	%	No.	%
1									
2									
3									
Total									

Xpert MTB/RIF Test Results for New Cases

Xpert MTB/RIF test results of new DR-PTCs by facility **Province/city _____ Quarter ____ Year _____**												
		MTB (+)		RR		T		TI		MTB (-)		No. of invalid results, no results, other errors
Facility	No. tested	No.	%	No.	%	No.	%	No.	%	No.	%	
1												
2												
Total												

Xpert MTB/RIF Test Results for Relapse Cases

Table _____. Xpert MTB/RIF test results of relapse DR-PTCs by facility
Province/city _____ Quarter _____ Year _____

Facility	No. tested	MTB (+) No.	%	RR No.	%	T No.	%	TI No.	%	MTB (-) No.	%	No. of invalid results, no results, other errors
1												
2												
Total												

Xpert MTB/RIF Test Results for Other Retreatment Cases

Table _____. Xpert MTB/RIF test results of other retreatment DR-PTCs by facility
Quarter _____ Year _____

Facility	No. tested	MTB (+) No.	%	RR No.	%	T No.	%	TI No.	%	MTB (-) No.	%	No. of invalid results, no results, other errors
1												
2												
Total												

TB Culture

TB Culture Contamination Rate

For province/city: _____

Culture contamination rates, by facility, year _____

	Q1	Q2	Q3	Q4
Culture lab 1				
Culture lab 2				
Liquid culture				

TB Culture Recovery Rate

For province/city: _____

Culture recovery rates, by facility, year _____

	Q1	Q2	Q3	Q4
Culture lab 1				
Culture lab 2				
Liquid culture				

DST

First-Line DST: Province: _____

Results of first-line DST by laboratory		**Quarter ____ Year_____**							
Lab	No. of pts	DR		MDR		Other resistance		T	
	No.	No.	%	No.	%	No.	%	No.	%
Lab 1									
Lab 2									
Total									

Second-Line DST: Province: _____

Second line DST performance by laboratory		**Quarter _____**		**Year _____**					
	No. of pts	DR		XDR		Other resistance		T	
Lab	No.	No.	%	No.	%	No.	%	No.	%
Lab 1									
Lab 2									
Total									

EQA

Data Collection Tool for QAP Participation, Provincial Level

Province _____	**Trend of quarterly EQA participation by TML**				
	Year _____				
TML	Q1 Y/N	Q2 Y/N	Q3 Y/N	Q4 Y/N	Participation level high/low
1					
2					
3					

Note: High TML QAP participation means that the TML participated for 4 quarters in a year. The information that can be obtained from the table is the number of laboratories in the province that achieved high level of participation.

Data Collection Tool for Trend of EQA Performance by Quarter

Province/city trend of EQA performance by quarter by TML					
	Year _____				Performance level for the year high/low
TML	Q1 Y/N	Q2 Y/N	Q3 Y/N	Q4 Y/N	
1					
2					
3					

Note: High performance-level means that the TML has acceptable performance (less than 5% major errors) in 4 quarters. The information that can be obtained from the table is the number of laboratories in the province that achieved high performance.

2) Operations (report annually)

- List the type of staff and their functions. Note their training status.

Laboratory staff by function and training status	**Year ____**	
Type of laboratory staff	Function	Training status

- Number of functional laboratories by technology (report annually)

Number of functional laboratories by technology	**Province _____**	**Year ____**
TMLs	GeneXpert	Culture	DST

- Downtime in number of days per technology per facility (report quarterly)
    - Downtime is the number of days the laboratory did not perform tests due to a variety of reasons (example: no med tech, no supplies, expired supplies, equipment breakdown)
- TAT per technology (report quarterly); check if TAT is within standards
- Supplies (report quarterly); the goal is to have no stock-outs or expired supplies
    - Stock-outs of supplies are monitored by type of commodity and duration in number of weeks/months
    - Expired supplies by date, type of commodity and their quantities are recorded
- Workload by technology by staff
    - Daily workload can be computed from the table on number of tests performed by technology
- Recording and reporting (quarterly)
    - Number/proportion of facilities that submitted complete, correct, and timely reports; this reflects the functionality of the recording and reporting system

3) Implementation of national policies and guidelines applicable to facilities

- Use of Xpert MTB/RIF for Sm (-) patients
- Collection of two specimens for diagnostic direct sputum smear microscopy

4) Annual provincial/city lab network strengthening plans including M&E plan

- Secure a copy of the provincial/city lab network strengthening and M&E plan, which is the basis for monitoring the activities of the province/city

5) Monitoring laboratory expansion

- To monitor laboratory expansion in the region/province/city, track the number of functional laboratories by technology

- It is recommended that the province/city maintain a directory (database) of laboratories by technology

Number of new laboratories established by technology and year versus targets

Municipality/city	Number of newly established laboratories (year)							
	TMLs		Xpert MTB/RIF		Culture		DST	
	Target	Acc.	Target	Acc.	Target	Acc.	Target	Acc.

Number of functional laboratories by technology in the locality

Municipality/city	Number of functional laboratories			
	TMLs	Xpert MTB/RIF	Culture	DST

- For regions and provinces/cities, internal monitoring of the laboratory expansion may be done

- The proportion of private laboratories that are participating in the NTP LNW indicates the level of participation by the private sector; these laboratories can be monitored by technology

6) Monitoring laboratory performance

- Monitoring the laboratory performance provides information on the contribution of laboratory facilities in case detection, staff workload, and laboratory supply needs

7) QA

- The QAP helps ensure accurate and reliable test results for clinicians

- The frequency of error results and QA provide information on the proficiency of the laboratories

- The current EQA program is for TB microscopy only; it is implemented by the provinces and cities through their QA teams; important data to collect are the following:

    - Number of TMLs, public or private, that participate quarterly in the QA program; frequency of TML visits; procedure for selecting slides and providing feedback to the laboratory staff
    - Number and percentage of laboratories that have acceptable performance
    - Collect regional and provincial data for EQA (see How to Manage Data); these tables (page 11) provide a summary of the EQA status in the region and/or province/city; the entries in these tables are derived from the existing EQA forms that area filled out by the QA team in the province/city

HOW TO MANAGE DATA

Monitoring involves periodic laboratory data collection and analysis to generate information regarding the status of operations, services provided, and accomplishments based on plans and objectives. Monitoring data needs to be managed and processed immediately so that managers will be provided with an up-to-date and robust basis for making decisions.

General Steps in Managing Monitoring Data

Collation and Organization of Data

Monitoring data increases its volume and for ease of data organization and analysis, it is necessary to collate them by integrating related quantitative and qualitative data by groupings such as person, geographic distribution, time, laboratory technology, laboratory system elements, and other categories of observations (e.g., behaviors and practices).

Data are summarized and organized into tables, charts, graphs, and maps to present them in meaningful graphical forms to assist in data analysis and interpretation and to facilitate understanding of the overall message derived from the monitoring report.

Data summaries will enable the monitor to make comparisons; establish trends; plot the level of accomplishments; list important observations, such as patterns of behaviors or occurrences of events; and even map cases identified by the laboratories.

Data Banking

Monitoring data must be saved in either the paper-based form or it may be encoded and stored in electronic form.

Archiving

Archiving is necessary to establish historical LNW data; draw trends; and for research purposes. The generation of monitoring data involves investment using government money and is subject to provisions of RA 9470 (National Archives of the Philippines Act of 2007). The rules of archiving must be followed and the office must provide space for the growing volume of data. Data must be stored for at least five years in its natural form (paper-based or e-record) and must be secured from degradation. Paper-based records may also be scanned and stored in hard drives in pdf form to reduce storage space requirements. Disposal of records requires formal arrangements with the LGU.

Providing Feedback

Providing feedback provides the opportunity to share the objective findings and recommendations with the field staff so that they can take action to improve the laboratory

performance. Verbal and written feedback can be given onsite before the monitoring team leaves the site. Feedback must include the findings and recommendations. The final monitoring report will be written after the monitoring team returns to the office.

The monitoring visit is a good opportunity to provide supportive supervision. Salient observations regarding practices and attitudes of the staff should also be discussed in light of improving performance. Commendations based on objective findings must be given to encourage continuous self-motivation.

Writing Final Monitoring Reports

Writing the monitoring report is required because it provides a solid basis for improvements on the basis of the laboratory performance status at the time of visit.

The final monitoring report should follow this format.

Introduction

This includes the basis and the purpose of the visit. Some information about previous performance or previous visit can be added as background

Findings, Analysis, and Discussion

The findings are based on objective review or records, reports, and other documents, interviews, and observations. Graphical presentations of summarized data are also presented.

This section describes the results of the visit, including the analysis and interpretation of data. Comparisons with previous performance are made and factors that affect the current status and performance of the laboratory must be included.

Conclusions

These are summary statements regarding the findings, including the lessons learned.

Action Points

These are agreed upon activities or interventions that the facility staff will implement after the visit. The implementation of these activities will be assessed during the next visit.

ANNEX 1. INDICATORS FOR LABORATORY STRENGTHENING UNDER THE END TB STRATEGY

Objective 1. Increase access to rapid and accurate detection of TB	
Indicator 1	Does the national diagnostic algorithm indicate a WRD (WHO-recommended rapid diagnostic) is the initial diagnostic test for all people with signs and symptoms of TB?
Indicator 2	Percentage of notified new and relapse TB cases tested with a WRD as the initial diagnostic test
Indicator 3	Percentage of notified new and relapsed TB cases with bacteriological confirmation
Indicator 4	Percentage of testing sites using a WRD at which a data connectivity system has been established that transmits results electronically to clinicians and to an information management system
Indicator 5	Does national policy indicate that TB diagnostic and follow-up tests provided through the national TB programme are free of charge or that fees can be fully reimbursed through health insurance, or both, for all people with signs and symptoms of TB?
Objective 2. Reach universal access to DST	
Indicator 6	Does national policy and the diagnostic algorithm indicate there is universal access to DST?
Indicator 7	Percentage of notified, bacteriologically confirmed TB cases with DST results for rifampicin
Indicator 8	Percentage of notified, rifampicin-resistant TB cases with DST results for fluoroquinolones and second-line injectable agents
Objective 3. Strengthen the quality of laboratory services	
Indicator 9	Percentage of diagnostic testing sites that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed
Indicator 10	Percentage of DST sites that have demonstrated proficiency by EQA panel testing for all DST methods performed
Indicator 11	Percentage of laboratories conducting culture, line probe assay, or phenotypic DST, or a combination of these, in which a formal quality management system is being implemented that aims to achieve accreditation according to international standards
Indicator 12	Is the National Reference Laboratory accredited according to the ISO15189:2012 standard?

RESOURCES FOR FURTHER READING

Philippines Department of Health. Research Institute for Tropical Medicine, National Tuberculosis Reference Laboratory. *National Tuberculosis Laboratory Biosafety Manual*. June 2012.

United Nations Development Programme. *Handbook on Planning, Monitoring and Evaluating for Development Results*. New York, USA. 2009.

WHO. *Framework of Indicators and Targets for Laboratory Strengthening Under the End TB Strategy.* 2016.

WHO. *Laboratory Biosafety Manual*. 3rd ed. 2004.