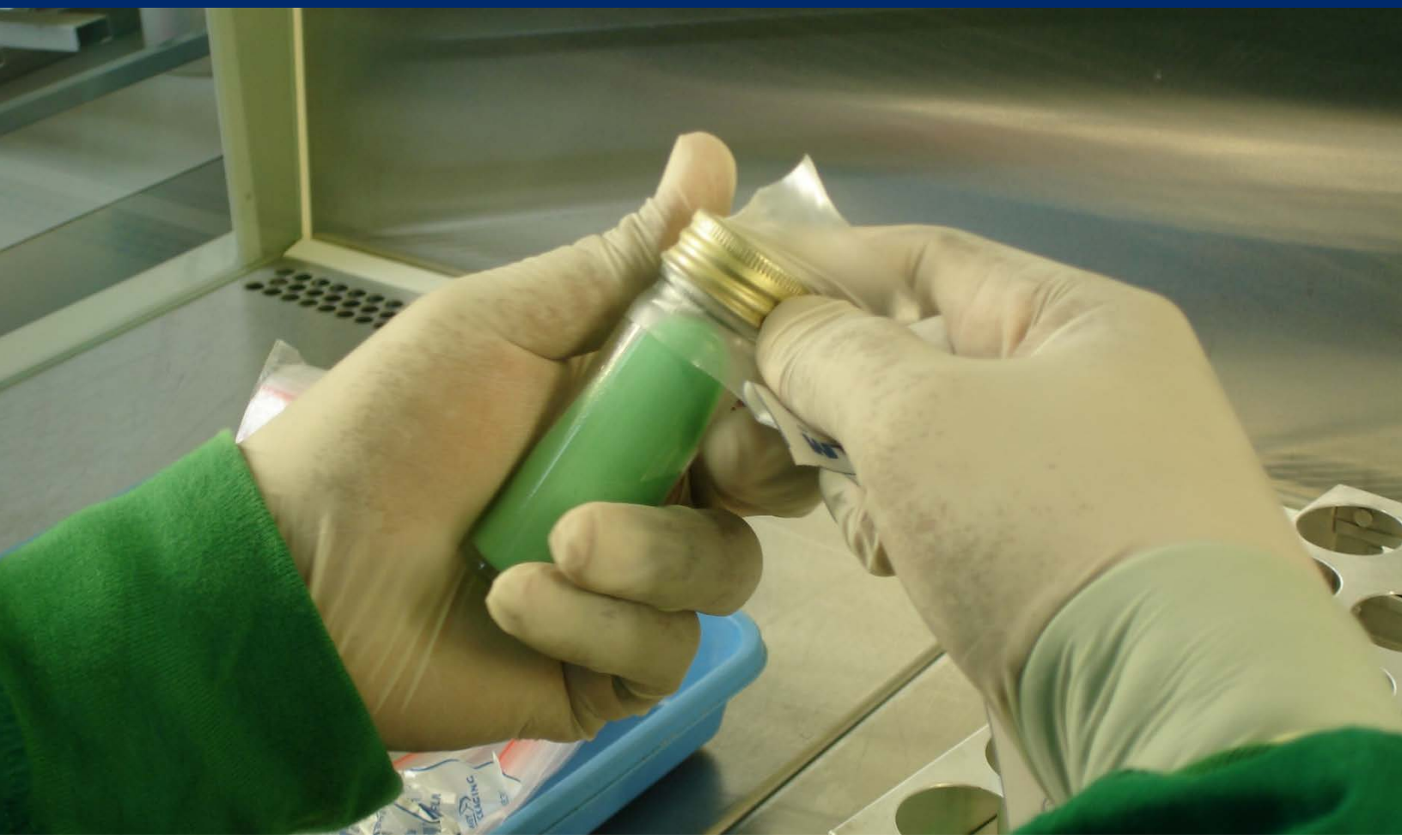
USAID | DELIVER PROJECT

Indonesia: Tuberculosis Laboratory Logistics Assessment

Phases I and II



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Indonesia: Tuberculosis Laboratory Logistics Assessment

Phases I and II

USAID | DELIVER PROJECT, Task Order 4
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Abstract

Between August 2013 and February 2014, the USAID | DELIVER PROJECT, with support from the National TB Program, the Ministry of Health, and TB CARE, conducted a two phased TB Laboratory Logistics Assessment of the National TB Program focused on the performance and availability of cold chain equipment at collection and retrieval sites, and during transport, waste management practices, the availability of guidance (i.e., SOPs) on cold chain management, and laboratory logistics system management. This report presents the findings of the assessment as well as recommendations to strengthen the TB lab logistics systems.

Cover photo: A lab technician handles TB test materials in Indonesia. USAID | DELIVER PROJECT. 2014.

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Contents

Acronyms

ATLAS	*Assessment Tool for Laboratory Services*
BLK	*Balai Laboratorium Kesehatan* (Public Health laboratory)
BBLK	*Balai Besar Laboratorium Kesehatan* (Advance Public Health Laboratory)
BPPM SK	*Direktorat Bina Pelayanan Penunjang Medik dan Sarana Kesehatan, Direktorat Jenderal Bina Upaya Kesehatan* (Directorate for Medical and Health Facilities Support Services, Directorate General for Health Efforts Guidance)
Dit P2ML	*Direktorat Pengendalian Penyakit Menular Langsung* (Directorate for Direct Transmitted Diseases, Ministry of Health)
Ditjen P2P-PL	*Direktorat Jenderal Pengendalian Penyakit dan Penyehatan Lingkungan, Kementerian Kesehatan* (Directorate General for Disease Control and Environmental Health, Ministry of Health)
DOT	directly observed therapy
DST	drug susceptibility testing
FEFO	first-to-expire, first-out
FK UGM	*Fakultas Kedokteran Universitas Gajah Mada, Yogyakarta* (Medical faculty, University of Gajah Mada)
HC	health center
ISO	International Organization for Standardization
JSI	John Snow, Inc.
LJ	Löwenstein–Jensen, TB culture media
LMIS	logistics management information system
MGIT	Mycobacteria Growth Indicator Tube
MOH	Ministry of Health
MDR TB	multidrug-resistant tuberculosis
NPS	National Prevalence Survey
NTP	National TB Program
NHRC	Novartis Hasanuddin Research Center
PMDT	Programmatic Management on Drug Resistant TB
PPE	personal protection equipment
RSPP	*Rumah Sakit Penyakit Paru* (Specialistic Hospital for Lung Diseases)
RIF	Rifampicin

SOP	standard operating procedure
Sub-dit	Sub-directorate
UN	United Nations
USAID	U.S. Agency for International Development
WHO	World Health Organization

Acknowledgments

The USAID | DELIVER PROJECT (the project) extends sincere thanks and appreciation to the Ministry of Health (MOH) and the U.S. Agency for International Development (USAID) for the opportunity to conduct Phase I and II of the TB Laboratory Logistics Assessment of the National TB Program (NTP) in select hospitals and laboratories that collect, process and sometimes transport TB specimens and TB specimen-receiving referral laboratories for culture and drug sensitivity testing.

The project is grateful for the initiative, and the collaborative spirit shown by the NTP; the MOH and its affiliates: Sub-directorate for TB Control; Directorate for Direct Transmitted Diseases; DG for Diseases and Environmental Health, MOH; Sub-directorate for Microbiology and Immunology, Directorate for Medical and Health Facilities Support Services DG for Health Efforts Guidance, MOH; ; TB CARE and all chiefs and staffs of the six hospitals/laboratories TB specimens collecting sites (RSUP Sanglah Bali, RSUP Adam Malik Medan, Rumah Sakit Penyakit Paru (RSPP) Cisarua, RSUP Dr. Sarjito Yogyakarta, RSU Dok II Jayapura, Papua and RSU Dr. Saiful Anwar Malang); the five receiving sites referral laboratories (RSUP Persahabatan; Microbiology Division of Gajah mada University Medical School (intermediary site); BLK Provinsi Jawa Barat ; BBLK Surabaya and BLK P[rovinsi Papua Jayapura and the six hospitals/laboratories performing testing on TB specimens covering BBLK Jakarta ; RSUP Adam Malik Medan, BLK provinsi Jawa Barat Bandung, BLK Provinsi Jawa Tengah Semarang, Clinical Microbiology Laboratory of FK-UI Jakarta, BBLK Surabaya, whose support enabled the assessment to take place.

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Jakarta, February 2014

Russell Vogel

Country Director

USAID|DELIVER PROJECT

Indonesia

Executive Summary

Indonesia, one of the highest tuberculosis (TB)-burdened countries in the world, has approximately 297 cases per 100,000 population; approximately 2 percent of these cases are multidrug-resistant TB (MDR) (WHO 2013). During the last decade, resistance to first line drugs (streptomycin, isoniazid, rifampicin, and ethambutol) and second line drugs (kanamycin, ofloxacin, and amikacin) have been reported in many parts of the world. These MDR cases make controlling the disease even more complex.

To support the TB control programs, laboratory diagnosis is essential; identifying viable organisms in specimens and reliably and accurately diagnosing multidrug-resistant tuberculosis (MDR TB) will improve the ability to control the disease. Reliable, accurate laboratory testing depends on many factors: the quality of the specimen collected, collection method, transportation, and storage conditions, including how the specimen is transported to the laboratories. While standard operating procedures (SOPs)/guidelines regarding the handling and testing of specimens are usually available in Indonesia, very little data is available about compliance to these SOPs in the field. Additionally, standardized laboratory logistics procedures and equipment maintenance policies are not in place. These policies are important as they ensure that quality laboratory supplies are available and facilities have well-functioning instruments.

To understand the current practices of specimen handling—including collection, storage, and transportation, as well as laboratory logistics systems and management—a two-phase TB Laboratory Logistics Assessment was conducted between August 2013 and February 2014.

The first phase of the assessment focused on—

- specimen collection
- supply availability
- transportation
- availability and management of cold chain equipment during specimen transport.

The second phase of the assessment focused on—

- current laboratory logistics system management practices
  - inventory control systems
  - logistics management practices
  - use of logistics information for making supply chain decisions.

Under phase I, assessment teams visited 11 sites—six collection sites and five referral laboratories. Using an adapted questionnaire, teams interviewed staff members at each site. During the visits, the teams also observed how the staff collected, stored, packaged, and transported specimens, and how they received specimens at the sites. Under phase II of the assessment, the team visited six high-level

TB laboratories that provide advanced testing services to the NTP. Using an adapted version of the Assessment Tool for Laboratory Services (ATLAS), the team interviewed the TB laboratory personnel who manage laboratory logistics systems.

During phase I, the team observed that containers of standardizing specification—i.e., sterile versus non-sterile, type of pot, and volume capacity—were not used. Also, specimen storage, transporation methods, and packaging for transport varied from site to site. Many facilities were following some type of safety protocol (i.e., wearing the proper safety gear when handling specimen), but SOPs for specimen handling across facilities were not used. In fact, most existing SOPs found in this assessment were locally developed and varied greatly across sites and programs. All facilities visited had cold chain equipment available; they were using the appropriate equipment for specimen storage. Cold chain was rarely used when specimens were transported.

In phase II, facilities using GeneXpert reported expiries of cartridges during the past year. In several facilities, the storage of laboratory supplies did not meet the recommended storage practices. SOPs were not used to manage laboratory supplies. Instead, each facility created and used various approaches. However, these guidelines were not documented. Also, staff in most of the visited facilities did not have any formal training in laboratory supply chain management, cold chain management, and/or waste management. Standardized forecasting methods were not used for demand planning when determining what TB laboratory supplies to procure.

Recommendations

Based on the findings, it is recommended that NTP and Dit. BPPM SK develop SOPs for proper specimen handling, storage, transportation, and cold chain maintenance. It is also recommended that laboratory staff and TB officers at the provincial-and district-level be trained in these SOPs and ensure they are enforced across all laboratories. To ensure the safety of laboratory staff and the community, standard safety equipment and support devices that meet the United Nations (UN)/World Health Organization (WHO) standards should also be introduced and enforced. Additionally, to reduce the risk of specimen deterioration and overload of current referral sites, more effective and efficient referral systems need to be established and reviewed.

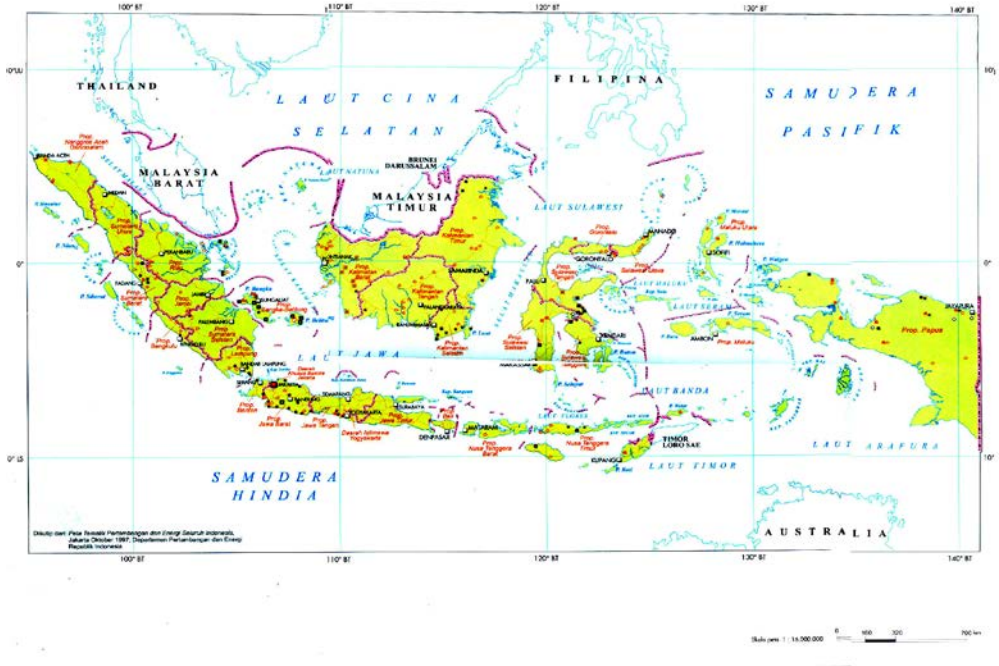
It is also recommended that a logistics system be developed and documented into SOPs to ensure that supplies are available, especially because the NTP plans to scale up its Programmatic Management on Drug Resistant TB (PMDT) program. The GeneXpert supply system for cartridges should be evaluated; and the ongoing deployment of GeneXpert must be coordinated carefully to ensure proper supply planning. NTP and stakeholders should also consider a more systematic forecasting and quantification approach for TB laboratory supplies. Generally, the TB laboratories visited are in good condition; however, more attention should be given to the storage facilities for the laboratory supplies in the institutions, especially outside the laboratories.

Background

Indonesia is an archipelago country comprised of 18,491 islands. It includes 34 provinces, 416 districts, and 98 municipalities; with 6,994 sub-districts and 76,343 villages. Indonesia is the fourth most populous country in the world, with an estimated population of 252 million (see figure 1). The islands of Java and Sumatra are the most populated, with 77 percent of Indonesia's population living on these islands (Wikipedia 2015). Administratively, the central government is in the capital city of Jakarta, on Java.

Health services are provided by 9,601 health centers (HC); approximately 6,000 can provide inpatient care; 22,171 sub-health centers also provide care (MOH, 2014). In addition to the static HCs, 6,253 mobile HCs serve hard-to-reach populations using cars or motorboats. The average catchment area served by HCs is approximately 25,000–50,000 patients; laboratory services are both public and private. Throughout Indonesia, 27 public health laboratories are at province capitals and 123 at district capitals. Also, 793 private health laboratories are located throughout the country. Eighteen MOH-managed hospitals provide services; local governments, armed forces, other ministries, and private enterprises own 1,175 hospitals (MOH, 2014).

Figure 1. Map of Indonesia



Communicable diseases are still common in Indonesia. TB, caused by *Mycobacterium tuberculosis,* is a major public health concern; Indonesia ranks among the highest TB-burdened countries in the world, with a prevalence of approximately 297 cases per 100,000 people (WHO 2013).

During the last decade, resistance to the first line drugs (i.e., streptomycin, isoniazid, rifampicin, and ethambutol) and second line drugs (i.e., kanamycin, ofloxacin, and amikacin) have been reported in

many parts of the world. According to the *Global Tuberculosis Report 2013*, 2 percent of the current cases of TB in Indonesia are multidrug-resistant tuberculosis (MDR TB).

In support to the TB Sub-directorate at the Directorate for Direct Transmitted Diseases (Dit P2ML) under the MOH, a National TB Program (NTP) was formed that includes experts from institutions within and outside the MOH; they have the capacity to enhance and support this program. International organizations—World Health Organization (WHO); USAID; KNCV Tuberculosis Foundation (KNCV); FHI 360; Management Sciences for Health; U.S. Pharmacopia; Global Fund to Fight AIDS, Tuberculosis and Malaria; and the USAID | DELIVER PROJECT—support NTP in various ways. TB CARE, an alliance group with multiple international partners, support operational activities, trainings, and logistics; they also introduce newer diagnostic technologies.

Health centers, hospitals, and laboratory facilities within the NTP laboratory network routinely collect and test specimens. Specimens that require further testing (i.e., culture and/or drug susceptibility testing [DST]) are referred to appropriately designated referral laboratories. However, limited information is available about the actual practice and detailed conditions about how the TB specimens are handled, including specimen collection, storage, transport, and receipt at referral laboratories. Information is limited for cold chain maintenance, availability of cold chain equipment, waste management practices, and the availability of standard operating procedures (SOPs)/guidance at the facilities.

Assessment Purpose and Objectives

Proper specimen collection and transportation, including appropriate cold chain practices—as well as the availability of good quality reagents, supplies, and reliable equipment—are key components for a successful TB program. To establish the current state of these elements, the USAID |DELIVER PROJECT, with NTP/BPPM SK and TB CARE, conducted a two-phase TB laboratory logistics assessment.

The goal of this assessment was to ensure the reliability and accuracy of laboratory diagnosis of TB specimens within the scope of the National TB program in Indonesia. The first phase of the assessment focused on specimen collection, supply availability, and transportation; plus the availability and maintenance of cold chain during transportation. The second phase focused on laboratory logistics system management, including inventory control systems, logistics management practices, and using logistics information to make supply chain decisions. This phase of the assessment also looked at the availability of reagents and supplies in laboratories and the state of laboratory equipment.

The specific objectives of phase I and II of the assessment, include—

Phase I objectives

- To assess the—
    - cold chain at hospitals/laboratories (collection sites) during transport of TB specimens and at referral laboratories (receiving sites)
    - performance and availability of various cold chain equipment and ancillary supplies at the collection sites—i.e., hospitals/laboratories and at the receiving referral laboratories
    - availability and use of temperature monitoring devices to prevent the biological TB specimens from freezing and from exposure to excessive heat

- management and handling of infectious material and waste from TB specimen collection at hospitals and laboratories
- availability of SOPs/instructions for collection, transport, and receipt of TB specimens at the facilities.

- To prepare recommendations and SOPs on cold chain management that will enhance the quality of TB specimens.

Phase II objectives

- To assess the—
  - challenges of the TB labs for the logistics requirements needed to provide expected laboratory services to lab supplies available and required at different levels of TB labs
  - challenges of TB labs in procuring quality and appropriate key laboratory equipment and supplies
  - maintenance system being used for key TB laboratory equipment
  - specimen/culture cold chain transportation mechanisms and TB laboratory linkage between facilities submitting specimen for GeneXpert, culture, and DST tests, including Programmatic Management on Drug Resistant TB (PMDT) treatment sites.
- To understand the forecasting methods at different levels of TB labs.

Methodology

The TB Laboratory Logistics Assessment was conducted in two phases. Phase I focused on the performance and availability of cold chain equipment at collection and retrieval sites, and during transport, as well as waste management practices and the availability of guidance (i.e., SOPs) on cold chain management for TB specimens at laboratories and hospitals. Phase II focused on laboratory services and laboratory logistics system management using an adapted version of the Assessment Tool for Laboratory Services (ATLAS), which the USAID | DELIVER PROJECT developed.

The USAID | DELIVER PROJECT carried out phases I and II, in partnership with personnel from the National TB Program—the Sub-directorate for TB Control; Dit P2ML; DG for Disease Control and Environmental Health (Ditjen P2-PL); Sub-directorate for Microbiology and Immunology Services; Directorate for Medical and Health Facilities Support Services (Dit. BPPM SK); DG for Health Efforts Guidance (Ditjen BUK); and TB CARE.

Phase I

The first phase of the assessment was conducted at 11 sites—six specimen collection sites (hospitals/laboratories) and five receiving sites (referral laboratories). Site selection was based on the ownership of the labs (e.g., under BPPM/Ministry of Medical education/provincial health systems) and the testing performed (laboratories doing only microscopy were not included). See table 1 for the site names and locations.

Table 1. Phase I Assessment Sites

Facilities Collecting and Transporting TB Specimens	Referral Labs Receiving TB Specimens/Isolates
RSUP Clinical Microbiology Lab, Sanglah Hospital, Denpasar, Bali	Microbiology-TB laboratory RSUP Persahabatan, DKI Jakarta
RSUP Clinical Microbiology Lab, Adam Malik Hospital, Sumatra Utara	Microbiology TB Laboratory, Medical Facility, Gajah Mada University, Yogyakarta (intermediary site)
Rumah Sakit Paru Dr. M. Goenawan Partowidigdo (RSPP), Bogor, West Java	BLK Provinsi Jawa Barat Bandung
RSUP Dr. Sarjito Hospital, Yogyakarta	BBLK Surabaya, Jatim
RSUD Saiful Anwar Hospital, Malang, East Java	BLK Provinsi Papua Jayapura
RSUD Dok II Hospital, Jayapura, Papua	

Phase I took place between August and October 2013 (see table 2); the assessment team included the USAID | DELIVER PROJECT and the NTP, including Sub-directorate (Sub-dit) TB Directorate P2ML, *Direktorat Jenderal Pengendalian Penyakit dan Penyehatan Lingkungan, Kementerian Kesehatan* (Ditjen P2P-PL), Dit. Bina Pelayanan Penunjang Medik dan Sarana Kesehatan (BPPM SK) Kemenkes.

Table 2. Phase I Assessment Timeline

Activity	August 2013				September 2013				October 2013			
Internal USAID | DELIVER PROJECT preparations	X	X	X									
Team assignment and discussions		X	X									
Develop assessment instrument/ questionnaire		X	X									
Finalize assessment tool and training on its use for field assessors			X									
Implement assessment in target sites				X	X	X	X	X				
Tabulate and analyze					X	X	X	X				
Write report on assessment results							X	X				
Disseminate report								X	X			
Hold periodic team meetings					X		X		X			

USAID DELIVER Jakarta developed the assessment questionnaire to aid in this assessment; it included a series of interviews and observations (see appendix A for assessment tool). Prior to field visits, the questionnaire was field tested and adapted, as needed. To ensure data consistency across all teams, each assessment team was trained how to use the tool and do the data collection. Using the questionnaire, assessment teams interviewed relevant staff members at each site, including the heads of the microbiology units/labs, lab supervisors, senior technicians, and nurses. Additionally, at each site, assessment teams observed practices of specimen collection, storage, packaging, transportation, and receipt of specimens at the receiving sites.

Phase I Outputs

Data collected were tabulated and analyzed for the following outputs:

- Data on the situation and condition of cold chain resources (equipment, performance) to support the quality of samples collected at the collection and receiving sites.
- Conclusions and technical recommendations to improve the cold chain performance for TB specimens.

Phase II

The second phase of the assessment was conducted at six high-level TB laboratories that provide advanced testing services for the NTP. To ensure quality testing, these laboratories are qualified to provide testing services; they are categorized as A and B. Category A laboratories are quality assured for culture and DST. Currently, the network has a total of six category A laboratories and four category B laboratories. As table 3 shows, four of the six category A sites, and two of the four category B sites, were visited for this assessment. Site selection was based on their level of readiness and contribution to the NTP.

Table 3. Phase Two II Hospital and/or Laboratory Sites

Category A Laboratories	Category B Laboratories
• BBLK Surabaya, East Java • BLK Provinsi Jawa Barat Bandung, West Java • BLK Provinsi Jawa Tengah, Semarang, Central Java. • Clinical Microbiology Laboratory FK-UI, Jakarta	• RSUP Adam Malik, Medan, North Sumatera • BBLK Jakarta, DKI Jakarta

Phase II of the assessment used ATLAS to conduct interviews with relevant TB laboratory personnel who manage laboratory logistics systems. ATLAS is a data gathering tool developed by the USAID | DELIVER PROJECT to assesses laboratory services and logistics. The assessment team adapted the ATLAS tool to meet the country-specific needs and used the adapted tool during a series of interviews and observations between December 2013 and February 2014 (see table 4).

Table 4. Phase II Assessment Timeline

Activity	December 2013				January 2014				February 2014			
Internal USAID DELIVER PROJECT preparations	X	X	X									
Team assignment and team discussions				X								
Develop draft assessment instrument/questionnaire	X	X	X									
Finalize assessment tool and training on its use for field assessors			X	X								
Implement assessment in				X		X	X	X	X			

6 TB laboratories												
Tabulate and analyze								X	X	X		
Write report on assessment results										X	X	X
Disseminate report										X	X	X
Hold periodic team meetings					X		X		X	X		

Phase II Outputs

Using the ATLAS tool, data were collected, then tabulated and analyzed for the following outputs.

To document the—

- status of the TB lab supplies
- forecasting methodology
- availability and use of SOPs
- procedure for the entire supply chain management cycle: forecasting, procurement, customs clearance, storage, distribution, recording, and reporting
- procedure for sample packaging, transportation, cold chain management, tracking, recording, and reporting.

Phase II Limitations

Ideally, all the laboratories in the network would have been visited as part of this assessment. As previously stated, only four of the six laboratories in category A, and two of the four laboratories in category B, were visited. Sites were not randomly selected, but were selected based on their level of readiness and contribution to the NTP. Therefore, because of the small sample size and specific selection criterion, these findings are not statistically representative. However, the findings do offer a general overview of the state of the logistics management systems in these laboratories.

Findings

This section describes the general findings of phase I and II of the TB Laboratory Logistics Assessment. See appendices C and E for the specific findings for each facility visited.

Phase I Findings

As noted previously, the assessment team studied the management of cold chain and transportation of TB specimens in 11 facilities across Indonesia—six collection sites and five receiving sites. See table 1 for a list of the names and locations of these sites.

Specimen Collection and Testing

Specimen collection

As shown in tables 5 and 6, the collection and retrieval sites vary widely in the number of specimen that are collected and/or received each month.

Table 5. Approximate Number of Specimens Collected and Referred to Reception Sites/Referral Laboratories per Month

Collection/Intermediary Site (Hospitals and Laboratories)	Approximate Number of Specimens Collected per Month from Suspected MDR
RSUP Clinical Microbiology Lab, Sanglah Hospital	150 specimens
RSUP Clinical Microbiology Lab, Adam Malik Hospital	100–200 specimens
RSPP Rumah Sakit Paru Dr. M. Goenawan Partowidigdo	1,000 specimens
RSUP Dr. Sarjito Hospital	20 specimens
RSUD Saiful Anwar Hospital	250 specimens
RSUD Dok II Hospital	50–60 specimens

Table 6. Approximate Number of Specimens Received for Culture and DST at reception Sites/ Referral Laboratories per Month

Receiving Site (Hospitals and Laboratories)	Approximate Number of Specimens Collected and Received per Month

Microbiology-TB laboratory RSUP Persahabatan	750 specimens from MDR suspected cases (others up to 2,500 specimens)
Microbiology TB Laboratory, Medical Facility, Gajah Mada University(intermediary site)	120–180 specimens
BLK Provinsi Jawa Barat, Bandung	200 specimens
BLK Provinsi Papua, Jayapura	60–70 specimens
BBLK Surabaya	200 specimens

Microbiology laboratories receive specimens from sentinel health centers, PMDT polyclinics, directly observed therapy (DOT) polyclinics, TB and HIV wards, and private facilities. Only a few facilities visited receive specimen from the National Prevalence Survey, a WHO designed survey targeted in the sampled cluster area. Depending on the testing requested, these laboratories refer the specimen to laboratories qualified to provide further testing.

Specimen Testing

Specimen testing varies across facilities, depending on their capacity and associated program at the laboratory. To diagnose TB, sputum smear microscopy is performed at most of the primary HCs and hospitals. Most facilities ask each patient for three specimens, but the sites vary as to where the sputum samples are collected—e.g., some facilities collect all samples onsite, while others collect one or two onsite and ask the patient to return with the other samples.

In addition to microscopy, cultures are done in many laboratories, but not all are followed with DST for suspected MDR TB cases. At present, more advanced laboratories are performing DST, but only six have been quality assured; those laboratories are assigned as referral laboratories, with a mandate to conduct culture and DST for NTP. The facilities are listed below.

Referral laboratories conducting culture and DST:

- RSUP Persahabatan
- BBLK Surabaya
- BLK Provinsi Jawa Barat, Bandung
- Novartis Hasanuddin Research Center (NHRC) Makassar
- BLK Provinsi Jawa Tengah, Semarang
- FKUI Jakarta.

Each referral laboratory has its own catchment of referring hospitals/laboratories. More laboratories are currently qualifying to become culture and first and second line DST referral laboratories.

According to the diagnostic algorithm of PMDT, any presumptive case of MDR TB is first tested by GeneXpert and, if the results are positive—shows Rif resistant—another specimen is cultured using either Löwenstein–Jensen (LJ) medium or Mycobacterium Growth Indicator Tube (MGIT) culture medium. If the cultures are positive for *Mycobacterium tuberculosis* (MTB), they have DST for both first and second line drugs. Because all the laboratories are not qualified for DST, cultures must be referred to a higher level laboratory.

Transportation of Specimens

Packaging and transporation methods vary from site to site, depending on the collection program for the specimen. Table 5 shows the program under which the specimen is collected and how it is packaged for transportation, including cold chain usage and temperature monitoring. Specimen samples coming into the microbiology laboratories from routine collection and sentinal sites are typically packaged in plastic pots with screw-top lids, and contained within plastic bags and boxes for shipment. Specimens from these sites are often in non-sterile pots and packaged without a parafilm seal.

The protocol for transporting specimens to referral laboratories from microbiology laboratories also varies from site to site. Most facilties that ship TB specimens isolate them in McCartney Bottles with screw caps and proper packaging. However, some sites still transport isolates in test tubes covered with cotton and paraffin because of the limited stock of McCartney Bottles. Parafilm is regularly used to seal specimens sent for referral. In general, there were no complaints from receiving sites about the packaging (leaking, broken) of specimens or the condition of the specimens upon arrival.

One important finding about the transporation and handling of specimens is that no biohazard warning labels and/or infectious material labels were attached to specimens at any level of the specimen handling and transport.

Table 7. Origin of Specimen, Packaging, and Cold Chain Usage during Transport

Institution/ Facility	Program	Type of Specimen Referred	Distance	Packaging	Temp Monitoring in Transport
Sanglah Hospital, Denpasar, Bali	Routine	-	Near (farthest ± 1 hour)	Pot, plastic bag & plastic box without cold chain	No
	PMDT	-	<3 hours	Pot and plastic bag without cold chain	No
		Isolate on LJ media	1–2 days	In compliance with SOP, no cold chain	No
	Sentinel	-	Near (farthest ± 1 hour)	Pot, plastic bag & plastic box without cold chain	No
Adam Malik Hospital, Medan, North Sumatera	Routine	-	Near (farthest ± 1 hour)	-	No
	PMDT	-	-	-	No
		Isolate on LJ	2 days	In compliance with SOP,	No

		media		without cold chain	
	Sentinel	-	Farthest ± 2 hours	Pot, plastic bag & plastic box/Styrofoam without cold chain	No
	NPS	-	1 day–2 days	In compliance with SOP with cold chain + thermometer	Yes
Dr. M. Goenawan Partowidigdo Hospital, Cisarua, West Java	Routine	-	-	-	N/A
Sarjito Hospital, Yogyakarta	Routine	Sputum to FK UGM University	Near, just a block away	Pot, plastic bag & plastic box/Styrofoam without cold chain	No
	PMDT				
Dok II Hospital, Jayapura, Papua	Routine	Sputum to BLK Jayapura	Near	Pot and plastic bag without cold chain	No
	PMDT				
Saiful Anwar Hospital, Malang, East Java	Routine	Sputum to (BBLK Surabaya	1–2 days	In compliance with SOP with cold chain, no thermometer	No
	PMDT				
Persahabatan Hospital, Jakarta	Routine	-	-	-	-
	PMDT	-	-	-	-
		-	No records	Pot, plastic bag and a container secured by wooden outer package. Use icepacks or ice cubes in plastic w/o thermometer	No

Medical Faculty, Gajah Mada University, Yogyakarta	Routine	-	Near (farthest ± 1 hour)	Pot, plastic bag & plastic box/Styrofoam without cold chain	No
	PMDT	-		Pot and plastic bag without cold chain	No
		Isolate	1–2 days	Pot, plastic bag , PVC pipe, Styrofoam box without cold chain	No
BLK Provinsi Jawa Barat, Bandung, West Java	Routine	-	-	-	-
	PMDT	-	-	-	-
		-	1–2 days	Pot, plastic bag , PVC pipe, Styrofoam box without cold chain (except for BLK Semarang/RS Muwardi *use ice packs* w/o thermometer)	No
	Sentinel HCs	-	1 day		No
	NPS	-	1 day	In compliance with SOP with cold chain,+ thermometer	Yes
BLK Provinsi Papua, Jayapura	Routine	-	Near	Pot and plastic bag without cold chain	No
	PMDT	-			
BBLK Surabaya, East Java	Routine	-	Farthest ± 2 days		
	PMDT	-	Farthest ± 2 days	In compliance with SOP with cold chain (except for Sanglah hospital without cold chain because	

				the specimen are isolates; w/o thermometer	
	Sentinel	-	1 day		
	NPS	-	1 day	In compliance with SOP with cold chain + thermometer	

Cold Chain in Transportation

As table 7 also shows, cold chain in transport (i.e., cold packs/ice and thermometers) of TB specimen is rarely done. Almost all specimens coming into and leaving microbiology laboratories for referral are transported at ambient temperature without thermometers attached for temperature monitoring. Only specimens under the National Prevalence Survey (NPS) regularly use cold chain for transport. Thermometers are attached to these specimen for temperature monitoring throughout transport.

Condition of Cold Chain in Laboratory Facilities

Equipment Availability

Almost every site visited during this assessment had some type of cold chain storage equipment (i.e., refrigerator or freezer) in their facilities. Only one site—the Sarjito Hospital in Yogyakarta—reported they do not use their cold chain equipment; they consider the cold chain equipment is unnecessary because the MDR/airborne unit does not store the specimens they collect. Most sites have both refrigeration and freezing capacity, with many sites having more than one of each type of unit. Table 8 shows the type of cold chain equipment and number of units available at each facility.

Table 8. Cold Chain Equipment Availability, by Site

Collection/Retrieval Facilities	Type of Equipment	Units
Clinical Microbiology Lab, Sanglah Hospital, Denpasar, Bali	Two-door domestic refrigerator	2
	Single-door domestic refrigerator	1
Clinical Microbiology Lab, Adam Malik Hospital, Medan, North Sumatera	Showcase refrigerator with 2 doors	1
	Deep freezer	1
Specialistic Lung Diseases / TB Hospital RSPP Dr. M. Goenawan Partowidigdo, Cisarua, West Java	Showcase refrigerator with 2 doors	1
Persahabatan Hospital, Jakarta	Single-door domestic refrigerator	1
	Freezer	1
	Deep freezer	1

Microbiology Laboratory, Medical Faculty, Gajah Mada University, Yogyakarta	Showcase refrigerator with 2 doors	2
	Deep freezer	1
Sarjito Hospital, Yogyakarta	Cold chain equipment is currently not used/needed because the MDR/airborne diseases unit does not store the specimens they collected and the distance to FK UGM is short.	
BLK Provinsi Jawa Barat, Bandung, West Java	Two-door domestic refrigerator	1
	Showcase refrigerator with 2 doors	2
	Deep freezer	1
BLK Provinsi Papua, Jayapura, Papua	Two-door domestic refrigerator	1
	Showcase refrigerator with 2 doors	2
	Freezer	1
	Deep freezer	1
Dok II, Hospital, Jayapura, Papua	Single-door domestic refrigerator at CST clinic	1
Saiful Anwar Hospital, Malang, East Java	Showcase refrigerator with 2 doors	2
	Freezer	1
BBLK Surabaya, East Java	Showcase medical refrigerator with 3 doors	1
	Showcase medical refrigerator with 2 doors	1
	Domestic refrigerator with 2 doors	1
	Deep freezer	1

It was observed that most of the cold chain equipment used for TB specimen storage was well maintained for all the collection and receiving sites visited. Three facilities (of the 10 using cold chain equipment) had poorly maintained cold chain equipment—thick layers of frost in freezers and lack of space for new specimen were some of the issues with the equipment (see appendix B).

While most facilities reported having sufficient cold storage equipment, several collection sites and receiving laboratories reported needing additional equipment, especially 2–8°C refrigerators for storing specimens, back-up specimens, LJ isolates, and reagents.

It was observed that temperature monitoring devices were available in most cold chain units across the collection and retrieval facilities. Built-in display thermometers were the most frequently available thermometers; however, several cold chain units had digital thermometers, Mueller thermometers, or glass liquid thermometers available (see table 9). While thermometers were generally available, very few facilities reported using them to monitor temperatures for cold chain equipment. As table 9 shows, only four out of the 10 facilities currently use cold chain equipment to monitor temperatures on a daily basis.

Table 9. Type of Temperature Monitoring Device and Temperature Monitoring Frequency

Collection/Retrieval Facilities	Type of Equipment	Temperature Monitoring Device	Temperature Monitoring
Clinical Microbiology Lab, Sanglah Hospital, Denpasar, Bali	Two-door domestic refrigerator	Digital thermometer	Twice a day
	Single-door domestic refrigerator		
Clinical Microbiology Lab, Adam Malik Hospital, Medan, North Sumatera	Showcase refrigerator with 2 doors	Mueller thermometer & built-in display thermometer	Once a day
	Deep freezer	Built-in display thermometer	
Specialistic Lung Diseases/ TB Hospital RSPP Dr. M. Goenawan Partowidigdo, Cisarua, West Java	Showcase refrigerator with 2 doors	None	None
Persahabatan Hospital, Jakarta	Single-door domestic refrigerator	None	None
	Freezer	Built-in display thermometer	None
	Deep freezer		None
Microbiology Laboratory, Medical Faculty, Gajah Mada University, Yogyakarta	Showcase refrigerator with 2 doors	Built-in display thermometer	Twice a day
	Deep freezer		
Sarjito Hospital, Yogyakarta	Cold chain equipment is currently not used at this facility		
BLK Provinsi Jawa Barat, Bandung, West Java	Two-door domestic refrigerator	Thermometer	None
	Showcase refrigerator with 2 doors	Thermometer & built-in display thermometer (one)	None
	Deep freezer	Built-in display thermometer	None
BLK Provinsi Papua, Jayapura, Papua	Two-door domestic refrigerator	None	None
	Showcase	Built-in display	None

Collection/Retrieval Facilities	Type of Equipment	Temperature Monitoring Device	Temperature Monitoring
	refrigerator with 2 doors	thermometer	
	Freezer	Built-in display thermometer	None
	Deep freezer	Built-in display thermometer	None
Dok II, Hospital, Jayapura, Papua	Single-door domestic refrigerator at CST clinic	None	None
Saiful Anwar Hospital, Malang, East Java	Showcase refrigerator with 2 doors	Thermometer (one of them)	None
	Freezer	Built-in display thermometer	None
BBLK Surabaya, East Java	Showcase medical refrigerator with 3 doors	Built-in display thermometer	Once a day
	Showcase medical refrigerator with 2 doors	Built-in display thermometer	
	Domestic refrigerator with 2 doors	Glass liquid thermometer	
	Deep freezer	Built-in display thermometer	

Availability of Standard Operating Procedures

This assessment found that uniform SOPs on how to handle TB specimens were not available. Some microbiology laboratories have literature from the MOH for specimen testing and guidance on specimen collection, receipt, and shipment; however, these publications are only available at microbiology laboratories. Most existing SOPs found in this assessment were locally developed and are significantly different across sites and programs. Even with the MOH guidance literature, most microbiology laboratories developed their own SOPs for internal use. The team also found that facilities with International Organization for Standardization (ISO) certifications (e.g., BLK and BBLK institutions) often have more sophisticated SOPs and job aids; however, even these typically only cover culture preparation and testing procedures. Although the MOH has developed the SOPs for transporting specimens, they are not available or followed in most of the places visited.

It is unclear how often the various SOPs are enforced; data are not available that illustrates whether compliance to the SOPs is actually practiced in the field.

Personal Protection Equipment and Safety Precautions

Staff at all facilities visited during this assessment practice appropriate safety precautions and wear proper personal protection equipment (PPE)—i.e., gloves, mask, and gown—when handling patients and specimens suspected of having TB.

Waste Management

This assessment showed that all facilities, generally, followed standard hospital regulations for the proper management and disposal of infectious waste. Facilities that manage infectious waste—sputum pots and gloves, etc.—collect the waste in yellow colored plastic waste bins, disinfect the infectious material either through autoclave or by using a disinfectant, and then incinerate the waste material. Incineration schedules varied across facility, ranging from every day to once a week. If the facilities do not have incinerators, they contracted out to third-party waste management firms.

For sharp objects (e.g., syringes) many of the facilities use plastic jerry cans or safety boxes for waste storage before incineration. However, several facilities do not have safety boxes for sharps waste.

Phase II Findings

As previously stated, the laboratories visited are categorized as A and B (see table 2). Category A laboratories are quality assured for culture and DST; these labs also receive referred specimens from the lower-level laboratories. The successful implementation of TB laboratory services relies heavily on the ability of these laboratories to deliver high-quality and uninterrupted testing.

Category B laboratories are in an advanced state toward certification to offer the same services as category A. Currently, they do not provide all the services because they are still in the certification process.

Each facility in this assessment performs a variety of tests and varying volumes. As seen in table 10, all facilities perform at least two tests; many perform each of the five tests recorded in this assessment. BLK Bandung, Micro FK-UI Jakarta, and BBLK Surabaya do the widest range of tests, while BLK Bandung and BBLK Surabaya do the highest volumes of tests.

Table 10. Total Test Performed across all Facilities in 2013

Test Performed	BBLK Jakarta	RSUP Adam Malik	BLK Bandung	BLK Semarang	Micro FK UI	BBLK Surabaya
MDR & NPS						
Microscopy	1,720 + 10,000 cross-checks	8,034	2,815	4,081	122	6,794
Culture	900	3,553	2,775	4,081	122	6,794
GeneXpert	-	345	190	-	644	500

DST line 1	-	405	1,922	-	89	400
DST line 2	-	-	1,922	-	3	200
Other tests performed						
Microscopy	-	-	1,628	107	5,844	2,073
Culture	-	-	1,374	77	3,906	1,568
GeneXpert	-	-	-	-	-	-
DST line 1	-	-	1,157	20	565	1,360
DST line 2	-	-	76	-	-	200

Organization

The laboratories providing services to the NTP are managed under different authorities, including the MOH, the Ministry of Education, and provincial governments. In order to successfully implement the suggested interventions, it is important to consider the different managing entities for each laboratory, especially at the provincial level as provincial governments vary considerably throughout the country.

While these laboratories provide TB testing services to the NTP, they are also responsible for providing other public health testing services. The provincial laboratories and the MOH laboratories also provide technical and supervisory oversight to laboratories within their provinces. These laboratories do not manage supplies for the lower-level laboratories; each laboratory manages its own supplies.

Laboratory Services and Availability of Supplies

Proper specimen collection, storage, and transportation—in addition to high-quality testing —are critical in producing clinically useful results for the patients. The supplies for specimen collection were found to be generally available. A stockout of specimen collection supplies means collection stops and services are not available to the public. However, without logistics data, it is not clear if services have slowed down in the past because of supplies running low or stocking out.

Laboratory reagents and supplies for TB testing were found to be generally available at the time of visit. However, because of the lack of logistics data, it is not easy to tell if the supplies on hand will be sufficient if there is an increase in demand after the planned scale up of the NTP.

Cartridge expiries were the most common issue reported in laboratories with GeneXpert. Several facilities reported that current stocks of cartridges were about to expire and cartridges had expired during the last 12 months. Expiries mean lost money; because a major component of laboratory budgets goes toward reagent and supplies procurement, controlling expires by providing the right quantities also means saving financial resources for the program.

SOPs and Guidelines

While national TB testing SOPs are not available in most of the laboratories, many have developed in-house SOPs. None of the visited laboratories had logistics SOPs, which help define the roles and responsibilities of laboratory and other personnel. These SOPs also help define the clear management responsibilities for laboratory supplies.

Staff Training on Logistics

For consistency in quality, training and refresher trainings are essential for staff skills to remain up-to-date. Technical staff in most laboratories usually received training and refresher training on technical aspects of TB testing —ranging from in-house training to external training. No training has been provided on supply chain management, at any facility. Cold chain management and infectious waste management training has been very limited.

Supervision

Monitoring staff performance through supportive supervision is one way to improve staff performance and morale, which usually results in quality work performance. This assessment found that laboratories have received supervision; but, it has focused mainly on technical issues, such as proper specimen preparation and testing. Only a few facilities report supervision focused on cold chain and waste management; no facility reported a focus on logistics management.

Reporting

Monthly and annual reports on laboratory activities are sent to management units and stakeholders. While laboratory activities seem to be monitored regularly, no reports on logistics —including stock status of supplies, consumption patterns, or equipment status —were being generated and sent to a higher level. Reporting and monitoring facility activities is important because it allows management to track progress, activities, and supplies; and to take corrective action, as needed, before the situation gets out of control. It is not clear what information is being used to make logistics decisions.

Planning and Budgeting

TB units are managed under the microbiology department. The TB units submit their plans and receive supplies through the department. The microbiology department also manages budgets for the TB units. A significant part of the budget is used to procure supplies.

The targets for the laboratory activities in TB programs come from the NTP through the administrative structures of the laboratories. At the time of the assessment in 2014, the TB laboratories did not know their specific roles and targets, which resulted in problems preparing the correct amount of needed supplies. Since supply procurement is made at the beginning of the fiscal year, earlier notice should be provided in concurrence with the budget planning so that supplies can be procured at the right time and in the right amount.

Determining targets for the upcoming years depends on laboratory capacity and equipment availability, including availability of functioning main equipment and sufficient supplies. Table 11 shows projections of the current potential of laboratories. The estimates, which the laboratories provided, are estimates based on the number of staff, testing capacity of staff, and equipment capacity.

Please note that these are only estimates for potential activity, not the number of tests that were provided. This information is useful for planning services provision and supplies demand planning for the NTP program.

Table 11. Projected Capacity of Each Laboratory

Activity	BBLK Jakarta	RSUP Adam Malik	BLK Bandung	BLK Semarang	Micro FK UI	BBLK Surabaya
Microscopy preparation & evaluation # slides	4,000	10,920	12,000	16,000	9,000	20,700
Culture: Media preparation	8,000	8,000	7,200	16,000	6,000	35,880
Culture: Inoculation & evaluation # tests	2,000	1,600	6,000	6,400	3,000	12,880
DST 1 LJ: Media preparation	-	600	1,200	720	7,500–15,000	2,760
DST 1 LJ: Inoculation & evaluation # tests	-				500–750	
DST 2 LJ: Inoculation & evaluation	-	-	1,200	-	-	2,760
MGIT Culture/DST-1 & 2 culture # of tests	-	-	-	-	4,000	

Laboratory Equipment

This assessment found that laboratories usually have the essential equipment needed to provide testing services to the NTP. Laboratories have reported equipment gaps; they need to replace aging equipment or increase capacity (see table 12). To maintain good quality testing, it is important for the laboratory equipment to operate properly.

Table 12. List of Equipment Gaps across all Facilities

BBLK Jakarta	RSUP Adam Malik	BLK Bandung	BLK Semarang	FK UI	BBLK Surabaya
Negative	Water	Negative	Hot air	Micropipette,	Laptop &

pressure	purifier	pressure	oven with blower	fix	LCD for use in trainings
IIB	Freezer - 20°	Hot air oven with blower	LE Showcase	Micropipette adjustable	Analytical balance
Water purifier	Inspissator	LE showcase		MGIT (additional)	Vortex mixer
Dehumidifier	MGIT	Cabinet for microscopes		LE showcase	
Fluorescence microscope		Electric micropipette		Laminar flow	
Maintenance of BSC		Stirrer hot plate			

Equipment maintenance and calibration is an essential component of both laboratory management and supply chain management. If equipment breaks down or produces unreliable results, supplies will be wasted because of expiries. Unreliable results may result in more frequent repeat requests and eventual loss of confidence in the system.

The major challenge facing many of the laboratories is the lack of service contracts for essential equipment. Partners are supporting most of the equipment, but without budgeting from the relevant authorities responsible for the laboratories. It is even more difficult if laboratories secure service contracts on their own because of the higher costs and weaker bargaining power as individual entities when compared to bigger corporations.

Inventory Management and Logistics Management Information Systems

Stock cards are used to monitor stock in storage. As supplies are received and removed from the storage area, it is important to keep track of the supplies. It is also important to compare the count on the stock cards to the actual physical count to verify the accuracy of the information on the stock cards. It was found that the use of stock cards varied across laboratories. Some facilities did not use stock cards; others used them, but they were out-of-date.

Good logistics data is needed for logistics decisions for budgeting, forecasting, procurement planning, including order schedules, quantity and quality of supply, and determining months of stock. A logistics management information system (LMIS) collects, aggregates, and organizes logistics data, which is then made available for users to make logistics decisions.

None of the visited laboratories have an LMIS in place; as a result, logistics information is not being used to make supply chain decisions.

Storage of Supplies

Supplies are stored to keep them safe and to maintain their quality; this will ensure they are readily available when needed. To prevent expiries and damage to supplies, and to preserve the quality of reagents and supplies, proper storage guidelines must be followed. The storage area temperature and

humidity for the dry store should be carefully monitored; supplies should be stored in an orderly way so they can be retrieved when needed and easily counted when during physical checks. It is also important to maintain the practice of first-to-expire, first-out (FEFO). Supplies requiring cold storage should be stored appropriately and the temperature of the cold storage equipment monitored regularly to ensure that the heat sensitive supplies are protected.

Storage space is a challenge in most laboratories. Many facilities do not have sufficient equipment, including racking, shelving, and pallets, to properly store supplies. Instead supplies are stored on the floor, which could lead to damage. While the temperature in the laboratories is generally monitored and recorded, storage areas do not have temperature records. Even if there are temperature records in storage area, most cases are not up-to-date.

Recommendations

Phase I Recommendations

- Create additional referral laboratories for GeneXpert, culture, and DST, in concurrence with an expansion of the PMDT project and its geographical locations.
- Enhance the capacity to perform TB culture needs to ease the access for the patients and to reduce the transport delays.
- Review and establish more effective and efficient referral systems to reduce the risks of specimen deterioration and overload at the current referral sites.
- Declare, handle, and transport specimens as infectious substances, including warning labels, for infectious materials.
- Clearly state, distribute to all facilities, and enforce the use of SOPs for collection, referral, and transportation; as well as when, where, and at what temperature cold chains are needed for sputum and isolates.
- Implement a cold chain transportation model to test for viability.
- Standardize specifications for sputum containers—sterile/non-sterile, type of pot, and volume capacity.
- Introduce and enforce the use of standard safe equipment and support devices for the project that meet UN/WHO; ensure safety precautions for the staff, environment, and community during the collection, storage, transport, and receipt of specimens.

Phase II Recommendations

- Provide supply chain training, including cold chain and laboratory waste management.
- Develop a forecasting methodology for TB supplies.
- Design a TB logistics system and develop SOPs for the system.
- Clean up storerooms and provide shelving, racking, and pallets to maximize existing storage space.
- Identify additional storage space that can be required for scale up.
- Compile a national inventory of TB equipment and monitor the condition of equipment; develop equipment maintenance strategies.
- Review the GeneXpert logistics system to identify challenges and opportunities to improve the supply system.

- Review the GeneXpert forecasting to align it to planned deployment of additional equipment.
- Coordinate GeneXpert deployment to facilities.
- Integrate management of supplies from different sources to simplify the management of TB supplies.

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Appendix A – Phase I Assessment Tool

Questionnaire for Collection site

Hospitals/laboratories on the collection and Transportation of TB specimen

Cold Chain Assessment Laboratory at Collection & Receiving Site of TB Specimen, NTP Program

Date : _____

Assessment Team : _____

: _____

: _____

Province : _____

Laboratory/Institution : _____

Address : _____

Phone/Fax : _____

A General Information

1 Name of Laboratory Director : _____

_____

2 Name of responsible person for specimen collection and shipment _____

B Specimen collection

1 Origin of patients
- ☐ Inpatient care ☐ Ambulatory care
- ☐ Treated at referring hospital
- ☐ Others: _____

2 Site for specimen collection?
- ☐ Wards ☐ Policlinic
- ☐ Special room for specimen collection
- ☐ Others: _____

3 Are workers wearing personal protective equipment when performing specimen collection?
- ☐Yes ☐ No

4 If Yes, what type of personal protective equipment are used?
- ☐ Gloves ☐ Mask ☐ Apron
- ☐ Others: _____

5 When collected?
- ☐ Morning ☐ Afternoon
- ☐ Others: _____

6 Volume of sputum collected?
- ☐ 3 mL - 5 mL ☐ > 5 mL
- ☐ Others: _____

7 Is all sputum collected sent to the referral lab.?

o All ☐ Made into aliquots ☐ Made on slides for staining/ microscopy

☐ Cultured onto LJ media in bottles for culture ☐ Others: _____

8 If not all sputum specimens collected are sent, how much volume that are sent to the referral lab? _____ mL

9 Other than sputum in pot, are there other types of specimen referred? ☐ LJ culture bottle ☐ Stained slides

☐ Dried sputum on filter paper

10 Where are the specimens handled after collection? ☐ Safety hood ☐ on lab banch

☐ Others: _____

11 If not directly shipped, where are the specimens stored?

☐ Refrigerator, temp: ____^{0}C, stored in: ☐ Freezer ☐ shelves ☐ Door

☐ Cold box/Styrofoam box with cold pack ☐ Cold box without cold pack

☐ At ambient temperature

12 If stored in the refrigerator:

12a Is a temperature monitoring device available? ☐ Yes ☐ No **(go to Q 12e)**

12b If yes, what type of temperature monitoring device? _____

12c Is the temperature recorded? ☐ Yes ☐ No

12d If Yes, when is recorded? ☐ Everyday, in the morning & afternoon

☐ Everyday, in the morning ☐ Everyday, in the afternoon ☐ Sometime ☐ Not recorded

12e Is there frozen ice? ☐ Yes ☐ No

13 How many hours are specimen shipped after being collected? _____hours

14 Are the outside of the pot cleaned with alcohol? ☐ Yes ☐ No

15 In performing specimen packaging, what steps are followed:

15a Attached a detail cover letter on specimen shipped ☐ Yes ☐ No

15b Fill in the specimen collection and transport form if used ☐ Yes ☐ No

15c Steps in specimens packaging:

15c1 Is each box (cold box/Styrofoam) sealed with tape and wrapped with paper on the outside? ☐ Yes ☐ No

15c2 Are spaces between packages filled with paper? ☐ Yes ☐ No

15c3 Is the bottom part covered with tissue or a hand towel and propped up with newspapers? ☐ Yes ☐ No

15c4 Are the pots arranged in a standing position? ☐ Yes ☐ No

15c5 Is it marked with an arrow pointing upwards on the outside? ☐ Yes ☐ No

15c6 Read and record the temperature of thermometer if available? ☐ Yes ☐ No

15c7 Is sputum pot sealed and put in Ziploc bag ☐ Yes ☐ No

15c8 How many pots per Ziploc? ____ /Ziploc

15c9 Are LJ isolate in McCartney Bottles contained in PVC/bio container? ☐ Yes ☐ No ☐ N/A

15c10 How many cold packs / ice cubes in a plastic bag are used in packaging? _____cold pack/ice cube per cold box

16 Average number of specimen collected per period? ____ /day ___ /week __ / month

17 Average number of specimen transported to referral receiving site per period? ____ /day ___ /week __ / month

18 Average frequency of shipmen per period? ____ /day ___ /week __ / month

19 How many hours are specimens shipped after being collected? ____ hours

20 Longest shipment duration of shipment to referral lab?

- How many hours after being collected ____ hours

- How many hours after being dispatched/shipped ____ hours

21 Mode of shipment?

☐ Vehicle ☐ Motorcycle ☐ Plane ☐ Others: _____

22 Are the temperature monitor and or packaging equipment sent back by the referral laboratory? ☐ Yes ☐ No **(go to Q 24)**

23 If yes:

23a When the equipment returned since it was dispatch/sent to referral lab? _____

23b Mode of transport for retuning the equipment

☐Car ☐ Motorcycle ☐ Plane ☐ Others: _____

24 Availability of equipment and supporting supplies for collection?

Supply Type	Type	Capacity (L)	Available Amount
PPE/part of PPE (gloves, mask, apron)			☐
Safety hood – with ultra violet lamp			☐
Sputum Pot			☐
Cotton swabs			☐
Object glass			☐
Ziploc bag			☐

Parafilm			☐
Alcohol 70%			☐
Spirit lamp			☐
Rubber band			☐
McCartney Bottle with LJ media			☐
Slide delivery box			☐
PVC tube with lid or bio- container for shipment of McCartney LJ Bottle			☐
Safety box/waste bag			☐

25 Equipment and supporting supplies for packaging and transport of specimens?

Supply Type	Type	Capacity (L)	Available Amount
Refrigerator			
Cold box		☐	
Styrofoam Box		☐	
Thermos		☐	
Cold pack		☐	
Ice cube in the plastic bag		☐	
Thermometer		☐	
Specimen collection and transportation form		☐	
Register book on specimen dispatch		☐	
Cover letter and Ziploc		☐	

26 Where specimens and infectious waste is placed?

☐ Safety box ☐ Waste bag without logo/color ☐ Waste bag with infectious logo ☐ Waste bag with color coding

27 How are the waste disposed?

☐Disinfection with disinfectants ☐ Autoclave ☐ Incineration

28 Is there a SOP/guideline on collection and shipment of TB specimens?

☐ Yes ☐ No

If Yes, describe:

_____

29 Is there a SOP/guideline on the cold chain management in collection and shipment of TB specimens?

☐ Yes ☐ No

If Yes, describe:

_____

Appendix B – Phase I Detailed List of Cold Chain Equipment and Status of Equipment

Institution/Laboratory	Type of Equipment	Amount	Temperature Monitoring Device	Temperature Monitoring	Maintenance	Need Additional Equipment
Clinical Microbiology Lab, Sanglah Hospital	Two door domestic refrigerator	2	Digital thermometer	Twice a day	Well maintained	
	Single door domestic refrigerator	1				
Clinical Microbiology Lab, Adam Malik Hospital	Show case refrigerator with 2 doors	1	Mueller thermometer & built-in display thermometer	Once a day	Well maintained	
	Deep Freezer	1	Built-in display thermometer			
Specialist TB Hospital RSP Dr. M. Goenawan Partowidigdo	Show case refrigerator with 2 doors	1	None	None	Well maintained	Deep freezer Thermometer
Persahabatan Hospital	Single door domestic refrigerator	1	None	None	Not well maintained with very thick ice frost	Refrigerator Deep freezer Thermometer
	Freezer	1	Built-in display thermometer	None	Not well maintained	
	Deep Freezer	1		None	Well maintained	

Institution/Laboratory	Type of Equipment	Amount	Temperature Monitoring Device	Temperature Monitoring	Maintenance	Need Additional Equipment
Microbiology Laboratory, Medical Faculty, Gajah Mada University	Show case refrigerator with 2 doors	2	Built-in display thermometer	Twice a day	Well maintained	
	Deep Freezer	1				
Sarjito Hospital, Yogyakarta	Cold chain equipment is currently not used/ needed because the MDR/Airborne diseases unit does not store the specimen they collected and distance to FK UGM is short.					
BLK Bandung	Two door domestic refrigerator	1	Thermometer	None	Not well maintained	
	Show case refrigerator with 2 doors	2	Thermometer & Build-in display thermometer (one)	None		
	Deep freezer	1	Built-in display thermometer	None	Well maintained	
BLK Jayapura	Two door domestic refrigerator	1	None	None	Well maintained	
	Show case refrigerator with 2 doors	2	Built-in display thermometer	None		
	Freezer	1	Built-in display thermometer	None		
	Deep freezer	1	Built-in display thermometer	None		
Dok II, Hospital	Single door domestic refrigerator at CST clinic	1	None	None	Not well maintained & fully occupied	Refrigerator

Institution/Laboratory	Type of Equipment	Amount	Temperature Monitoring Device	Temperature Monitoring	Maintenance	Need Additional Equipment
Saiful Anwar Hospital	Show case refrigerator with 2 doors	2	Thermometer (one of them)	None	Well maintained	
	Freezer	1	Built-in display thermometer	None		
BBLK Surabaya	Showcase medical refrigerator with 3 doors	1	Built-in display thermometer	Once a day	Well maintained	
	Showcase medical refrigerator with 2 doors	1	Built-in display thermometer			
	Domestic refrigerator with 2 doors	1	Glass liquid thermometer			
	Deep freezer	1	Built-in display thermometer			

Appendix C – Phase II ATLAS Tool

ASSESSMENT TOOL
Phase II TB Laboratory Logistics Assessment

January 2014

I. General Information

1. Name and Organization of Interviewer			
MOH (NTP/Sub-dit TB/BPPM) USAID | DELIVER PROJECT TB Care/ KNCV	1. 2. 3. 1. Patrick Msipa 2. Anton Widjaya 3. Juhartini 1. 2. 3.		
2. Date of visit			
3. Name of facility			
4. Address:	_____ Phone:Fax: Email:		
5. Name, position of person interviewed:	Name	Position	Years at facility

II. ACTIVITY IN TB PROGRAMS/SURVEYS

No	Programs/ Surveys	Catchment Areas	Test Performed	ESTIMATED TARGET	
				2014	2015
1.	PMDT		Microscopy		
			GeneXpert		
			Culture		
			Dst 1st line		

			Dst 2nd line		
2.	NPS		Microscopy		
			GeneXpert		
			Culture		
3.	TB program services		Microscopy		
			GeneXpert		
			Culture		
			Dst 1st line		
			Dst 2nd line		
	Private institution services (paying customer)		Microscopy		
			GeneXpert		
			Culture		
			Dst 1st line		
			Dst 2nd line		

III. LABORATORY ACTIVITY/CAPABILITY IN TB DIAGNOSIS AND AVAILABILITY OF SUPPLIES

No	Activity	If Yes	Amount/Capacity per month	Supplies Available (month)	Remarks
1.	Sputum specimen collection from patients	☐ Yes ☐ No →**If YES**: ☐ in sterile pots ☐ In non-sterile pots			
2.	Temporary storage of sputum	☐ Yes ☐ No →**If YES**: ☐ in refrigerator ☐ In freezer ☐ 0thers_____			
3.	Transport sputum to other referral lab	☐ Yes ☐ No →**If YES**: ☐Seal pots with parafilm ☐Use cold box ☐Use cold packs ☐Use thermometer ☐Use hazard/infectious material warning labels			
4.	Receive referred sputum	☐ Yes ☐ No →**If YES**: ☐Pots sealed with parafilm ☐ Use triple packaging ☐ Use cold box ☐ Use cold packs ☐ Use thermometer ☐ Use hazard/infectious material			

No	Activity	If Yes	Amount/Capacity per month	Supplies Available (month)	Remarks
		warning labels			
5.	Receive referred TB isolates	☐ Yes ☐ No →**If YES:** ☐ in test tubes, sealed w/cotton-paraffin ☐ in McCartney Bottles, sealed with parafilm ☐ Use triple packaging ☐ Use cold box ☐ Use cold packs ☐ Use thermometer ☐ Info on temp exposure during transport ☐ Use hazard/infectious material warning labels	Upon arrival: ☐ Inspect and record temperature and condition ☐ Temporary storage in: ☐ 4-8°C refrigerator ☐ (-) 20°C freezer ☐ (-) 80°C deep freezer		
6.	Perform microscopy slide test	☐ Yes ☐ No →**If YES:** ☐Ziehl-Neelsen staining ☐ TTH Kinyuon-Gabbet cold staining ☐Kinyuon staining			
7.	Perform fluorescent microscopy	☐ Yes ☐ No →**If YES:** ☐ Fluorescent Auramine staining			

No	Activity	If Yes	Amount/Capacity per month	Supplies Available (month)	Remarks
8.	GeneXpert test (Identification + Rifam)	☐ Yes ☐ No			
9.	Hain's test (Identification + – Rifam –INH)	☐ Yes ☐ No			
10.	Culture in media	☐ Yes ☐ No →**If YES:** ☐ on Lowenstein Jensen LJ media ☐ on Ogawa media ☐ in Liquid media (MCIT) ☐ in Middlebrook media			
11.	Drug sensitivity test (DST)	☐ Yes ☐ No →**If YES:** ☐ 1st line drugs (SIRE) ☐ 1st line drugs (SIRE) + Pyrazinamide ☐ 2nd line drugs (AOK) ☐ other 2nd line drugs: _____			
12.	Thin Layer Agar (TLA) gel electrophorese	☐ Yes ☐ No			
13.	PCR/RT-PCR	☐ Yes ☐ No			

No	Activity	If Yes	Amount/Capacity per month	Supplies Available (month)	Remarks
14.	Other diagnostic tests	☐ Yes ☐ No →**If YES:** ☐ ☐ ☐			
15.	Decontamination/ Sterilization	☐ Phenol ☐ Bleach ☐ Plastic waste bag ☐ Safety box ☐ Other:_____			
16.	PPE	☐ Goggle ☐ Gloves ☐ Masker ☐ Cap ☐ Laboratory gown ☐ Other: _____			

IV. SOPS AND GUIDELINES

1.	Are national guidelines and protocols for laboratory testing procedures available in this laboratory? *Check for these and other procedures inquired on below, physically.*	☐ Yes ☐ No
2.	Who is responsible for the implementation of correct laboratory testing procedures?	_____ _____
3.	Are written national guidelines on safety precautions available in this laboratory? *(Check all that apply)* - Infection prevention - Use of PPE - Safe disposal of biohazards medical waste - None available - Other (*specify*)	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No _____
4.	Are written national guidelines for specimen referral available in this laboratory?	☐ Yes ☐ No
5.	Are written national guidelines for laboratory waste management available in this laboratory?	☐ Yes ☐ No
6.	Are there written national guidelines for disposal or destruction of damaged and/or expired products?	☐ Yes ☐ No
7.	Are written national guidelines for storage of laboratory products available?	☐ Yes ☐ No
8.	Are written national guidelines for the service and maintenance of equipment at the facility available?	☐ Yes ☐ No
9.	Are the national standard operating procedures (SOPs) for the laboratory logistics system available in this laboratory?	☐ Yes ☐ No
	Comments:	

For more information, please visit deliver.jsi.com.

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