



USAID | DELIVER PROJECT

MALAWI: LABORATORY SERVICES AND SUPPLY CHAIN ASSESSMENT



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USAID | DELIVER PROJECT, Task Order 1

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Abstract

In January and February 2009, the Ministry of Health (MOH), with technical assistance from the USAID | DELIVER PROJECT, Task Order 1, conducted an assessment of laboratory services and the management of the supply chain for laboratory commodities and equipment in government and Christian Health Association of Malawi (CHAM) health facilities in Malawi.

The assessment's overall objective was to provide the MOH with information on the current status of laboratory services and the supporting supply chain that could be used to develop the Five-Year Strategic Laboratory Plan. During the assessment, a quantitative baseline was established on which to measure future improvements to laboratory services and the supporting supply chain. This report presents the methodology and findings of the assessment, as well as recommendations to improve the supply chain to support laboratory services in Malawi.

Cover photo: Collecting assessment information at the Bangwe Health Center Laboratory, Blantyre District, Malawi, February 2009.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ATLAS	Assessment Tool for Laboratory Services
CD4	T4 or helper lymphocytes (the quantitative count of these cells)
CDC	Centers for Disease Control and Prevention
CHAI	Clinton HIV/AIDS Initiative
CHAM	Christian Health Association of Malawi
CHSU	Community Health Sciences Unit
CMS	Central Medical Stores
DHMT	District Health Management Team
DHO	District Health Office
EMLS	Essential Medical Laboratory Services
EQA	external quality assurance
EU	European Union
GOT	glutamate oxaloacetate transaminase (a liver function test)
Hb	hemoglobin
HC	health center
HIV	human immunodeficiency virus
HTC	HIV testing and counseling
JHU	Johns Hopkins University
JSI	John Snow, Inc.
LMIS	logistics management information system
MBTS	Malawi Blood Transfusion Services
MBTST	Malawi Blood Transfusion Service Trust
MOH	Ministry of Health
NGO	nongovernmental organizations
OJT	on-the-job training
PAM	Physical Assets Management Unit
PEP	post-exposure prophylaxis

PPS	probability-proportional-to-size
QA	quality assurance
RFQ	Requests for Quotes
RMS	Regional Medical Stores
SCMgr	Supply Chain Manager (software)
SOP	standard operating procedure
SWAp	sector wide approach
TB	tuberculosis
TOT	training-the-trainers
T*TI	transfusion transmitted infection
UK NEQAS	United Kingdom National External Quality Assessment Service
UNC	University of North Carolina
UNICEF	United Nations Children’s Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

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The authors would like to thank the assessment teams for their tireless effort collecting the information needed for this assessment and for sharing their professional experiences in laboratory services and supply management. We would also like to acknowledge the support that the Malawi Ministry of Health gave us for this assessment. The authors are grateful to hospital and health center staff, donors, nongovernmental organizations, and cooperating agency staff (listed in the appendices) who participated directly in this laboratory services and supply chain assessment. The strengthening of laboratory services in Malawi will depend on the continued collaboration, goodwill, and hard work of all partners to meet the many challenges of ensuring a continuous supply of quality laboratory reagents, consumables, and durable goods to the people who need them, where and when they need them.

Executive Summary

In the last several years, in response to the development of the Essential Medical Laboratory Services package, the Ministry of Health (MOH) has focused on improving laboratory services. Much attention is currently being placed on laboratory services to improve health services nationwide. The MOH will soon develop its Five-Year Laboratory Strategic Plan. From January 26 to February 13, 2009, to help inform the strategic plan, the Malawi MOH, with assistance from the USAID | DELIVER PROJECT, conducted the Malawi Laboratory Services and Supply Chain Assessment. Data for the assessment was collected during key informant interviews, a one-day central- and intermediate-level workshop, and field visits to 40 health facilities. Data collection tools were adapted from the DELIVER project's *Assessment Tool for Laboratory Services (ATLAS)*.

The assessment results provide—

- current information on laboratory services and the supporting supply chain for laboratory supplies and equipment
- information on the availability of key laboratory supplies and equipment
- a baseline on which to measure improvements to laboratory services and the supporting supply chain.

Some of the strengths of the Malawi laboratory services and logistics system include the development of national laboratory policies and draft standard operating procedures (SOPs); dedicated staff at central-, intermediate-, and service-levels; adequate storage capacity; and an improving laboratory infrastructure. However, efforts need to be made in disseminating and applying the policies and procedures; standardizing testing services; strengthening laboratory quality assurance; training, deploying, and supervising laboratory staff per the national policy; designing and implementing appropriate inventory control and logistics management information systems; and using logistics information for supply management, quantification, and procurement planning.

This report recommends next steps for strengthening policy, quality assurance, human resource development, logistic management systems, forecasting and procurement methodologies; and improving coordination among key stakeholders. It also provides specific recommendations for integrating laboratory commodities into the ordering and direct delivery system currently in place for other health commodities. Critical to the success of implementation will be collaboration among laboratory and pharmaceutical units at all levels in the system, resource mobilization in support of activities, and the engagement of key MOH units, partners, and stakeholders.

Background

As part of the national Poverty Reduction Strategy and to improve access to essential health care for the most common diseases affecting the poor nationwide, the Malawi Ministry of Health (MOH) developed the Essential Health Package during its Fourth National Health Plan activities. To support these health services, the Essential Medical Laboratory Services (EMLS) project was developed to determine what laboratory services are needed at the district hospitals. The results from the project, which ended in 2002, define the basic laboratory services that are needed and the services that the district level are able to perform. The EMLS project was classified as critical; the MOH recommended that the following laboratory services be established at the district level to address the public health priorities of safe motherhood, malaria, tuberculosis (TB), and HIV: hemoglobin (Hb) estimation

- malaria microscopy
- TB testing using sputum smear microscopy
- HIV testing using rapid testing devices
- blood screening for blood-borne disease for transfusions (established through a national blood transfusion service).

In addition, the project recommended that the following tests, classified as important, be included after the critical tests were established:

- cerebrospinal fluid examination
- stool and urine examination
- blood glucose testing
- syphilis screening
- white blood cell count.

It was also recommended that testing services be established at health centers, if possible.

The expansion of programs for HIV and AIDS, tuberculosis (TB), and malaria require strong, supportive laboratory services. With the expansion of antiretroviral therapy (ART), additional laboratory testing will be required to monitor patients being treated for AIDS.

The MOH recognizes the importance of laboratory services and the need to strengthen the systems to support these services, including the supply chain for laboratory commodities. This assessment, conducted by the MOH, with assistance from the USAID | DELIVER PROJECT, is an initial step in strengthening the supply chain for laboratory services.

Objectives of the Assessment

The mandate for the USAID | DELIVER PROJECT in Malawi has expanded to include laboratory supplies, a relatively new area of focus for the Malawi MOH. To build local capacity and strengthen supply chain management of laboratory commodities in Malawi, the project, with the MOH, will be supporting several lab-related activities. This assessment of the MOH laboratory system represents the first activity of the project's technical assistance to the MOH in laboratory logistics.

This assessment focused on managing and providing laboratory services and on the performance of the supply chain for managing laboratory supplies.

The objectives of the assessment were to provide the MOH with—

- current information on laboratory services and the supporting supply chain for laboratory supplies and equipment
- information on the availability of key laboratory supplies and equipment
- a baseline on which to measure improvements to laboratory services and the supporting supply chain.

The assessment included collection and analysis of data on the organization of the national laboratory system, policies, infrastructure and equipment, personnel, testing services, quality assurance, and laboratory management information systems. The supply chain component of the assessment focused on current policies, procedures and capacity for quantification, procurement, inventory management, storage and distribution of laboratory supplies, and the availability of selected products.

The assessment results will be used at the MOH Laboratory Strategic Planning Workshop and will help to inform the Five-Year Laboratory Strategic Plan.

Methodology

Representatives from the Malawi MOH laboratory and pharmacy services and the USAID | DELIVER PROJECT staff used adapted questionnaires from the *Assessment Tool for Laboratory Services (ATLAS)* to conduct the assessment.

Assessment Activities

The activities during the three-week assessment included preparation, key informant interviews, a one-day central- and intermediate-level workshop, team training, field site visits, and presentation of the findings. The following steps were taken to prepare for and conduct the laboratory services and the supply chain assessment.

During the first three days of the assessment, the project's consultant team interviewed key stakeholders and adapted the ATLAS for the Malawi laboratory system context. Personnel from the following MOH departments and units were interviewed: Diagnostics Unit, Planning Department, MOH Procurement Unit, Community Health Services Unit (CHSU), and the Central Medical Stores (CMS). Personnel from the following programs were interviewed: HIV and AIDS Unit, Malaria Control, and TB Control. Partners interviewed included USAID, the Clinton HIV/AIDS Initiative (CHAI), UNICEF, the Global Fund, the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and Howard University. Additional key informant interviews were conducted with the College of Medicine (Blantyre), Malawi Blood Transfusion Services (Blantyre), Johns Hopkins University Project (Blantyre), and the University of North Carolina (Lilongwe). See the appendix for a list of people contacted.

The consultant team held a one-day workshop during the first week; participants were from the MOH, CHSU, CMS, and central and district hospital laboratory and pharmacy personnel. After a brief introduction to logistics and the assessment purpose and process, participants worked in small groups to answer the central- and intermediate-level questions adapted from the *ATLAS*. Participants presented their results, focusing on strengths and weaknesses of laboratory services in the following areas:

- organization
- policy
- forecasting and procurement
- financing
- storage and distribution
- inventory control system
- laboratory services and logistics management information systems (LMIS)
- staffing
- supervision.

The results of the workshop, information from the key informant interviews, and data collected during the field visits to was used by the project to formulate the findings in this report. See the appendix for a list of participants from the workshop.

Feedback from the workshop participants was used to adapt the facility-level questionnaire in preparation for the field visits.

Twelve participants from the workshop were chosen to join the project consultants; they formed four assessment teams for the field visit component of the assessment. Assessment team members were trained in how to use the adapted *ATLAS* facility-level questionnaire. The tool was then field tested at Mchinji and Salima district hospital laboratories. The facility-level questionnaire was finalized by the participants after input from the field tests and from use during the field visits.

Field visits took place during the second week and part of the third week of the assessment at selected facilities (see section on Sampling Methodology for more information about site selection). Application of the questionnaire at each facility included interviewing laboratory and stores personnel, verifying the availability of key laboratory commodities and equipment by observing and reviewing stock cards, and inspecting the laboratory infrastructure and storage space.

The final days of the assessment focused on data entry from the field visit questionnaires, synthesis of the assessment results and findings, presentation of the results to stakeholders, and preparation of the draft report by the team.

Assessment Tools

The tools used for this survey were adapted from the *ATLAS*, which is a data-gathering instrument developed by the USAID | DELIVER PROJECT to assess laboratory services and logistics. The *ATLAS*, also a diagnostic and monitoring tool, can be used for a baseline survey, an annual assessment, or as an integral part of the work planning process. The tool is primarily qualitative, with a small sample of facility quantitative survey of available commodities, testing services, and equipment. The information collected with the *ATLAS* is analyzed to identify issues and opportunities and to outline further assessment and/or appropriate interventions. The *ATLAS* has three questionnaires:

1. A central-level questionnaire is used to collect information on national policies and guidelines, and organizational aspects of the system.
2. An intermediate-level administrative questionnaire is used to gather information on regional policies, guidelines, and facilities numbers and types.
3. A facility-level questionnaire is applied in laboratories at the central-, regional-, and district-level, and in health centers.

For this assessment, the central- and intermediate-level questionnaires were adapted for the one-day workshop; the facility-level questionnaire was adapted for the service-level field visits. See the appendix for copies of the questionnaires.

Assessment Team

The assessment team comprised the following members from MOH laboratory and pharmacy units, CHSU, and the USAID | DELIVER PROJECT.

Table 1. Members of the Assessment Team

Team Member	Designation	Team Member	Designation
Team 1—South		Team 2—South	
Barbara Felling	Senior Technical Advisor, USAID DELIVER PROJECT, Arlington, VA	Doris Butao	Laboratory Logistics Advisor, USAID DELIVER PROJECT, Malawi
Elizabeth Mkandawire	Senior Pharmacist, Zomba Central Hospital	Laphiod Chisuwo	SMLT, EMLS Regional
Alwin B Mbene	Laboratory Manager, Mzuzu Central Hospital	David Mwalilino	Laboratory Manager, Mzimba District Hospital
Mandigore Yassin	Lab Technologist, CHSU	Vockly S Mkandawire	Pharmacy Technician, Central Medical Stores
Team 3—Central		Team 4—North	
Patrick Msipa	Laboratory Logistics Advisor, USAID DELIVER PROJECT, Arlington, VA	Manondo S. Msefula	Logistics Advisor, USAID DELIVER PROJECT, Malawi
Miriam Nyenje	TB Zonal Supervisor - South West, QECH	Scotch Santula	Laboratory Manager, Ntcheu
Clement Nyanga	Pharmacy Technician QECH	Saile Kamanga	Pharmacy Technician, Lilongwe DHO
Innocent Zungu	Assistant Diagnostics Officer Ministry of Health	Mabvuto Chiwaula	Senior Lab Technologist, CHSU

The team was divided into four assessment groups that were tasked with visiting the 40 health facilities and other institutions. See the appendix for the schedule of field visits.

Sampling Methodology

A sampling frame, produced for the assessment, included 13 randomly selected districts from all three provinces and from randomly selected facilities within those districts. All the districts were included in the random selection of districts; all facilities with labs were included in the random selection of facilities within the districts. The list of facilities with laboratories was developed using information provided by the MOH Diagnostics Unit and the TB program. In developing the frame, a probability-proportional-to-size (PPS) sampling was used to determine which districts to sample, thereby obtaining a greater representation of districts in the Southern Region, and reducing the chance of over-sampling areas with fewer facilities. Facilities were selected using simple random sampling of equal probability. Assumptions were made as to the number of facilities that could be visited in the time available.

A total of 40 health facilities were selected for the sample—22 facilities were selected in the Southern Region (55 percent of the sample), 10 facilities in Central Region (25 percent of the sample), and 8 facilities in the Northern Region (20 percent of the sample). All facilities in the

sample were visited, except one (a similar facility was substituted); the original facility selected did not provide laboratory or testing services. The team discovered during the field visits that seven of the facilities, of the 25 health centers visited, only provided HIV testing and no other laboratory services. Table 2 lists the types of sites visited.

Table 2. Facilities Visited during the Malawi Laboratory Services and Supply Chain Assessment

Type of Facility	Total Number Visited	Government	CHAM
Central Hospital	2	2	0
District /Community Hospital	13	4	9
Health Center	25	15	10

Limitations of the Assessment

The primary limitations of the assessment were the limited number of facilities sampled because of the resource constraints and the time available, and the availability of a few key informants during the interviews. Of the 211 government and the Christian Health Association of Malawi (CHAM) health facilities in Malawi purportedly providing laboratory services, 40 facilities, or 19 percent, were included in the sample. Of the 40 facilities visited, seven offered HIV testing only; they did not provide other laboratory services.

While the team was able to interview many key informants, not all key informants were available during the three-week assessment. The team planned to but were unable to speak with the director of CHAM, the director of the sector wide approach (SWAp), or the head of the HIV and AIDS unit, as they were on travel during the time of the assessment.

While 30 individuals were invited to participate in the one-day Laboratory Services and Supply Chain Management Assessment Workshop, 22 attended. This may have limited the information gathered during that workshop.

Findings

Organization

The diagnostics unit of the health technical support services (HTSS) department in the MOH has overall responsibility for managing the laboratory services in hospitals and health centers in Malawi; the primary emphasis is on ensuring that the national laboratory policies are followed.

Malawi Laboratory System

The hospital management is responsible for the routine oversight of laboratory services at the hospitals; the district health management teams have the day-to-day responsibility for oversight at the health centers.

Laboratory services for the general population are provided in—

- central hospitals
- district hospitals
- CHAM hospitals
- community hospitals
- urban and rural health centers.

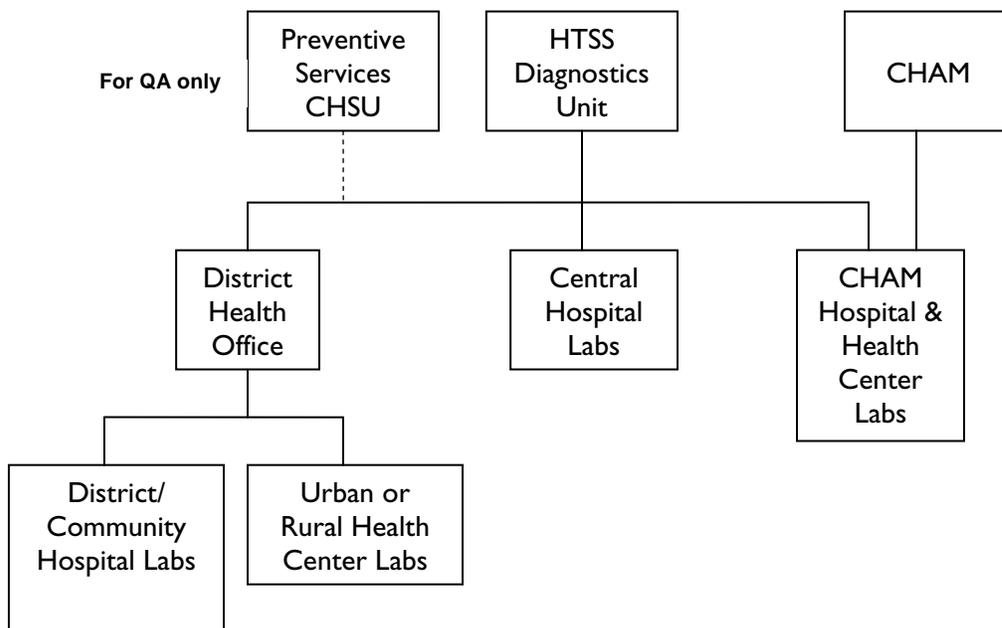
The CHSU serves as the national public health reference laboratory and is primarily responsible for laboratory quality assurance in the government facilities. Organizationally, CHSU is under the direction of the Preventive Health Services of the MOH.

The Malawi government, through the MOH, and with the financial and technical assistance of the European Union (EU), has established the Malawi Blood Transfusion Service Trust (MBTST) as the national body, with a mandate to provide adequate quantities of safe blood and blood products for Malawians. The Malawi Blood Transfusion Service (MBTS) is the operational arm of the trust. To ensure a safe blood supply to the nation, MBTS conducts testing for transfusion transmitted infections (TTIs). The CHAM supplements the government-provided health services by offering services, including laboratory services, through community hospitals and health centers.

Vertical programs—TB, HIV and AIDS, and malaria—provide program-specific oversight, technical support, and, in some cases, provision of supplies directly to health facility laboratories.

Figure 1 represents the relative organizational relationships for laboratory services in Malawi.

Figure 1. Organizational Chart of the Malawi Laboratory Services



Without specific guidelines on oversight and lines of communication, the current organization of laboratory services related to the responsibility for laboratories in CHAM facilities and the relationship of CHSU to all facilities is unclear. In addition, no position within the District Health Office (DHO) has specific responsibility for supporting district hospital and health center labs; this role is filled by a fragmented combination of district-level program staff and the laboratory personnel of the district hospital.

Laboratory Supply Chain

The supply chain for routine resupply of laboratory commodities in Malawi varies by the location and the type of laboratory and the type of commodity being resupplied. In most cases, general laboratory supplies are distributed directly from Regional Medical Stores (RMS) to central and district hospitals. Health center laboratories usually receive their supplies monthly from the district hospital laboratory. In the Blantyre district, where the DHO maintains a district store of pharmaceuticals and other health commodities, health centers receive their laboratory supplies from the DHO-managed district store.

UNICEF procures HIV test kits and distributes them through the RMS to the DHO HIV testing and counseling (HTC) coordinators. Health center HTC counselors pick up the HIV tests from the district-level HTC coordinators.

The RMS also distributed TB program laboratory reagents and supplies to hospitals when they supply the other laboratory supplies. Health centers pick up their TB reagents from the district TB coordinator.

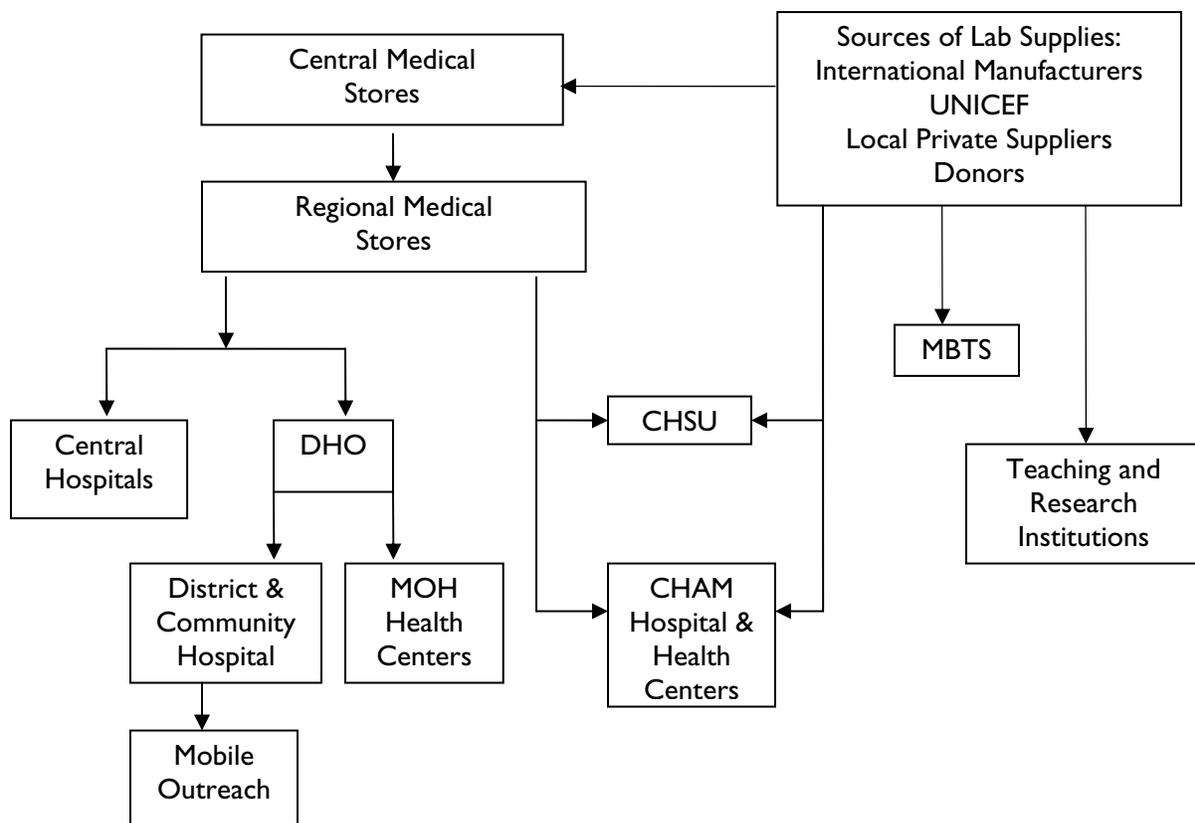
In addition to receiving laboratory supplies from the RMS or the DHO, CHAM hospitals and health centers purchase laboratory supplies from the local private suppliers.

With the exception of CHSU, research institutions and MBTS procure and receive their laboratory supplies from international manufacturers and private local suppliers. CHSU orders laboratory supplies from RMS and purchases supplies from local suppliers.

While these are the most common ways to receive the supplies that support laboratory services, it was noted during the field visits that, on occasion, facilities receive direct donations of laboratory supplies from private nongovernmental organizations (NGOs) and faith-based organizations.

Figure 2 represents the general supply chain for laboratory services in Malawi.

Figure 2. Malawi Supply Chain for Laboratory Commodities



The organization of the supply chain for laboratory commodities is usually established for central and district hospitals. For these facilities, the RMS usually provides the supplies. But, even these facilities may purchase supplies from local suppliers when commodities are not available through the RMS; facilities will occasionally receive supplies from partner organizations, such as Howard University. The supply chain for health centers is more informally organized, with several possible channels for the receipt of supplies from the DHO (vertical programs, district store for Blantyre, and other sources); they also depend on the district hospital laboratory for routine resupply of basic laboratory commodities. If the actual operation of the supply chain is inconsistent, it can result in inefficiency, overstocks, stockouts, and waste.

Laboratory Policy and Guidelines

National Level

In March 2003, the National Laboratory Steering Group formed a working group to develop the national laboratory policy. Published in 2007, the *National Medical Laboratory Policy, Ministry of Health, Malawi*, provides general guidance for integrated laboratory standards and systems to support the national health care system in the following areas:

- medical laboratory service provision
- management and organization of laboratory service
- financing and budgeting
- human resources
- laboratory regulation
- laboratory premises
- laboratory equipment and supplies
- quality assurance
- monitoring and evaluation
- safety
- research and development
- ethics.

While the policy does not include specific standards, it does state that standardized profiles should be developed and adhered to for—

- tests provided at each level of care
- test methodologies by level and type of facility
- laboratory infrastructure
- laboratory equipment, including specifications
- laboratory supplies.

The development and dissemination of these essential aspects of laboratory policy would greatly facilitate the procurement, distribution, and management of laboratory commodities. While the national laboratory policy has been published, most laboratories visited were not aware of this document.

A working group is developing national laboratory standard operating procedures (SOPs). In addition to step-by-step instructions for conducting a test, the draft SOPs also include supply and equipment lists and general laboratory safety precautions. The SOPs do not indicate the level of the laboratory at which the test should be performed; do not cover information on post-exposure

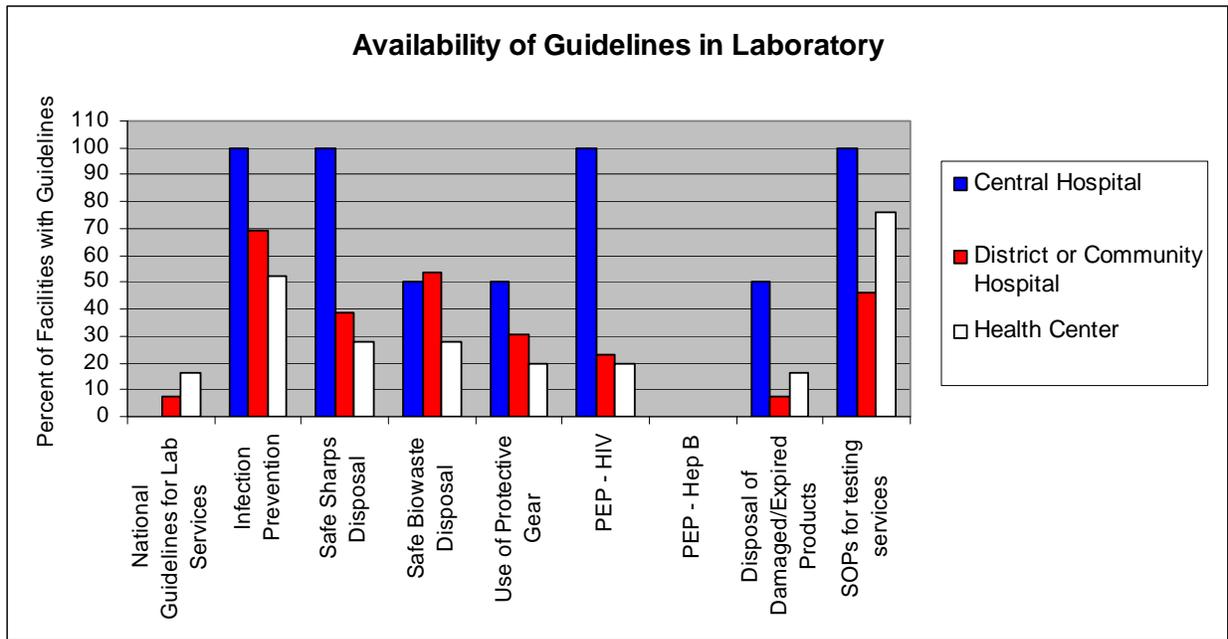
prophylaxis (PEP) for HIV or hepatitis B or C; and do not include procedures for disposal of damaged or expired laboratory products. The SOPs are drafts; they have been disseminated.

Facility Level

Most laboratories interviewed had some program-specific SOPs available for HIV testing and for preparing slides using field stains, but they did not have documented SOPs for other tests. In general, most laboratories had infection prevention procedures posted on the walls in the laboratory. No laboratory knew the procedures for PEP for hepatitis B, and most of the laboratories did not have specific procedures for PEP for HIV, although they did have procedures for universal infection prevention. While most laboratory personnel stated that they would separate and notify the DHO if they discovered damaged or expired laboratory products, no laboratory had written procedures available for how to dispose of unusable laboratory commodities.

As shown in figure 3, most central hospitals have guidelines available in the laboratory for personnel as they perform their jobs and undertake standard safety procedures. The lack of guidelines at the district hospitals and health centers pose a safety risk to the limited laboratory personnel at these levels. In some cases, personnel interviewed stated that the guidelines may be stored in the office of the in-charge of the facility, but they were not available in the laboratory. SOPs and written guidelines are valuable job support and safety guidelines for workers on the job; they facilitate the transition when new workers begin laboratory posts.

Figure 3. Availability of Guidelines in Laboratory



Testing Services

Laboratory services are organized in three levels: central hospital–level, district hospital–level, and health center–level. Not all health centers have laboratory services. Some health centers, however, offer limited laboratory services, mostly for TB, malaria, and Hb. Rapid HIV testing is also available; at this level, it is usually done by HCT counselors. For various reasons, laboratories are not always able to offer standard tests using the recommended techniques. Some reasons given were that personnel are not trained in the technique, or equipment is not available, or reagents for the technique are not available. In some cases, clinicians are not aware of the available tests. For all these reasons, the result is that laboratories do not offer the same services, in the same way, at the same level.

As shown in figure 4, not all health centers are able to do the basic tests; figure 5 shows the main reasons the health centers gave for not doing the tests.

Figure 4. Percentage of Health Centers Performing Basic Tests

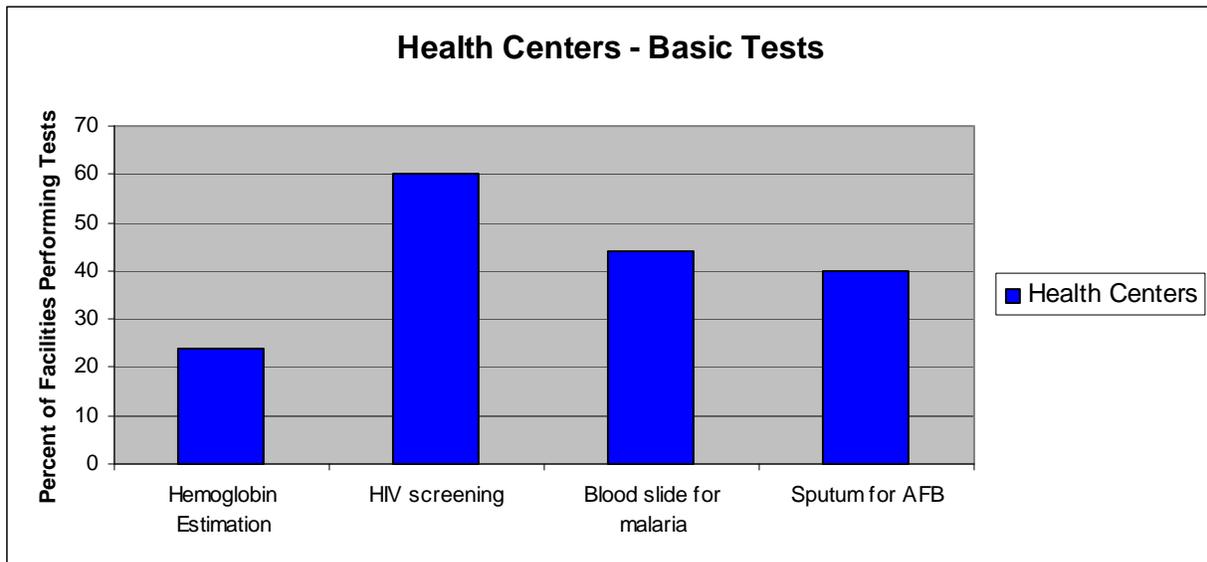
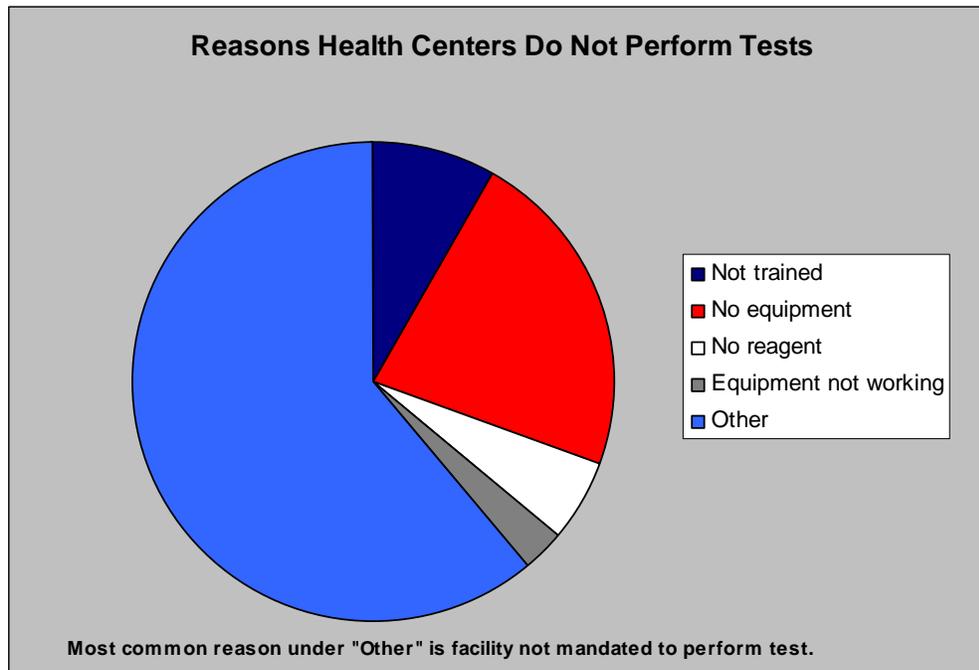


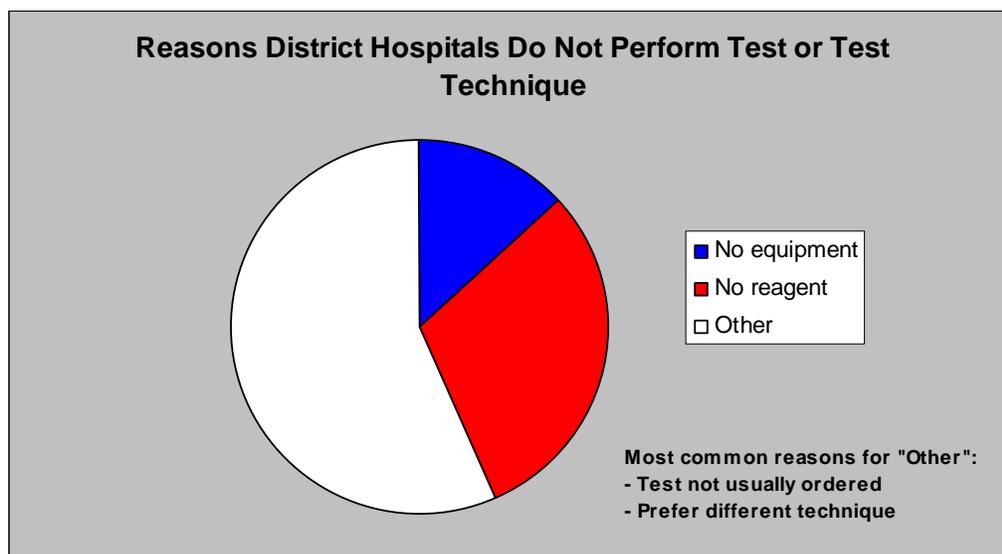
Figure 5. Reasons Health Centers Are Not Performing Basic Tests



District hospital laboratories, while they offer tests recommended in the EMLS final report, they are not providing all the tests needed, at all times. Because the district level is the next level of service after the health center level, the failure to provide tests at this level causes considerable problems for the people who need the tests; for most people, it is much more difficult to go to the central level facilities for testing.

The lack of equipment and reagents was reported as one of the reasons why tests are not always available. But, most notable is the lack of communication between the laboratories and clinicians about the tests that are available in the facility. Laboratories are not doing tests because no one is asking for them, even when the lab can do the tests. This lack of information as to what tests are available may result in tests not being requested. When new tests become available, either due to the availability of trained staff or new equipment, clinicians should be told about the new available tests. Figure 6 shows the main reasons why testing is not always available or performed at the district-level laboratories.

Figure 6. Reasons District Hospitals Not Performing Test or Technique



Quality Assurance

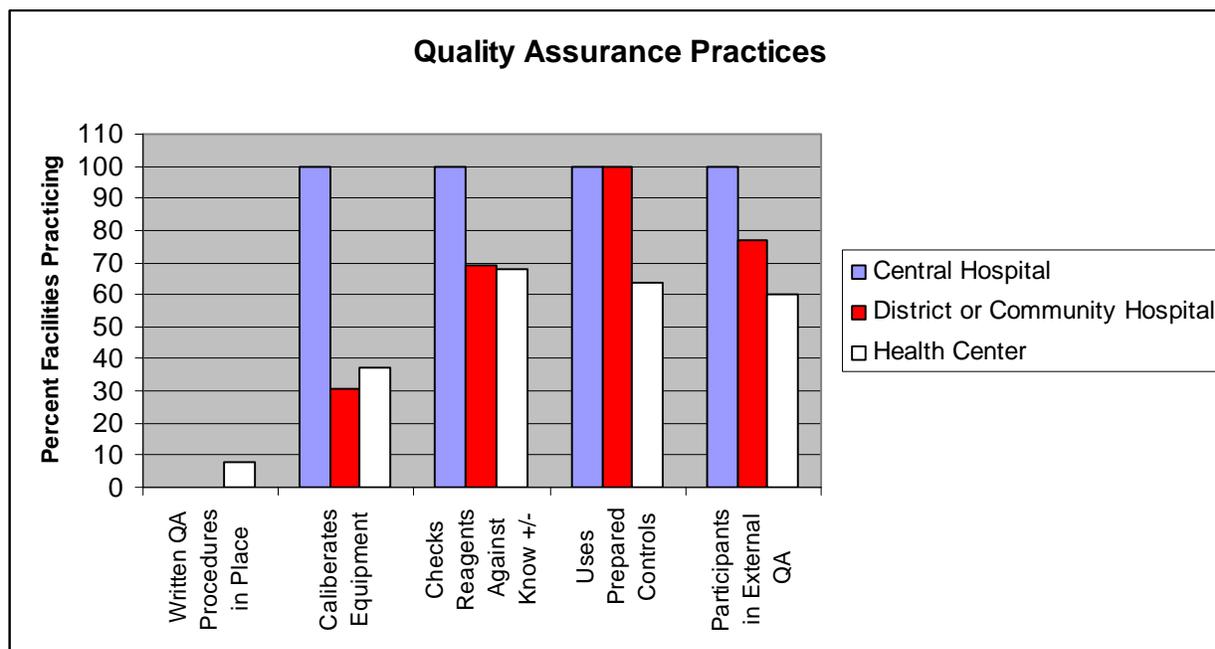
In resource-limited settings, accurate and reliable clinical laboratory testing is an important component of a public health approach to disease management. Laboratory data are essential if clinicians are to accurately assess the status of patient's health, make an accurate diagnosis, formulate treatment plans, and, subsequently, monitor the effects of treatment. The clinician must be able to trust the laboratory's test results if they are to use them for clinical diagnosis and treatment. As such, the results must be accurate, reliable, and timely.

To validate and ensure quality laboratory testing, laboratories in Malawi use internal and external quality control activities. CHSU provides external quality assurance (EQA) for laboratories; they send samples to laboratories for testing. The testing laboratories blind-test samples and send the results back to CHSU, which compares the laboratory results with CHSU's expected result. If discrepancies show up in the results between the expected values and the reported values from the laboratories, CHSU works with the laboratories to identify the probable cause and correct it. Currently, this is done for TB, HIV, and T4 or helper lymphocytes (CD4). United Kingdom National External Quality Assessment Service (UK NEQAS), an international quality assurance organization, assists with the CD4.

CHSU cannot provide external quality assurance testing for other laboratory tests because of their limited human and financial resources. Therefore, some laboratory tests do not have regular external quality assurance checks. The laboratory's overall performance cannot be established; therefore, areas that need strengthening cannot be identified and laboratory services across all areas of testing cannot be improved. Because of limited transport, it is difficult for CHSU to get quality control samples to all sites. CHSU delivers the samples to the district; the district delivers the samples to the health centers—when they can—usually when they go on supervisory visits. This is not an ideal situation for an EQA program, because the sites may never receive the results from CHSU, or the quality assurance samples will not get to the sites in time and in good condition, resulting in erratic and inconsistent EQA activity. Despite these constraints, CHSU also has other activities; they monitor disease outbreak, do research, and participate in other activities.

Figure 7 summarizes many of the current quality assurance practices. While laboratory personnel can explain the quality assurance activities they are expected to carry out, the documentation for these activities is usually unavailable. The laboratories do not have quality assurance procedures manuals. Laboratory staff understand the need for quality assurance activities; however, in many cases, documentation on what is being done; how it is being done is not available.

Figure 7. Quality Assurance Practices



Central-level laboratories reported calibrating and maintaining equipment, using controls to check new batches of reagents before use, and participating in EQA. For district-level laboratories, only one-third of the laboratories reported equipment calibration, and maintenance. While 70 percent of the district laboratories use controls to check reagents, all laboratories use controls when they run tests. Approximately 80 percent participate in EQA. Sixty percent of health center laboratories participate in EQA; the same percentage reported using controls in running tests. Equipment maintenance records were not available for the microscopes in the health center laboratories.

Staffing, Supervision, and Training

Staffing

The *National Medical Laboratory Policy, Ministry of Health, Malawi*, states that a minimum of two trained laboratory technicians should be assigned to each district/mission hospital and every urban and rural health center; and every department within a central hospital laboratory. The policy also states that a diploma in medical laboratory technology is the minimum qualification for laboratory personnel at hospitals and urban health centers.

The lack of trained laboratory personnel in all categories significantly restricts even basic laboratory services; expanding services, as needed, to support the goals of the EMLS; and implementing the necessary quality assurance activities.

As figures 8 and 9 show, health centers are usually staffed with microscopists or laboratory attendants—both have minimal training. Microscopists are usually health surveillance assistants (HSA) who only have a few months of training. More than 70 percent of the district hospitals have at least one laboratory technician, while central hospitals have staff from laboratory technologists to laboratory attendants, although usually not in the numbers needed, considering the types of tests central hospitals should be offering. The current range of tests available at all levels of services is limited by the level of staff working at these facilities, but it is particularly acute at the health centers where only a handful have staff with more training than a microscopist.

Figure 8. Laboratory Personnel by Facility Type

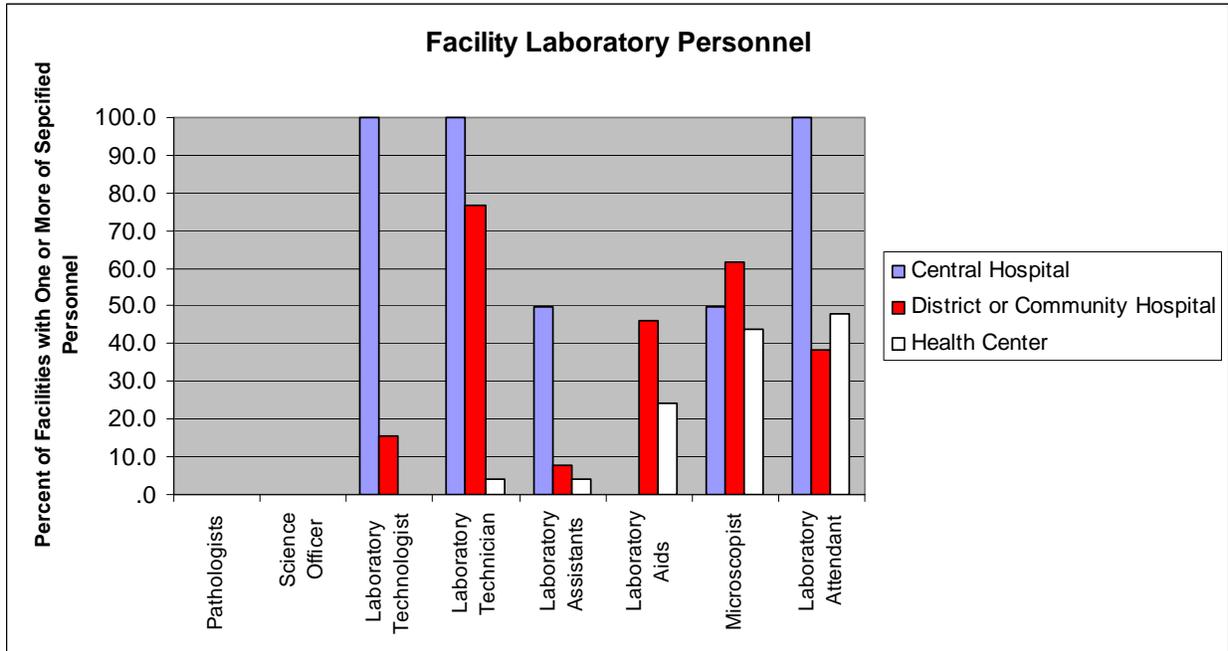
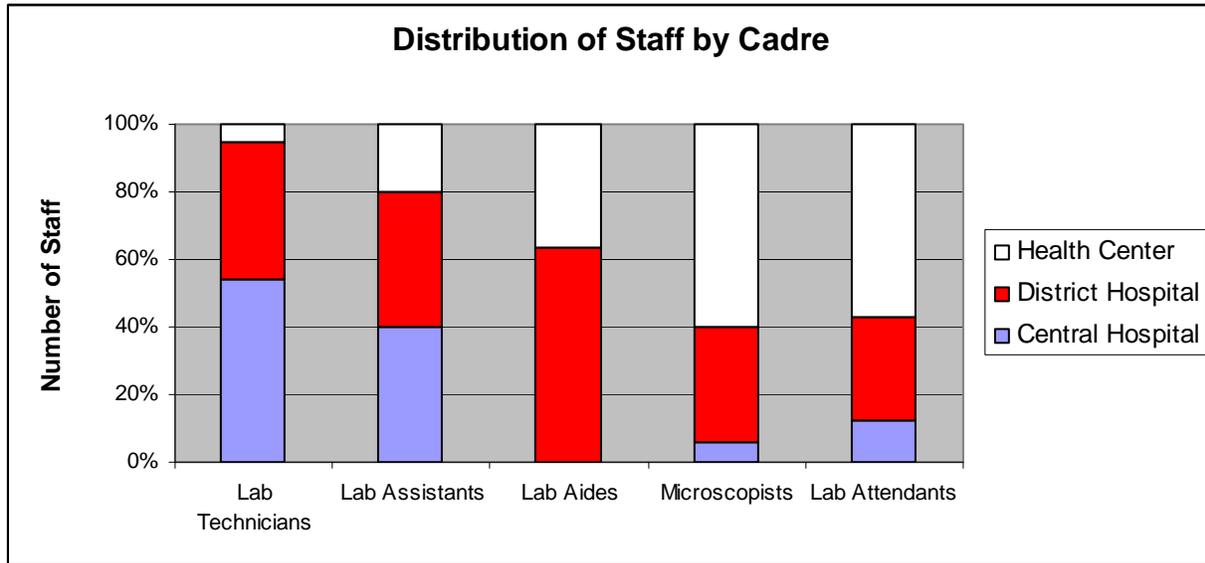


Figure 9. Distribution of Staff by Cadre by Facility Type

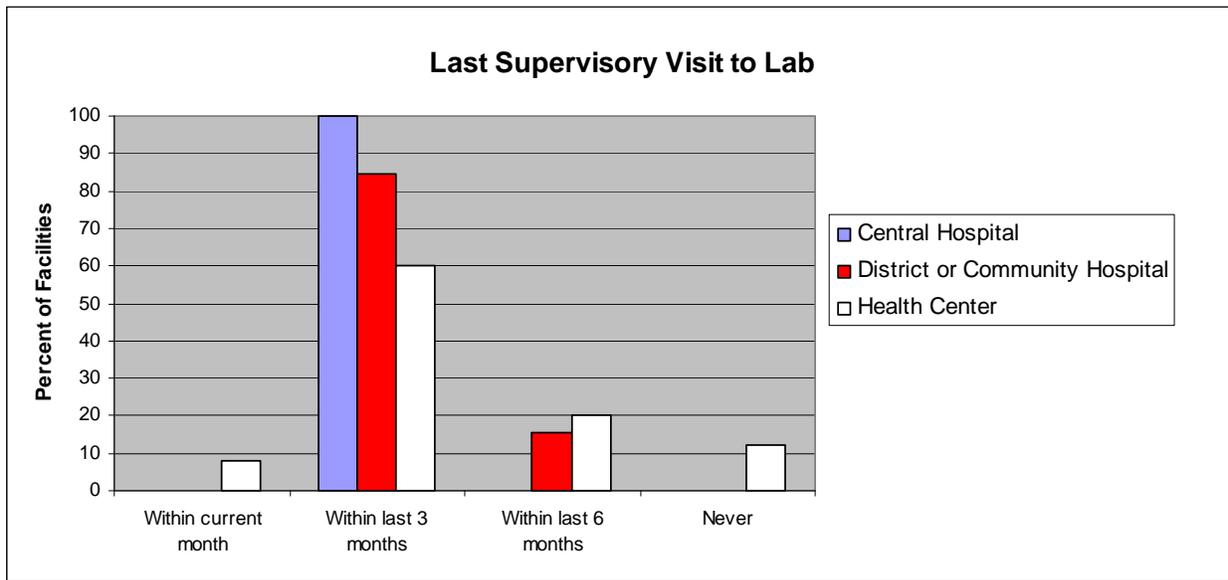


To attract laboratory personnel to work in community hospitals and health centers posts—for example, laboratory technicians who have more training—the MOH will need to improve the living facilities for staff and for the students living in hostels during their practical training.

Supervision

According to the policy document, each laboratory will receive quarterly supervisory visits from qualified, experienced laboratory personnel. As shown in figure 10, most facilities visited had a supervisory visit within the last three months. Six regional laboratory supervisors have been designated to provide supervision to district hospital laboratories in the three regions. Interviews with these supervisors indicate that, due to limited funding for fuel and per diem, supervisory visits actually take place less frequently and, in some cases, only once every six months. The District Health Management Team (DHMT) supervise the health center laboratories. Vertical program personnel—for example, the district TB coordinator or the district HTC coordinator—provide program-specific supervision to health center laboratory staff. But no one person is responsible for supervising laboratory services specifically at the health center.

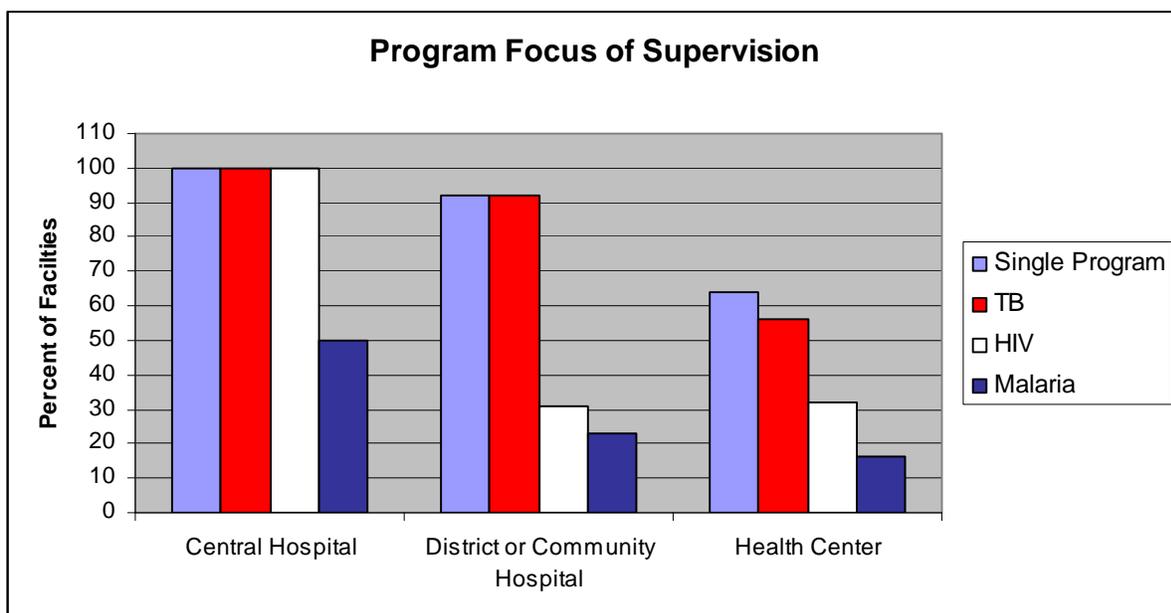
Figure 10. Time of Last Supervisory Visit to Laboratory



As most laboratory activities are conducted by under-trained staff, good supervision is essential to ensure quality services. Even though, at the time of the field visits, the majority of facilities reported a supervisory visit within the last three months, supervisors from a specific program primarily conducted the supervisory visit, usually the TB program (see figure 11). Usually, this visit does not include supervision of general laboratory operations beyond the specific program needs.

The most frequent activities conducted during supervisory visits included inspecting equipment, checking record keeping for tests performed, checking inventory of supplies, and following up on quality control procedures. In addition, supervision at the central hospitals included checking equipment maintenance records.

Figure 11. Program Focus of Supervision



Training

Pre-service training for laboratory personnel is available through the Malawi College of Health Sciences, the Malamulo Mission Hospital, and the Malawi College of Medicine. The following programs are available in-country:

- laboratory technologists: four-year Bachelor of Science in Medical Technology at the College of Medicine
- laboratory technician: three-year diploma program at Malawi College of Health Sciences and the Malamulo Mission Hospital
- laboratory assistants: two-year certificate program at Malawi College of Health Sciences (current class supported by CHAI).

While CHAI is currently supporting the training of 74 laboratory assistants, the MOH previously discontinued this group so they could encourage the training of laboratory technicians. Given the limited number of laboratory personnel, reinstating the training of laboratory assistants would help fill the current manpower gap. At the time of this report, the MOH did not know if they would be able to sponsor the next class of laboratory assistants; CHAI indicated that they will not continue their support after the current class graduates in December 2009.

Advanced laboratory training by the College of Medicine is hindered by the lack of opportunities for practical training. The College of Medicine depends on nearby Queen Elizabeth Central Hospital (QECH) to provide practical training for students. Laboratory services at QECH are reportedly limited by a lack of reagents for the automated analyzers they use in the labs. Because of this, some students complete their practical training through the College of Medicine research affiliates, the Johns Hopkins Project, and Wellcome Trust.

The TB program trains the HSAs as microscopists during a three-week program.

Staff received in-service refresher training (see table 3). Most of the training focuses on a single program, primarily HIV testing protocols. Laboratory personnel have not received training for supply chain management.

Table 3. Percentage of Staff by Facility Type Receiving Refresher Training in Last 12 Months

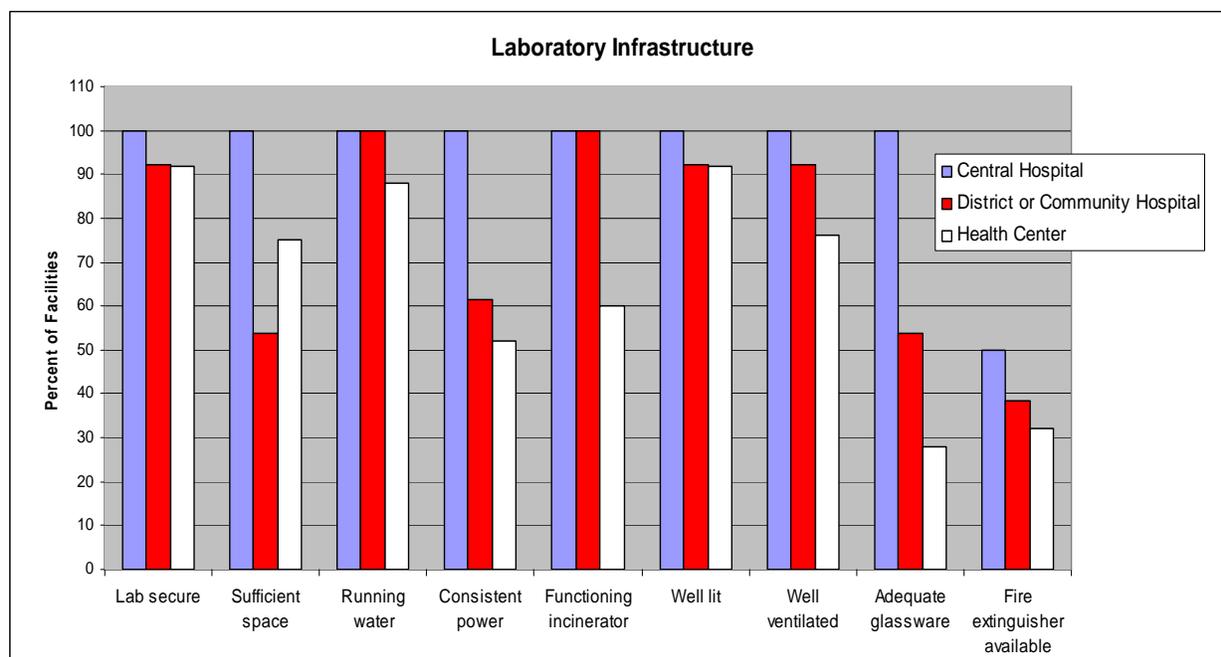
	Lab Technologist	Lab Technicians	Lab Assistants	Lab Aides	Microscopists	Lab Attendants
Central Hospital	100	95	100	NA	50	0
District Hospital	67	63	0	0	50	85
Health Center	NA	0	0	0	33	49

Laboratory Infrastructure

To provide laboratories that offer a safe, suitable physical environment with ample space, electric power, climate control, and water access, the MOH is building, refurbishing, and renovating laboratories from the central hospitals to the health centers on a massive scale. Kamuzu Central Hospital laboratory is now housed in a new building that meets international standards. The National TB Reference Laboratory is being upgraded to a level 3 containment, which will enable them to safely do TB cultures and drug sensitivity testing for first and second line drugs. The newly constructed laboratory for Lilongwe Bottom District Hospital is nearly complete. This ambitious activity is being undertaken in many parts of the country; the project was expected to be further along than it is. However, due to challenges being faced by contractors, some of the projects have been delayed. To ensure that the services are available for the people of Malawi, the Malawi government is determined to complete the laboratories.

As shown in figure 12, central-level laboratories have strong security, adequate space, and available running water and electricity. They are well lit, have good ventilation, and adequate glassware. One of the central-level laboratories did not have a fire extinguisher in the laboratory and storage area. Functional incinerators are available.

Figure 12. Condition of Laboratory Infrastructure by Facility Type



District-level laboratories have running water and functioning incinerators. Most of them are secured and have good ventilation and adequate lighting. However, only 50 percent have adequate working space; only 60 percent have a continuous supply of electricity. Adequate glassware was found in 54 percent of the laboratories. Fire extinguishers were available in only 38 percent of the district laboratories; this poses a very serious fire hazard in the working areas.

Most health center laboratories are secure. Three-quarters of the labs have adequate space for the tests they offer; however, if the scope of testing increases, space requirements would need to be reviewed. Most centers have running water available; however, only half have consistent electrical

power. Sixty percent have functioning incinerators; only one-third have adequate glassware. Only one in every three laboratories has a fire extinguisher. Health center labs are usually small single rooms, but they do have good benches and cabinets

Availability of Equipment and Supplies

Equipment

To a large extent, the range of testing services a laboratory can offer depends on the availability of equipment to do testing. After equipment is available, the next step is to ensure that the equipment remains functional. Equipment requires servicing, maintenance, spare parts, and supplies to work properly. Keeping equipment in good working order is essential when providing laboratory services.

Different types of equipment have different requirements; as more types of equipment are added, the more complex it becomes to keep them working properly, both for maintenance and for supply. Standardizing the equipment by facility type will improve both the servicing of the equipment and the management of consumable commodities because fewer products will be required. Training on the use of equipment can also be standardized. Another factor in keeping equipment operational is ensuring that the people who use it have adequate training and can handle the equipment correctly.

The assessment found very basic equipment available at the health centers, usually appropriate for the level of testing being conducted. However, there were significant limitations in the availability and functionality of the equipment. Less than half the health center laboratories visited have microscopes; and of the available microscopes, only 67 percent were functional. Hemacue, the recommended method for Hb estimation, is available in about one-fifth of the health center laboratories, and of these, fewer than half are working. Only 5 percent of the health center laboratories have autoclaves; none were functioning at the time of the field visits. Weighing balances, which are needed for reagent preparation, are available in only 18 percent of the laboratories. While TB samples are handled at most of the sites, safety cabinets are not available. Table 4 summarizes the availability and functionality of basic equipment that should be at a health center that performs the basic tests described in the *Testing Services* section above.

Table 4. Equipment Available and Functioning—Indicator Items at Health Center

Health Center	Percentage (%) of Facilities with Equipment	Percentage (%) Available Equipment Functioning
Autoclave	5	0
Weigh balance	18	100
Electric microscope	44	69
Haemacue	16	40
Spirit lamp	40	100
Wire loop	36	100

Consistent with the testing services offered at the district level, the district hospital laboratories have quite a few automated machines for testing samples. As shown in table 5, chemistry machines are

available in half the laboratories and all are in working order. Thirty-nine percent have CD4 machines and 46 percent have hematology auto-analyzers. One-third of the district laboratories have autoclaves and 62 percent have digital balances—all are working. Only 23 percent of the laboratories have a biosafety hood installed.

Table 5. Equipment Available and Functioning—Indicator Items at District Hospital

District or Community Hospital	Percentage (%) of Facilities with Equipment	Percentage (%) of Available Equipment Functioning
Autoclave	31	100
Chemistry auto-analyzer	54	100
Electrical digital balance	62	100
Flowcytometer CD4	39	100
Hemo-auto-analyzer	46	100
Biosafety Hood	23	33

As shown in table 6, all central hospital laboratories visited had chemistry machines, CD4 machines, hematology machines, and biosafety hoods. With the exception of chemistry machines, the equipment was functioning.

Table 6. Equipment Available and Functioning—Indicator Items at Central Hospital

Central Hospital	Percentage (%) of Facilities with Equipment	Percentage (%) of Available Equipment Functioning
Chemistry auto-analyzer	100	67
Flowcytometer CD4	100	100
Hemo-auto-analyzer	100	100
Biosafety hood	100	100

An inventory of the brands of machines in use showed four different brands of CD4 machines, six different hematology machines, and four different chemistry analyzers (see table 7). Different machines require different reagents, consumables, and spares; the wider the range of different machines, the larger the number of items required for the machines to run. Therefore, the more complex the supply chain becomes.

Table 7. Brands of Automated Equipment Observed

Hematology Machines	CD4 Machines	Chemistry Machines
ABX Pentra 60	EPIC	Humalyser 2000
Coulter ACT Diff 5	BD FACS Count	Humalyser 3000
Coulter ACT Diff 8	Partec Cyflow	Vitros DT 60
Sysmex KX21	Point of Care	Humastar 180
Micros 60		
Humacount		

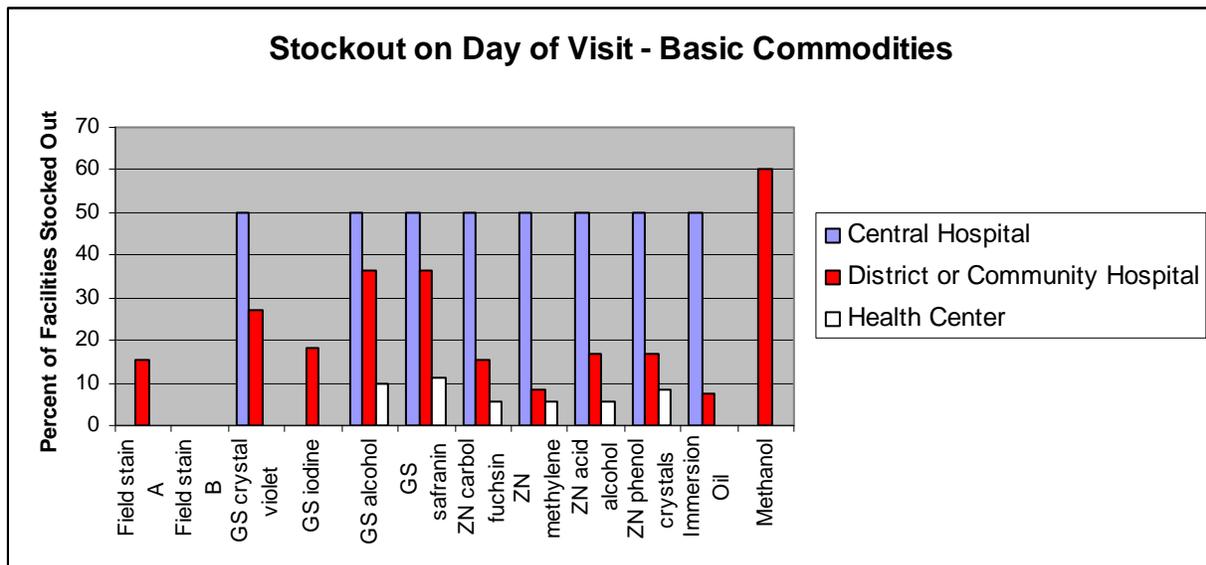
All equipment requires post-sales servicing. For the servicing, a biomedical engineer is needed who has training on the equipment and access to spares for the machines. When equipment breaks down, laboratory personnel report to the hospital equipment maintenance unit; they arrange for service to repair the equipment. Maintenance records of the equipment are generally not available and preventative maintenance schedules are also not in place at all the levels of laboratory services. This may indicate challenges in keeping the equipment functional, due to the lack of back-up service. While a list of equipment requirements for laboratories is available at the Physical Assets Management Unit (PAM) unit, the list is not specific. Available equipment records are primarily refrigerator charts; most of them are not up-to-date. The diagnostic unit of HTSS has recommended some machines, but this information still has to be published and disseminated to all stakeholders. This is a good development that will lead to the creation of a standard equipment list.

MBTS, Johns Hopkins University (JHU), University of North Carolina (UNC), and some CHAM hospitals have service and supply agreement with equipment manufacturers. With this arrangement, the suppliers provides reagents and servicing and maintenance for the equipment. This model, while not widely used, seems to have some advantages in reducing the down-time for equipment because of a lack of reagents or breakdown; this model is being explored for public-sector laboratories.

Supplies

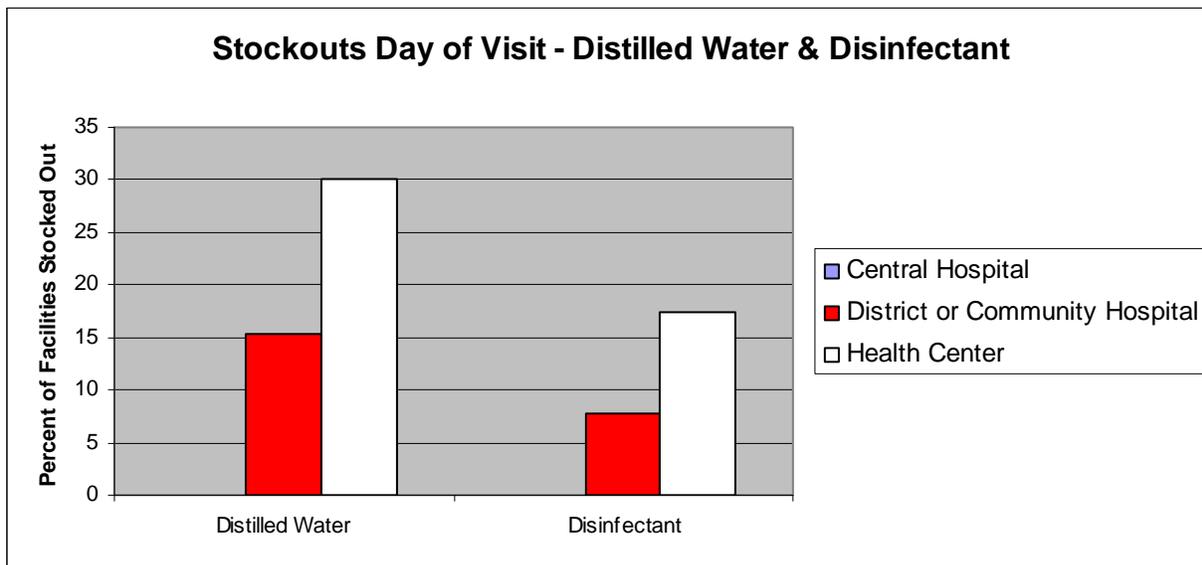
The availability of reagents is an important part of providing laboratory services. Health centers mostly use Field stain A and Field stain B for staining malaria, as well as ZN for staining TB. Immersion oil, which is used in microscopy work for TB and malaria, was in stock in all health centers on the day of our visit. Methanol, which is also important in stain preparation for microscopy, was stocked out in 60 percent of the district hospitals on the day of the visit. Figure 13 shows stockouts of basic commodities needed for TB and malaria testing on the day of the visit.

Figure 13. Stockout on Day of Visit—Basic Commodities



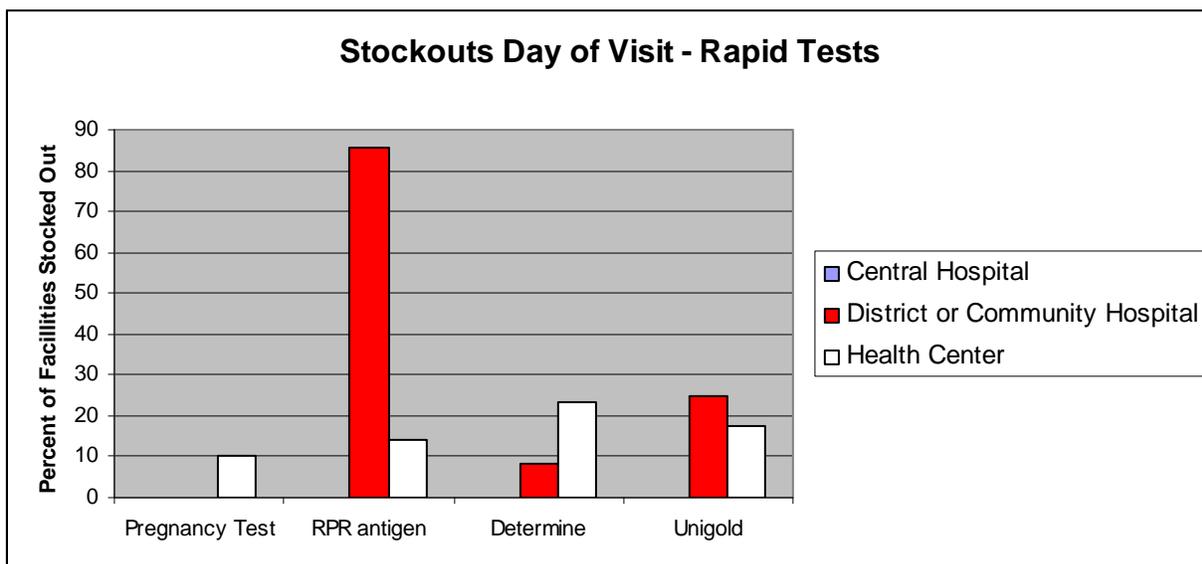
See figure 14 for the rates of stockouts for distilled water and disinfectant. Of concern is that 30 percent of the health center laboratories did not have distilled water; 17 percent did not have disinfectant on the day of the visit. The situation at district hospitals was better, with 15 percent without distilled water on the day of the visit; 8 percent did not have disinfectant in stock. Central-level laboratories did not report stockouts of these commodities. Distilled water is needed in the laboratory for reagent and specimen preparation and testing. When distilled water is not available, the laboratory cannot provide services even if everything else is in place. In addition, if materials for sterilizing the laboratory working area are not available, it is impossible to run tests because laboratory staff will be exposed to possible infections. To ensure continuity of service, it is very important that the stock of these products, as well as the others, be maintained at all times. Any stockouts of distilled water, disinfectant, reagents, or supplies will affect the quality of the service provided.

Figure 14. Stockouts Day of Visit—Distilled Water and Disinfectant



See figure 15 for an analysis of stockouts for rapid tests. Eighty-five percent of district hospitals were stocked out of RPR for syphilis testing on the day of visit. Twenty-two percent of health center laboratories were stocked out of Determine and 18 percent were stocked out of Unigold on the day of the visit. District hospital laboratories also had stockouts of HIV tests—8 percent of laboratories at this level were stocked out of Determine and 25 percent were stocked out of Unigold on the day of the visit.

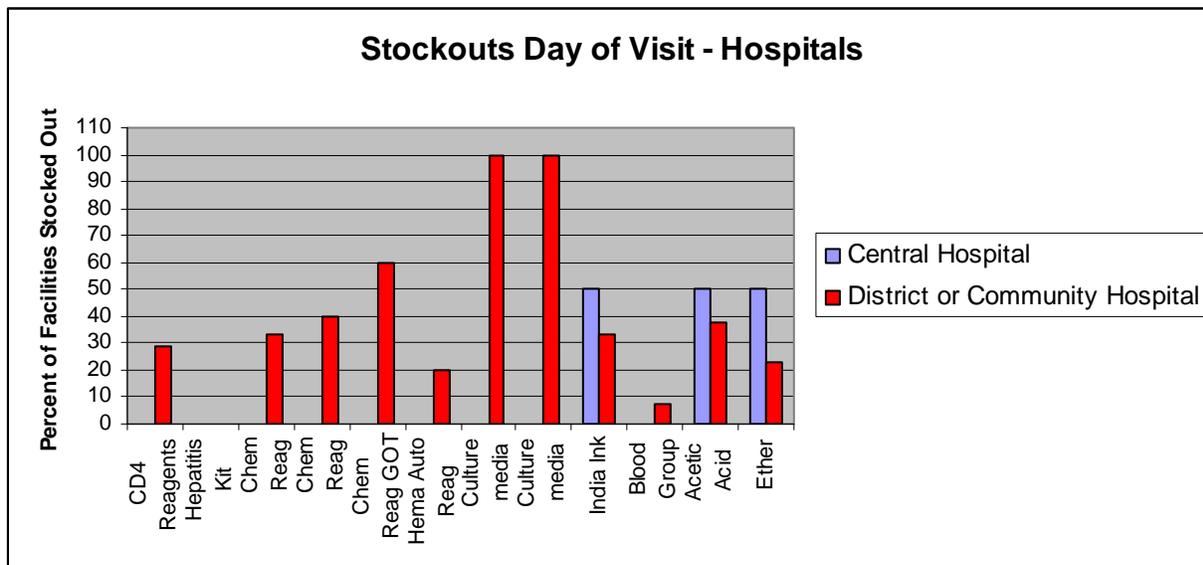
Figure 15. Stockouts on Day of the Visit—Rapid Tests



Some district and central hospitals were stocked out of machine reagents on the day of the visit. As shown in figure 16, 28 percent of the district-level laboratories were stocked out of CD4 reagents; the central level had no stockouts of CD4 reagents. Chemistry reagent for glutamate oxaloacetate transaminase (a liver function test) (GOT) was stocked out in 60 percent of the district hospitals.

Twenty percent of the district hospital laboratories did not have hematology reagents on the day of the visit.

Figure 16. Stockouts on Day of Visit—Hospitals



Forecasting and Quantification

The diagnostics unit, with the Pharmaceutical Unit of HTSS, is responsible for forecasting and quantifying for general laboratory supplies. Needs are forecasted annually using the number of tests performed in prior years as the basis for forecasting the number of tests in the future. The forecasted number of tests are then converted into the product required, based on assumptions about the types of laboratory supplies needed to conduct the types of tests. As tests and test techniques are not standardized, this conversion of tests to product is based mainly on assumption. No stock data is collected for general laboratory products, so the quantification of needs does not consider stocks currently held in the pipeline, actual consumption or issues, or anticipated losses. The general impression of key informants is that the reported information on tests performed is not accurate or complete; therefore, the quantification process is based on poor data of limited use in doing quantification. This impression is further supported by the irregular structure of the laboratory reporting system.

Forecasting and quantification for the TB program, HIV and AIDS, and malaria is slightly more rigorous. Once a year, using a combination of service data (tests performed, patients counseled), morbidity data, population data, and some logistics data from the central level, the HTSS Pharmaceutical and Diagnostics Units does forecasts for HIV tests.

Once a year, the TB program uses consumption, service, and morbidity data to prepare a forecast and quantification for TB reagents and supplies.

Once a year, CHSU uses service data to prepare a forecast for laboratory supply requirements for quality assurance activities.

Procurement

Procurement of laboratory commodities, as well as refurbishment of facilities, training, and other service support is financed by a combination of funding from the MOH, SWAp funds, and Global Fund grants, with material support from CDC, UNICEF, Howard University, USAID, and other partners.

Central Medical Services

It is the responsibility of the CMS to procure laboratory reagents and supplies. The CMS is increasing its capacity to procure and manage laboratory supplies. A common comment made by key informants was that the CMS lacks experience with and knowledge of laboratory commodities. Anecdotal evidence says that, because of this, reagents have expired in storage; CMS has claimed that a specific reagent was not available at CMS when it was in stock. The management of CMS is aware of these weaknesses; they have asked for technical support from the diagnostics unit to assist with laboratory commodity management.

The CMS floated its first two-year tender for all laboratory commodities in 2007; a delay has altered the procurement years to 2008–2010. The tender process takes approximately 15 months. Standard contracts, not framework contracts, were awarded for this tender, so commodities are delivered in two shipments, one per contract year, rather than drawn down–based stock levels and timed-based on a phased procurement plan.

Unfortunately, the review of this first tender did not include laboratory personnel. The tender included laboratory controls that have short shelf lives. Because controls are received in single, annual shipments, some controls will probably expire before they are distributed.

Requests for Quotes (RFQs) of less value than a tender can be issued to complement tenders when additional commodities are needed. The lead time on RFQs from issue to receipt of supply can take as little as six weeks.

CMS updated its catalogue of laboratory commodities in late 2008 with the assistance of senior MOH lab personnel. Because the MOH does not have a standardized test and test technique menu, the catalogue reflects a large variety of commodities; the catalogue currently includes more than 250 items. CMS does not stock all items listed in the catalogue, but it will procure these special items on a case-by-case basis.

Hospitals may request and receive a *no-objection* from CMS to procure outside the CMS system if CMS does not have the required laboratory commodity. CMS reports that it usually takes one week to approve a no-objection request, although some facilities have experienced delays in receiving approval.

While CMS is building its capacity to procure reagents, UNICEF is currently procuring most of the HIV and Hb testing reagents for the country.

CMS indicated the challenges they face in procuring laboratory commodities include the lack of—

- standardization and specification of laboratory supplies and equipment
- technical knowledge of laboratory commodities
- logistics data for quantification and management of laboratory commodities
- ability to test the quality of laboratory supplies upon receipt at CMS.

While CMS attempts to maintain maximum and minimum stock levels and monitors the stock status of indicator products, it currently does not have a procurement plan or pipeline monitoring system in place for laboratory commodities.

MOH Procurement Unit

The MOH Procurement Unit procures laboratory equipment and services, such as equipment maintenance contracts. As of September 2008, the Government of Malawi had established international competitive bidding procurement procedures. The procurement process takes at least six months to complete. While there are no specific guidelines for the procurement of laboratory equipment, procurement of these items follows the same general guidelines as for procurement of medical equipment.

Medical equipment, including laboratory equipment, is managed by the Physical Assets Management (PAM) unit of the MOH. This unit maintains a general list of equipment that should be found at facilities, by type of facility. The list does not include technical specifications for the equipment required. Technical specifications of equipment is a major challenge; most units specify equipment requirements by brand name, but regulations do not allow for procurement by brand. Provision of technical specifications will simplify procurement. While procurement of equipment does not allow sole source procurement, sole source procurement for spare parts and reagents can be made if there is sufficient justification. The proliferation of types and brands of equipment, particularly closed laboratory systems, which resulted from a lack of standardization and the requirement to compete each procurement, makes procuring reagents exponentially more difficult.

The MOH, with assistance from partners, is exploring laboratory equipment reagent-rental agreements to help ensure that reagents and service agreements are available for all laboratory equipment and to ease the burden of equipment procurement.

Inventory Management

In central and district hospitals, laboratory commodities and supplies are usually stored and managed by pharmacy personnel; while, in health centers, laboratory staff manage most laboratory commodities. The exception is HIV tests, which are almost always controlled and managed by the HTC counselors.

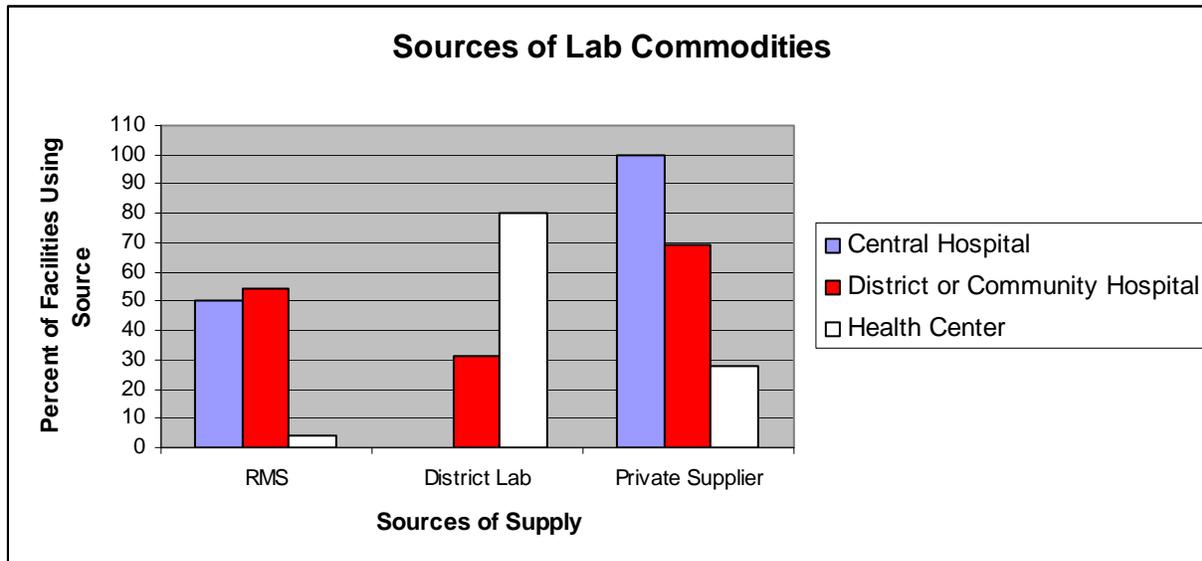
There is no standard inventory control system (established maximum or minimum stock) in place for managing laboratory commodities at any of the facilities. The majority of facilities order laboratory commodities routinely, usually monthly, with the laboratory staff taking primary responsibility for determining what and how much of each laboratory commodity to order. However, there are no standard procedures for determining the quantity of commodities to order. Less than 50 percent of the facilities estimate quantities needed based on the number of tests that will be performed in the next month; even fewer facilities consider the remaining stock balances when determining the order quantity.

As shown in figure 17, health centers usually order laboratory commodities from the district hospital lab, although in the Blantyre district commodities are ordered from the Blantyre district store. Some CHAM health centers purchase laboratory commodities from local commercial suppliers, as do district and central hospitals. Hospitals also order laboratory commodities from RMS.

In the past, it has been difficult for facilities to order laboratory commodities from RMS because the product specification and coding system for laboratory commodities in the RMS catalogue is not

well defined and the RMS staff is not familiar with the products. Some of this difficulty has been addressed with the recently republished catalogue; the assignment of laboratory personnel to the RMS would also help solve this problem.

Figure 17. Source of Laboratory Commodities by Facility Type



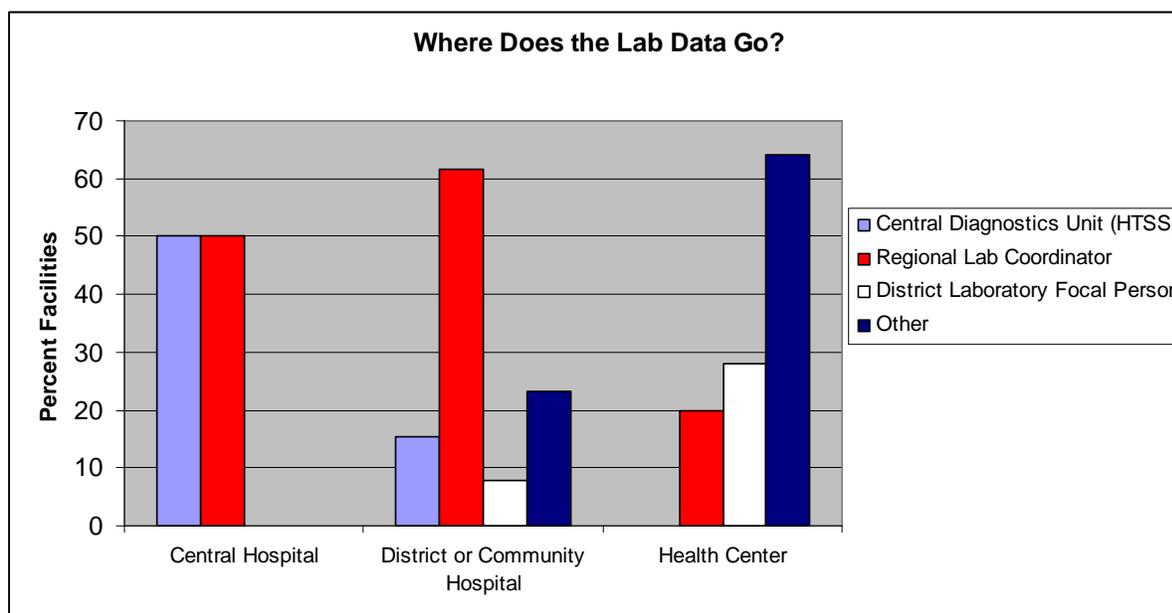
Of the two central hospitals visited, one placed three emergency orders during the last year; the other placed four. Seventy percent of the district hospitals placed one or more emergency orders in the last year, while 60 percent of the health centers had at least one emergency order in the last year. Emergency orders were usually placed when commodities were completely stocked out; facilities do not have set emergency order points to avoid stockouts.

Laboratory Information Systems

With the exception of the forms used to collect and report data about HIV tests performed, no standardized laboratory forms are routinely used at health facilities. HIV test reports provide an extensive demographic profile on patients tested and the test results. Data on TB tests performed and test results are routinely recorded in ledger books and documented in hand-written reports. In a few cases, similar data on malaria tests performed and the results were collected and reported. Seventy percent of facilities report this laboratory data monthly; 30 percent report quarterly. Hospitals complete an annual worksheet of laboratory tests performed, with each month representing a column on the worksheet. This information is provided to the diagnostics unit at the end of each year; it is used during the quantification process. The Patient Health Passport Book is the primary document used by many facilities to order the tests a patient requires. Information on quality assurance activities is inconsistently collected and reported. No other laboratory information is reported.

Figure 18 illustrates where the laboratory information is reported. As expected, facilities generally report to the level above them. The majority of health centers report information directly to HTC and TB program personnel at the district. District HTC coordinators and TB coordinators report directly to the national-level programs. With the exception of the annual worksheet of laboratory tests performed, data on general laboratory services is not routinely reported.

Figure 18. Recipients of Laboratory Data by Each Facility Type



Logistics Management Information Systems

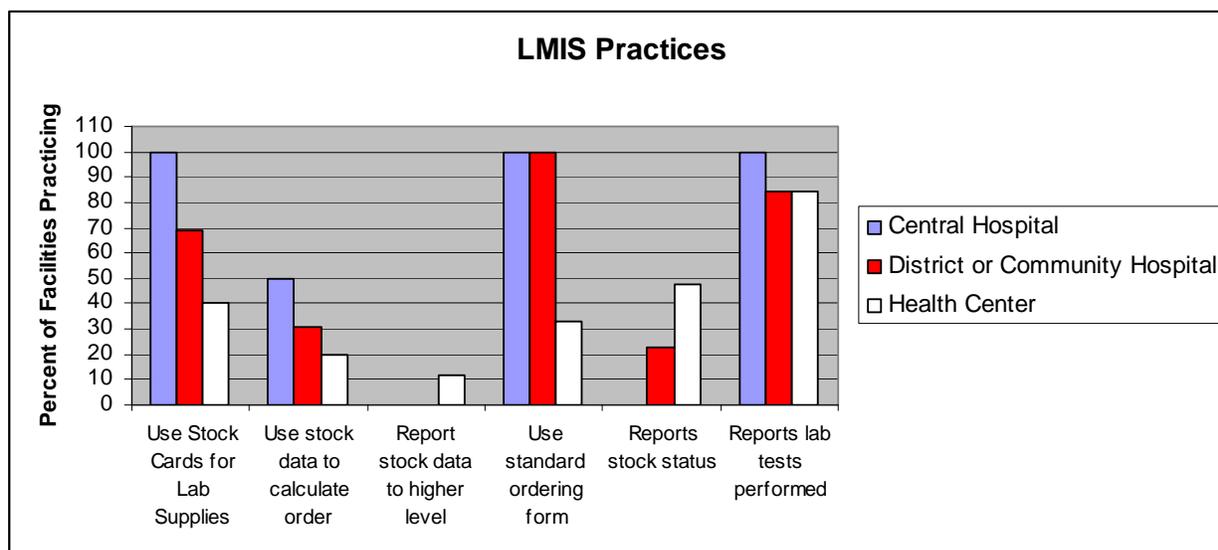
A complete LMIS comprises three types of records (stockkeeping records, transaction records, and consumption records) that collect the three essential logistics data items (stock on hand, losses and adjustments, and dispensed-to-user data) and the reports that move that data to the personnel who make logistics decisions. The direct delivery system currently used in Malawi for contraceptives and other health products uses issues data as a proxy for dispensed-to-user data; therefore, relying entirely on stock cards as the primary source of logistics data.

As seen during the field visits and illustrated in figure 19, stock cards are being used for laboratory commodities in facilities where these commodities are stored in the pharmacy with other health commodities. They are usually not being used when laboratory commodities are stored in the lab or in the HTC counseling room. Observation of the stock cards during the field visits showed that many were not kept up-to-date or well maintained.

Many facilities use requisition and issues vouchers or similar ordering forms. Facilities ordering from an RMS use the standard Med 194 form. Health centers in Blantyre and Zomba use locally designed district specific requisition and issues vouchers.

Little to no logistics data on laboratory supplies is routinely reported or used for important logistics decisions (e.g., determining order or procurement quantity, forecasting, or monitoring system performance).

Figure 19. Logistics Management Information System Practice by Facility Type



Supply Chain Manager (SCMgr) is the automated LMIS that the district pharmacies currently use in Malawi to order health commodities from the RMS for the district hospitals and health centers and to report logistics data. SCMgr currently includes only a subset of the 89 laboratory commodities for the district level in its product list, and two laboratory commodities for the health center-level. While not based on standardized test and test technique menus, the CMS catalogue offers approximately 253 laboratory items. If SCMgr is used for laboratory commodities in the future, the product list in SCM will need to be updated with the standardized list of products, by service level.

Storage

Figure 20 displays the percentage of facilities that practice good storage procedures. While, in most cases, more than half the facilities visited are storing laboratory commodities appropriately, there is room for improvement, particularly in storing hazardous materials, compliance with first-to-expire, first-out management of commodities, and handling of damaged and expired products.

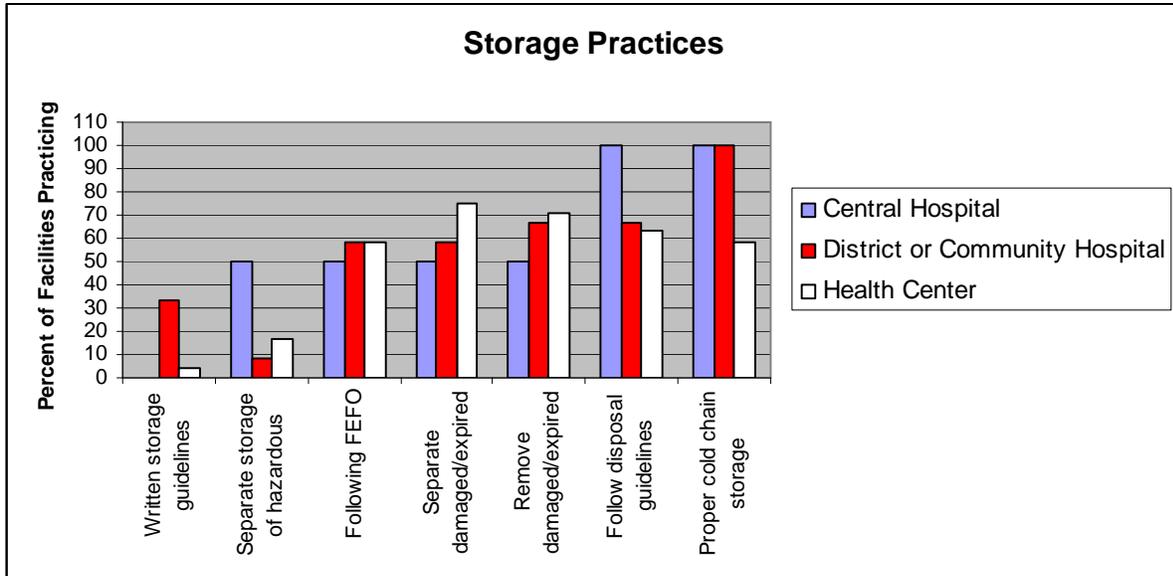
Transportation and Distribution

The mechanism and method of transport and distribution of laboratory commodities to health facilities in Malawi varies. In most cases, the laboratory picks up laboratory supplies while, at the same time, other health commodities are being delivered directly to the same facilities. Eighty-four percent of the health center laboratories pick up their laboratory supplies from the district. In most cases, HIV tests are distributed separately from other laboratory products. In any single health center, the microscopist will travel to the district to pick up supplies; the HTC counselor will travel separately to pick up HIV tests on a different day; and health commodities will be delivered directly to the health center. This system is inefficient and should be replaced.

In just over 50 percent of the health centers, facility transport is available; the rest of the time, public transport is used. Sixty-nine percent of the district hospitals visited are responsible for picking up their laboratory supplies from their suppliers. In general, about 50 percent of the facilities visited had vehicles that could be used for commodity pick-up and 50 percent had funds for fuel. The most

common problems cited related to transport and distribution were shortages of vehicles and lack of funds for fuel.

Figure 20. Storage Practice by Facility Type



Recommendations

The recommendations that follow are suggestions for many of the topics discussed in the previous section, *Findings*. The last section of this chapter, *Next Steps*, describes actions to take to implement these recommendations.

Policy

We recommend that the Ministry of Health Diagnostics Unit do the following:

- Disseminate the national laboratory policy as soon as possible. This would not only communicate the MOH policies on laboratory services, but it would also call attention to the ministry's intentions and activities in this key area of service provision.
- Develop standard tests menus and testing techniques by level, that all clinical and laboratory staff agree on and these tests should be advocated for, disseminated, and implemented. This will help ensure that physicians and laboratory staff agree on the tests that are offered at each facility and that physicians order those tests when needed. This will also ensure that the appropriate equipment and supplies are procured for the tests and techniques and will simplify the management of those commodities.
- Lead the effort to strengthen, finalize, and disseminate the technical SOPs for laboratory services. The SOPs should include the standardized test and test technique menus, by level; laboratory supply and equipment lists by level; specific quality assurance (QA) protocols and procedures and staffing, by level; and safety precautions. They should also include procedures on PEP for HIV and hepatitis B and for disposal of damaged and expired products. The SOPs should be disseminated and the staff trained in their contents and use. The SOPs should be used during supervision and on-the-job training (OJT). Additional development and finalization of the SOPs should be a collaborative effort, with significant input from the facility staff from all levels.

Staffing, Supervision, and Training

- Working with the Malawi government's human resources department, the MOH should strengthen the human resources plan for laboratory services by re-establishing the position of laboratory assistants. In addition, the MOH should develop a plan to implement appropriate staffing, by level; and upgrade staffing levels at facilities, which would improve services and meet the goals set forth in the laboratory policy, .
- The Ministry of Health Diagnostics Unit should work to strengthen the supervision of laboratory services by providing additional financial and technical support to regional laboratory supervisors; they should also identify appropriate personnel to supervise the health center laboratories. To integrate supervision of the laboratory services into that structure, the diagnostics unit should review the current structure for the general health system supervision. In addition, laboratory supervision issues should be integrated into general or program-specific supervision checklists or other supervision tools currently in use. If checklists are not in use, the

MOH should work to develop and train laboratory supervisors in their use. As possible, they should also develop structured OJT tools for supervisors and laboratory managers.

- The Malawi College of Health Sciences, with the Ministry of Health Diagnostics Unit, should include the logistics management of laboratory commodities in pre-service training for all laboratory personnel. The current classes of laboratory assistants and laboratory technicians should receive this training, including a module on logistics management in the standard curricula for the training of laboratory personnel. A similar effort should be made to include logistics management in the training of laboratory personnel at other training schools, including the College of Medicine.

Quality Assurance

The Ministry of Health Diagnostics Unit, with CHSU, should—

- ...strengthen facility quality assurance activities by training laboratory supervisors to emphasize quality assurance during supervisory visits. Supervisors should be trained to ensure that appropriate quality assurance practices are taking place in the laboratories, such as running internal controls, as required, and participating in external quality assurance activities, as outlined in the guidelines. In addition, supervisors should be trained to manage or solve issues that arise from these activities and to offer staff support in helping them to manage the quality issues. While external quality assurance providers may conduct supervisory visits from time to time, to develop a culture of quality awareness in every member of staff, laboratory supervisors should check on quality assurance issues every time they have any contact with the lab staff.
- ...establish a system for ensuring the quality of reagents used in the health facilities. Specific procedures for reagent preparation and reconstitution should be included in the SOPs, with clearly detailed quality assurance steps that should be taken to test the quality of the prepared reagents. Laboratory personnel and supervisors should be trained in both the preparation and quality assurance procedures for reagents.
- ...establish a unit at the central level that has external quality assurance as its only mandate. This unit should focus on—
 - preparing EQA panels for blind testing, retesting, and proficiency testing for all laboratory disciplines;
 - distributing EQA materials;
 - collecting and consolidating results from sites;
 - producing EQA reports for the sites and the ministry.

This unit should focus on site assessments; developing quality management systems for laboratories; and providing training in quality assurance. It should also advise the MOH on accreditation of laboratories and supervise quality assurance activities.

- ...integrate external quality assurance for all tests so that quality assurance activities are not fragmented but are provided as a package. The laboratory should be approached and managed as a unit. EQA panels should be provided with all the tests in the scheme that represent the testing services the laboratory is providing. Tests for all disciplines should be coordinated from a single point.

Logistics Management

The Ministry of Health Diagnostics Unit—

- ...working with the HTSS Pharmaceutical Unit, and with the assistance of the USAID | DELIVER PROJECT, should integrate the management of laboratory supplies and reagents into the CMS/RMS ordering and direct delivery system currently being used for pharmaceuticals. After the integration, laboratory supplies and reagents should be stored in the storeroom with other health commodities and, as such, managed by the pharmacist-in-charge of the health facility stores. Laboratory personnel should work closely with the pharmacist-in-charge to ensure that needed laboratory supplies are ordered at the same time essential medicines and other health commodities are ordered for the facility. Integrating laboratory supplies into the same system should produce the following benefits:
 - Laboratory commodities will be ordered every month and delivered directly to the facility.
 - Stock levels of laboratory commodities will be monitored and maintained within established maximum and minimum stock levels to avoid stockouts or overstocks.
 - Stock cards will be maintained for all laboratory commodities, which will make logistics data available.
 - Logistics data on laboratory commodities will be reported monthly in the combined ordering and reporting system, and the data will be available to central level for forecasting, quantification, procurement, and program and logistics system performance monitoring.
- ...after reviewing the current system, the integration of laboratory commodities should be planned to determine any adjustments that may need to be made to the periodicity and flow of commodities; plans can also be made, if needed, for any additional pipeline parameters for special or highly sensitive laboratory commodities.
- ... working with the HTSS Pharmaceutical Unit, and with assistance from the USAID | DELIVER PROJECT, should establish the routine collection and reporting of logistics data (stock on hand, issues, and losses) for laboratory supplies that are tracked using LMIS forms and the SCMgr software system. This should be done, as described above, by integrating laboratory commodities into the system currently used for other health commodities. Integrating the LMIS will require revisions to the current LMIS forms and the automated SCMgr system.
- ...should strengthen the monitoring of the laboratory supply chain. This can be accomplished by increased access to stock and consumption data as the integrated LMIS is being established. The Ministry of Health Diagnostics Unit should identify system performance indicators, such as maintenance of stock between established stock levels, stockout rates, and product losses, by which to measure their success of ensuring a continuous supply of laboratory commodities for testing services.
- ...should develop and standardize a laboratory management information system to complement the LMIS and regularly report laboratory service statistics to the central level. This would be not only a check against logistics data but would also provide useful information for forecasting, quantification, and procurement planning at the central level.
- ... working with the HTSS Pharmaceutical Unit, should strengthen the logistics communication between pharmacy store managers and laboratory staff within health facilities. The success of

integrating the management of laboratory commodities will depend on good communication and cooperation between the pharmacy and the laboratory units at the facilities. In addition to other mechanisms, the development of a strong working relationship can be addressed during training activities after the new system for laboratory commodities is initiated.

Forecasting and Procurement

- The Ministry of Health Diagnostics Unit, with the HTSS Pharmaceutical Unit, CMS, and program units should use logistics data and service data to forecast and quantify laboratory supplies. They should improve the accuracy of forecasting by collecting current, appropriate data through the integrated LMIS. While service statistics should still be used for forecasting, in addition to logistics data, the data should be collected and reported more regularly so that it is available at the appropriate time for forecasting. Eventually, logistics data will be preferred over service statistics. Logistics data provide more accurate data about the usage of the supplies; service statistics provide data about the number of tests conducted, which often does not easily correlate with the supplies required.
- The CMS should establish a procurement planning and pipeline monitoring process that continuously checks the stock levels of laboratory supplies and allows new tenders to begin before the end of the previous tenders or issuance of RFQs. This will ensure that stock levels are always maintained above the facility's set minimum levels and that supplies are always available for distribution, as needed.
- The CMS, with assistance from the USAID | DELIVER PROJECT, should use the PipeLine software to establish pipeline monitoring for the most vital laboratory supplies.
- To facilitate the recommendation above, CMS should establish framework contracts with suppliers so that laboratory commodities can be received from suppliers, in the quantities required, at the time needed, to maintain continuous appropriate stock levels at the CMS. This is particularly important for laboratory commodities with short shelf lives or those that are more sensitive to changes in storage conditions or, for any reason, require closer management.

Coordination

- To improve the way the commodity procurement is coordinated and other resource inputs that support laboratory services, the Ministry of Health Diagnostics Unit should establish a Laboratory Supply Management sub-group of the National Laboratory Technical Working Group. The sub-group would meet quarterly to review supply needs and the procurement actions in process, and to handle other issues related to supply. The group should include all stakeholders and development partners who are involved in the use, procurement, or management of laboratory equipment and supplies.
- The Ministry of Health Diagnostics Unit should assign laboratory technical staff to each RMS to assist in specifying orders from health facilities, to monitor the quality of laboratory commodities in storage, and to assist with managing laboratory supplies. Laboratory technical staff assigned to each RMS should also work with the RMS staff to familiarize them with the characteristics and storage requirements of laboratory commodities and to ensure that appropriate stock levels of laboratory commodities are held at each RMS.

Next Steps

To begin implementing the recommendations above, the following next steps are suggested. The times are illustrative and do not consider already planned or established activities of the Ministry of Health Diagnostics Unit or other MOH units.

1. *Convene the Laboratory Supply Management sub-group of the National Laboratory Technical Working Group.*

The Ministry of the Health Diagnostics Unit should identify and invite members and convene the first meeting of the sub-group. This activity does not depend on other activities; it can occur as soon as feasible. In addition to discussing any immediate supply issues, the sub-group should, at the initial meeting, define the group's mission, identify group leadership and membership responsibilities, determine the group's processes, and set a schedule for routine meetings.

2. *Conduct a Laboratory Standardization and Strategic Planning Workshop.*

The Ministry of Health is planning this workshop as part of the process for developing the Five-Year Strategic Plan for Laboratory Services. The workshop should also bring together the MOH, relevant stakeholders, development partners, and health facility clinical and laboratory staff to define the standard test menus by level of service, the test techniques for each test, and the lists of equipment and supplies that are needed to perform the test techniques. All participants should agree on the test and technique menus and the equipment and supply lists; these should inform the CMS procurement process, the development of the laboratory information system, and the revisions to the LMS for integrated health commodities, including laboratory commodities. This workshop should take place in March 2009, as planned.

3. *Finalize and disseminate laboratory SOPs.*

After standardizing the test and technique menus, and equipment and supply lists, the National Laboratory Technical Working Group should finalize the SOPs for laboratory services, including the standardized lists and elements detailed in the recommendations. They should develop a plan to disseminate the SOPs and to integrate the SOPs into pre-service training and supervision activities, and provide in-service training in how to use the SOPs. This activity is contingent on completing the standardization workshop; it could begin in April 2009.

4. *Hold laboratory logistics system design workshop.*

If the MOH accepts the recommendation to integrate laboratory commodities into the current ordering and direct delivery system used for other health commodities, they should hold a workshop to review the current design of the logistics system and, to accommodate laboratory commodities, make any changes to the LMIS or other aspects of the system. This activity depends on the completion of the standardization workshop; it could begin in April or May 2009. The USAID | DELIVER PROJECT can assist with this activity if the MOH and USAID agree.

5. *Conduct training-of-trainers (TOT) workshop for logistics management of laboratory commodities; develop strategy for training laboratory and pharmacy personnel.*

After revising the design of the LMS to accommodate the integration of laboratory commodities, the Ministry of Health Diagnostics Unit should update the SOPs for the LMS and the curriculum used to train staff in the system. The same group should develop a strategy for training laboratory and pharmacy staff in the revised procedures and conduct a TOT workshop. This activity is contingent on the completion of the Laboratory Logistics System Design

Workshop. The activity could take place in July 2009, with assistance from the USAID | DELIVER PROJECT, if the MOH and USAID agree to the plan.

6. *Conduct logistics management pre-service training for laboratory assistants.*

The current class of laboratory assistants will graduate from the Malawi College of Health Sciences in December 2009. Before they graduate, the Ministry of Health Diagnostics Unit should work with the College and, with assistance from the USAID | DELIVER PROJECT, offer a module on the laboratory LMS. The curriculum in logistics management that has been developed for the pharmacy technician's program can be adapted for the revised system for laboratory supplies. This activity depends on the completion of the Laboratory Logistics System Design Workshop and the finalization of the logistics management SOPs. It should take place before November 2009.

7. *Review laboratory technician pre-service supply chain management module.*

To ensure that supply chain management is part of the pre-service training of laboratory personnel, the Ministry of Health Diagnostics Unit, with assistance from the USAID | DELIVER PROJECT, if the MOH and USAID agree, should meet with the College of Health Sciences to plan how to provide this training as a regular part of the laboratory technician program. This activity could take place before the end of the year.

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Appendix A

Contact List

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Mrs. Doris Butao, Laboratory Logistics Advisor, USAID | DELIVER Malawi

Mr. Kisimbi Thomas, Country Director, CHAI, Malawi

Mrs. Veronica Chipeta Chirwa, Deputy Director of Health, CHAI, Malawi

Mr. Evance Moyo, Assistant LMIS Associate, USAID | DELIVER Malawi

Mr. Elias Mwalabu, Assistant LMIS Associate, USAID | DELIVER Malawi

Ms. Emily Hughes, Program Management Advisor, HPN, USAID Malawi

Mr. Innocent Zungui, Diagnostics Unit, MOH

Mr. Patrick F. Zimpita, Director of Planning & Policy Development, MOH

Mrs. Mhango, ART Coordinator, NAC Program, MOH

Mr. Maxson, Procurement Unit, MOH

Mrs. Jellita Gondwe, Laboratory Technician, Community Health Sciences Unit, Public Health Reference Laboratory

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Mrs. Kundai Moyo, Laboratory Technician, Community Health Sciences Unit, Public Health Reference Laboratory

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Ms. Sara Hersey, Epidemiologist, CDC, Global AIDS Program, Malawi

Dr. Lilian Chunda, District Health Officer, Blantyre District

Dr. Kamiza, Medical Director, Deputy Dean, College of Medicine, Blantyre
Thom Land Mfunu, Laboratory Manager, Malawi Blood Transfusion Service, Blantyre
Mr. Kisombe, Pharmacy Technician, Blantyre District Store
Mr. Betilinyu Bango, Laboratory Manager, QECH, Blantyre
Nicole Carpenetti, Laboratory Manager, The Johns Hopkins Project, Malawi College of Medicine, Blantyre
Mrs. Debbie Kamwendo, UNC
Mr. Reuben Mwenda, Deputy Director, Ministry of Health, HTSS Diagnostics
Mrs. Ivy M. Zingano, Director, Ministry of Health , Central Medical Stores
Dr. Catherine Mundy, Principal Program Associate for Laboratory Services, MSH Arlington (telephone interview)

Appendix B

Laboratory Services and Supply Chain Management Assessment Workshop Participants

No.	Name	Place of Work	Title	Contacts	
				Telephone	Email
1	Alwin B Mbene	Mzuzu Central Hospital	Laboratory Manager	08 873 667	alwinmbene@yahoo.co.uk
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17	Vockly S Mkandawire	Central Medical Stores	Pharmacy Technician	08 683 625	-
18	Lynn Turner	Kamuzu Central Hospital	Lab Technologist	05 752 107	turnerlynsey@aol.com
19	Edwin Chitandale	Kamuzu Central Hospital	Lab Technician	08 688 064	-
20	Mandigore Yassin	CHSU	Lab Technologist	08 135 976	mandiyassin@gmail.com

No.	Name	Place of Work	Title	Contacts	
21	Dorica S Chirwa	Ministry of Health	Logistics Officer	08 367 402	doricas@gmail.com
22	R Mwenda	Ministry of Health	DDHTSS (D)	09 667 034	rmwenda@yahoo.com
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Appendix C

Malawi Laboratory Services and Supply Chain Management Assessment Workshop Group Questionnaire

I. ORGANIZATION

1. How are the laboratories organized? Describe all levels of the program and the relationships between the levels. Attach an organizational chart (include documents that define responsibilities and services provided at each level).

-
2. How many laboratories does the MOH/this program manage at each level?

-
3. Are all laboratory supplies managed (reporting, ordering, distribution, and storage) through one system or through multiple systems (e.g., TB, HIV/AIDS, essential medical supplies)? List all the systems currently operating in the country. Diagram supply pipelines if possible.

-
4. Are duplicate supplies (reagents and consumables) and equipment distributed through multiple programs? Describe.
-

<p>5. Is there a laboratory unit/division/committee operating that coordinates vertical laboratory activities in the country?</p>	<p><input type="checkbox"/> Yes (<i>specify</i>)_____</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Don't know/not sure</p>
<p>6. Which unit is responsible for the following logistics cycle components for laboratory supplies?</p> <p><input type="checkbox"/> Product Selection: _____</p> <p><input type="checkbox"/> Forecasting & Quantification: _____</p> <p><input type="checkbox"/> Procurement: _____</p> <p><input type="checkbox"/> Storage and Distribution: _____</p> <p><input type="checkbox"/> Laboratory Information Systems: _____</p> <p><input type="checkbox"/> Logistics Management Information Systems: _____</p> <p><input type="checkbox"/> Finance: _____</p>	
<p>7. Does the regional level have responsibility for managing laboratory services or supplies? If yes, please describe the responsibilities.</p>	<p><input type="checkbox"/> Yes (<i>specify</i>)_____</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Don't know/not sure</p>
<p>8. Does the district level have responsibility for managing laboratory services or supplies? If yes, please describe the responsibilities.</p>	<p><input type="checkbox"/> Yes (<i>specify</i>)_____</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Don't know/not sure</p>

Comments:

II. POLICY

1. Is a unit responsible for formulating national policies on laboratory services?	<input type="checkbox"/> Yes (<i>specify</i>) _____ <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
2. Is there a national policy document for laboratory services?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to Q. 6) <input type="checkbox"/> Don't know/not sure (go to Q. 6)
3. What areas are covered in this policy document (e.g., staffing by level, administrative protocol, product selection, procurement, etc.)?	
4. Does the policy document include the process of evaluating and approving reagents for disease screening tests (HIV, hepatitis, STIs)?	<input type="checkbox"/> Yes (<i>specify</i>) _____ _____ <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
5. Does the policy document include the following:	
a. Laboratory services packages by level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
b. Laboratory test techniques by level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>Please provide a copy of any policy documents.</i>	
6. Are there documented standard operating procedures (SOP) for tests performed at each level?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to Q.9) <input type="checkbox"/> Don't know/not sure (go to Q.9)
7. Does the SOP provide a list of essential supplies (reagents and consumables) by level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
8. Does the SOP provide a list of essential equipment by level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>Please provide a copy of the SOP manual.</i>	

<p>9. Are there written guidelines on safety precautions? <i>(Check all that apply.)</i></p>	<input type="checkbox"/> Infection prevention <input type="checkbox"/> Safe disposal of sharps (i.e., needles, etc.) <input type="checkbox"/> Safe disposal of biohazardous medical waste <input type="checkbox"/> Use of protective gear <input type="checkbox"/> Other <i>(specify)</i> _____ <input type="checkbox"/> None available
<p>10. Are there written guidelines for post-exposure prophylaxis for HIV?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>11. Are there written guidelines for post-exposure prophylaxis for hepatitis B?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>12. Are there written guidelines for disposal or destruction of damaged and/or expired products?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>13. Are there written national laboratory procedures for quality assurance?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>a. Are procedures for internal quality assurance included?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>b. Are procedures for external quality assurance included?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<p>14. Is the automated equipment for hematology, immunology, and chemistry standardized in the country? <i>(Specify for each.)</i></p>	

Comments:

III. FORECASTING AND PROCUREMENT

- | | |
|---|---|
| 1. Are forecasts made for needed laboratory supplies (reagents and consumables) for all programs? | <input type="checkbox"/> Yes
<input type="checkbox"/> No
<input type="checkbox"/> Don't know/not sure |
|---|---|

2. List programs where forecasts are prepared, how often each forecast is prepared, the title of the person or division responsible, and the information used to forecast laboratory supply needs.

Program	Frequency	Title of Person Responsible	Information Used

3. List programs where forecasts are not prepared.

4. Are there national procurement guidelines for:

a. Laboratory supplies (reagents and consumables)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
b. Laboratory equipment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

5. Describe the procurement process for the national level. (*Specify any differences by program and/or donor.*)

6. What is the average lead time for each program and/or donor specified above.

7. Is a person or division responsible for:

a. Procuring laboratory supplies (reagents and consumables) and equipment? *(Specify by person or unit by program.)*

b. Monitoring the procurement process? *(Specify by person or unit by program.)*

c. Coordinating procurements across programs? *(specify person or unit)*

8. Who is currently responsible for procuring laboratory supplies for each program?

9. In general, are adequate amounts of all laboratory supplies received in an appropriate timeframe? *(Specify any program differences.)*

- Yes
 - No
 - Don't know/not sure
-

10. Is pipeline status regularly monitored so that procurement decisions can be made and actions can be taken in time to avoid stockouts?
Comments:

- Yes
 - No
 - Don't know/not sure
-

11. What is done to monitor/manage the coordination of procurement plans among suppliers/donors?

Comments:

IV. FINANCING

1. What are the sources of funds for laboratory services, including infrastructure, supplies (reagents and consumables), and equipment. What percentage of total funding is contributed by each source:	
a. Government?	_____ % of total funding
b. User's fees/cost recovery?	_____ % of total funding
c. Donors (list by donor)?	_____ % of total funding
Donor 1: _____	_____ % of total funding
Donor 2: _____	_____ % of total funding
Donor 3: _____	_____ % of total funding
d. Local budget (region, district)	_____ % of total funding
e. Other? (specify) _____	_____ % of total funding
2. Are funds sufficient to cover the needed supplies and equipment? If not, what is the gap?	<input type="checkbox"/> Yes <input type="checkbox"/> No (specify amount) _____ <input type="checkbox"/> Don't know/not sure
3. Does a committee or division coordinate the different sources of funds?	<input type="checkbox"/> Yes (specify) _____ <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. How are financial resources allocated to laboratories? Describe all levels of the program and the relationship between the levels. Attach a financial organizational chart. (Specify what financial decisions are made at each level.)	
5. Is there a separate budgetary line item for laboratory services?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
6. Is there a separate budgetary line item for laboratory supplies (reagents and consumables)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
7. Is there a separate budgetary line item for laboratory equipment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

8. Is there a separate budgetary line item for logistics management (storage, distribution, etc.) of laboratory supplies and equipment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
---	---

Comments:

V. STORAGE AND DISTRIBUTION

1. Is there a central level store for laboratory supplies and equipment? *(Specify by program.)*

2. Is the existing storage capacity adequate to handle the current quantities of laboratory supplies at the national level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
3. Is the existing cold storage capacity adequate to handle the current quantities of cold chain reagents at the national level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. Is the existing storage capacity adequate to handle the current quantities of laboratory products at regional and district levels?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
5. Is the existing storage capacity (including cold chain) adequate to handle the expanded program goals for the next three years?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

If no, specify what is inadequate.

6. Is there an established distribution system for laboratory supplies and equipment for all levels?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
--	---

7. Describe the current system for distributing laboratory supplies (reagents and consumables) and equipment to all levels:

8. ***Are a sufficient number of functioning vehicles available to meet the distribution schedule at the following levels:***

<i>a. Central?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>b. Regional?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>c. District?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>d. Health centers?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

9. ***Are there vehicles equipped to handle cold chain materials?***

<i>a. Central?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>b. Regional?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>c. District?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
<i>d. Health centers?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

VI. INVENTORY CONTROL SYSTEM

1. Do laboratories at all levels have a set minimum stock level for reagents and consumables at which orders need to be placed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
2. Do laboratories at all levels have a set maximum stock level for reagents and consumables above which the inventory level should not go?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
3. Who determines how much to order?	<input type="checkbox"/> Laboratory <input type="checkbox"/> Higher-level authorities <input type="checkbox"/> Other (specify): _____

4. What are the order intervals between the different levels in the system?

5. Are stock balances at all levels monitored regularly so that procurement decisions and actions can be made on time to avoid stockouts? (Specify any program differences.)

6. Does the higher/intermediate level need to reconstitute some stains so they are ready to use at the lower levels?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
--	---

If yes to question 6, specify why:

Lack of technical expertise

Lack of weighing balances

Other (specify) _____

Comments:

VII. LABORATORY SERVICES AND LOGISTICS MANAGEMENT INFORMATION SYSTEM(S)

1. Is there a laboratory services management information system?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
2. Are standard national forms available and used to collect and report laboratory services management information?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
3. Do the forms include the following data:	
a. Service statistics? (specify) _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
b. Logistics data? (specify) _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
c. Laboratory test requested and/or conducted? _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
d. Other data? (specify) _____ _____ _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. Is any other system used to collect any of the above data items?	<input type="checkbox"/> Yes (Specify type of data and system to collect it.) _____ <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
5. Is there a reporting system for data collected?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to Q.8) <input type="checkbox"/> Don't know/not sure (go to Q.8)
6. Describe the reporting system in detail, including the reporting level, the flow of information, the units that receive and process information, the information reported, and the reporting frequency (monthly, bimonthly, quarterly).	

7. Is this system integrated with the MOH health information system?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
8. Are the following data items for laboratory supplies (reagents and consumables) included in reports?	
Stock on hand?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
Consumption (amount used)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
Losses and adjustments (stock damaged, lost, transferred, etc.)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
9. Approximately what percentage of districts/laboratories sends these reports each reporting period, according to the schedule?	_____ % of districts _____ % of laboratories <input type="checkbox"/> Don't know/not sure

10. ***How do managers monitor reporting rates and follow up to obtain missing reports?***

11. What decisions are based on information received in reports?	
<input type="checkbox"/> Forecasting/quantification <input type="checkbox"/> Procurement <input type="checkbox"/> Transport/delivery	<input type="checkbox"/> Monitoring of stock balances <input type="checkbox"/> Resupply quantities <input type="checkbox"/> Other (specify) _____
12. <i>Is the information system used to monitor and evaluate the program's performance?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

VIII. STAFFING

1. Are there policies that specify the rank of laboratory personnel by level or type of facility? If yes, please specify the requirement.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Are there sufficient personnel to provide laboratory services and manage laboratory supplies and equipment at each of these levels? Please comment.	
a. National laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Regional laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. District laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Health center laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. How frequently do laboratory personnel receive in-service training? (on-the-job, classroom, etc.)	
a. National laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
b. Regional laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
c. District laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
d. Health center laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
4. What have been the topics of the most recent training activities? Who received this training?	
5. Are there other staff development activities for laboratory staff? If so, please describe.	

Comments:

IX. SUPERVISION

1. Is scheduled laboratory supervision available at the following levels:

e. National laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Regional laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
g. District laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No
h. Health center laboratories?	<input type="checkbox"/> Yes <input type="checkbox"/> No

2. How often are supervisory visits conducted?

e. National laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
f. Regional laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
g. District laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____
h. Health center laboratories?	<input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Annually <input type="checkbox"/> Other (<i>specify</i>)_____

3. What activities are routinely done during the supervisory visit? Is there a standard supervision checklist or protocol? If yes, please provide a copy.

4. Is there a mechanism to monitor the performance of the supply chain for laboratory reagents and consumables? If so, please describe.

Comments:

X. GENERAL QUESTIONS

- 1. What are the major areas of concern for laboratory services at the national level? At intermediate and service levels?**

-
- 2. How can these areas of concern be addressed nationally? Locally?**
-

Appendix D

Schedule of Field Visits

LIST OF HEALTH FACILITIES FOR ATLAS							
Region	District	Selected Facility	Members	Route	Day	Date	
South	Blantyre	Bangwe HC	Barbara	1	1	2/2/2009	
		Chilomoni HC			1	2/2/2009	
		MBTS			2	3/2/2009	
		College of Medicine			2	3/2/2009	
		Blantyre District Store			3	4/2/2009	
		John Hopkins			3	4/2/2009	
		Lirangwe HC			4	5/2/2009	
		Mpemba HC			4	5/2/2009	
		St Vincent HC			5	6/2/2009	
		Nsanje	Kalemba HC			6	9/2/2009
			Trinity Fatima			6	9/2/2009
South	Phalombe	Nambazo HC	Doris	2	1	2/2/2009	
		Phalombe Mission			1	2/2/2009	
	Zomba	Magomero HC			2	3/2/2009	
		Zomba Prison Disp			2	3/2/2009	
		Hparker Sharp (Domasi Mission)			3	4/2/2009	
		Namasalima HC			3	4/2/2009	
		St Lukes Hosp			4	5/2/2009	
	Machinga	Mposa HC			4	5/2/2009	
		Nayinunje HC			5	6/2/2009	
		Ntaja HC			5	6/2/2009	

LIST OF HEALTH FACILITIES FOR ATLAS						
Region	District	Selected Facility	Members	Route	Day	Date
	Mangochi	Mkope HC			6	9/2/2009
		Mulibwanji Hosp[6	9/2/2009
		Mangochi DH			7	10/2/2009
South	Balaka	Chilipa HC	Patrick	3	1	2/2/2009
		Mbera HC			1	2/2/2009
Centre	Lilongwe	Chileka HC			2	3/2/2009
		St Gabriel Hosp			2	3/2/2009
		Kamuzu Central Hosp			3	4/2/2009
		Community Health Sciences Unit			3	5/2/2009
		UNC			4	5/2/2009
		Lilongwe Bottom Hosp			4	6/2/2009
		Nathenje HC			5	6/2/2009
		Dzenza HC			5	6/2/2009
	Dedza	Mua Hosp			6	9/2/2009
		Mikondi Disp			6	9/2/2009
Centre	Nkhotakota	Matiki HC	Manondo	4	1	2/2/2009
		St Anne's Hosp			1	2/2/2009
North	Mzimba	Ekwendeni Hosp			2	3/2/2009
		Mzuzu Central Hosp			2	3/2/2009
		Mzambazi Hospital			3	4/2/2009
	Rumphi	Rumphi DH			3	4/2/2009
	Mzimba	Kalikumbi			4	5/2/2009
	Rumphi	DGM Livinstonia			5	6/2/2009
	Karonga	Iponga HC			6	9/2/2009
		Nyungwe HC			6	9/2/2009

Appendix E

Malawi Laboratory Services and Supply Chain Assessment Facility Level Questionnaire

GENERAL INFORMATION

1. Name of interviewer:	
2. Date:	
3. Name, qualification, and title of person being interviewed:	
4. Name of facility:	
5. Region:	
6. District:	
7. Level of the facility:	<input type="checkbox"/> Central Hospital <input type="checkbox"/> Health Center <input type="checkbox"/> District/Community Hospital
8. Type of facility:	<input type="checkbox"/> Government <input type="checkbox"/> CHAM <input type="checkbox"/> Other (specify) _____
9. Physical and postal address:	
10. Telephone:	
11. General notes:	

I. NATIONAL GUIDELINES AND PROTOCOLS

1. Are national guidelines and protocols for laboratory services available in this laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
2. Are written guidelines on safety precautions available in this laboratory? <i>(Check all that apply.)</i>	<input type="checkbox"/> Infection prevention <input type="checkbox"/> Safe disposal of sharps (i.e., needles, etc.) <input type="checkbox"/> Safe disposal of biohazardous medical waste <input type="checkbox"/> Use of protective gear <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> None available
3. Are written guidelines for post-exposure prophylaxis for HIV available in this laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. Are written guidelines for post-exposure prophylaxis for hepatitis B available in this laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
5. Are there written guidelines for disposal or destruction of damaged and/or expired products?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
6. Are the national standard operating procedures (SOPs) available in this laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

II. LABORATORY PERSONNEL**1. Current working staff by category:**

	Number	Number who have attended refresher laboratory-related training course or workshop in the past 12 months
Pathologist		
Laboratory Scientific Officer		
Laboratory Technologist		
Laboratory Technician		
Laboratory Assistants		
Laboratory Aide		
Microscopists		
Laboratory Attendants		
2. When did this laboratory receive the last supervisory visit?		<input type="checkbox"/> Never <input type="checkbox"/> Within the current month <input type="checkbox"/> Within the last 3 months <input type="checkbox"/> Within the last 6 months <input type="checkbox"/> More than 6 months ago
3. Did the supervision focus on one program or multiple integrated programs?		<input type="checkbox"/> One <input type="checkbox"/> Multiple <input type="checkbox"/> Don't know/not sure
4. What programs were covered during the supervision? (Check all that apply.)		<input type="checkbox"/> Malaria <input type="checkbox"/> STI <input type="checkbox"/> HIV/AIDS <input type="checkbox"/> TB <input type="checkbox"/> None <input type="checkbox"/> Other (specify)_____

<p>5. What was done during the supervisory visit? (Check all that apply)</p>	<input type="checkbox"/> Infrastructure inspected <input type="checkbox"/> Equipment inspected <input type="checkbox"/> Reinforcement of universal safety precautions <input type="checkbox"/> Record keeping for performed tests checked <input type="checkbox"/> Inventory of supplies checked <input type="checkbox"/> Maintenance records checked <input type="checkbox"/> Cold chain records checked <input type="checkbox"/> Stockcards, stock ledgers, and/or reports checked <input type="checkbox"/> Quality control <input type="checkbox"/> On-the-job training/coaching <input type="checkbox"/> Feedback to/from staff <input type="checkbox"/> None of the above <input type="checkbox"/> Other (specify) _____
--	---

Comments:

III. LABORATORY TESTING SERVICES

In the second column, check the laboratory tests that are performed by the laboratory. If any test is done using non-standard techniques or if the test is not done, select the code from the list below and write the code number in the third column.

1 = Not trained in the technique
 2 = Equipment not available
 3 = Reagent not available

4 = No adequate staff to perform the technique
 5 = Equipment not working
 6 = Other (specify)

I. Tests Performed at Health Center Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Hemoglobin estimation	<input type="checkbox"/> Cyanmethemoglobin <input type="checkbox"/> Azidemethaemoglobin.	
<input type="checkbox"/> Platelet count	<input type="checkbox"/> Manual hemocytometer	
<input type="checkbox"/> Red blood cell count	<input type="checkbox"/> Manual hemocytometer	
<input type="checkbox"/> Reticulocyte count	<input type="checkbox"/> New methylene blue or brilliant blue stain	
<input type="checkbox"/> Total white cell count	<input type="checkbox"/> Manual, hemocytometer using Turk's fluid	

I. Tests Performed at Health Center Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Differential white cell count	<input type="checkbox"/> Manual, using stained thin film	
<input type="checkbox"/> Blood grouping	<input type="checkbox"/> Tube method	
<input type="checkbox"/> Rhesus typing	<input type="checkbox"/> Tube	
<input type="checkbox"/> Direct Coombs Test	<input type="checkbox"/> AHG	
<input type="checkbox"/> Indirect Coombs Test	<input type="checkbox"/> AHG	
<input type="checkbox"/> HIV screening	<input type="checkbox"/> Rapid screening kits	
<input type="checkbox"/> Blood slide for haemoparasites	<input type="checkbox"/> Field stain	
<input type="checkbox"/> Syphilis screening	<input type="checkbox"/> RPR/VDRL carbon antigen <input type="checkbox"/> Rapid	
<input type="checkbox"/> Sickle cell screen	<input type="checkbox"/> Sodium metabisulphite	
<input type="checkbox"/> Stool microscopy for parasites	<input type="checkbox"/> Direct saline, iodine	
<input type="checkbox"/> Sputum for AFB	<input type="checkbox"/> ZN stain <input type="checkbox"/> Auramine O	
<input type="checkbox"/> Skin slit for AFB	<input type="checkbox"/> ZN stain	
<input type="checkbox"/> Urine sediment microscopy	<input type="checkbox"/> Direct microscopy	
<input type="checkbox"/> Urine protein, sugar	<input type="checkbox"/> Uristix	
<input type="checkbox"/> Genito-urinary tract specimens	<input type="checkbox"/> Wet prep/ Gram stain/ KOH	
<input type="checkbox"/> Pus swabs	<input type="checkbox"/> Gram stain	
<input type="checkbox"/> Bubo aspirate (plague)	<input type="checkbox"/> Wayson staining	
<input type="checkbox"/> Crypto LA test	<input type="checkbox"/> Agglutination	
<input type="checkbox"/> Cerebrospinal fluid microscopy	<input type="checkbox"/> Gram/Leishman/Turk's fluid/India ink	
<input type="checkbox"/> Cerebrospinal fluid chemistry	<input type="checkbox"/> Turbidimetric	
<input type="checkbox"/> Pregnancy test	<input type="checkbox"/> Immobilized anti HCG antibody (strip)	
<input type="checkbox"/> Sperm count	<input type="checkbox"/> Manual counting chamber	
2. Are there documented SOPs for the tests performed at this facility?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

I. Tests Performed at Health Center Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
3. Do the testing procedures at this laboratory follow the national SOPs?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

4. Tests Performed at District/Community Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Hemoglobin estimation	<input type="checkbox"/> Cyanmethemoglobin <input type="checkbox"/> Azidemethaemoglobin.	
<input type="checkbox"/> Platelet count	<input type="checkbox"/> Manual hemocytometer	
<input type="checkbox"/> Red blood cell count	<input type="checkbox"/> Manual hemocytometer	
<input type="checkbox"/> Reticulocyte count	<input type="checkbox"/> New methylene blue or brilliant blue stain	
<input type="checkbox"/> Total white cell count	<input type="checkbox"/> Manual, hemocytometer using Turk's fluid	
<input type="checkbox"/> Differential white cell count	<input type="checkbox"/> Manual, using stained thin film	
<input type="checkbox"/> Complete Blood Count (CBC)	<input type="checkbox"/> Hematology analyzer	
<input type="checkbox"/> CD4/CD8 count	<input type="checkbox"/> Flow cytometer <input type="checkbox"/> Non-cytofluorimetric <input type="checkbox"/> Manual	
<input type="checkbox"/> Viral load	<input type="checkbox"/> HIV RNA <input type="checkbox"/> Real-time PCR <input type="checkbox"/> Heat-dissociated p24 antigen <input type="checkbox"/> Cavid RT	
<input type="checkbox"/> PCR	<input type="checkbox"/> Roche	
<input type="checkbox"/> Sickle cell screening test	<input type="checkbox"/> Sodium metabisulphite	
<input type="checkbox"/> Blood slide examination for parasites	<input type="checkbox"/> Manual microscopy (field) <input type="checkbox"/> Concentration	
<input type="checkbox"/> Film comment	<input type="checkbox"/> Manual microscopy <input type="checkbox"/> Field stains, Giemsa stain or Lieshman	
<input type="checkbox"/> Stool microscopy	<input type="checkbox"/> Direct saline/ iodine concentration	
<input type="checkbox"/> HIV screening	<input type="checkbox"/> Rapid screening kits <input type="checkbox"/> ELISA	
<input type="checkbox"/> Hb types	<input type="checkbox"/> Electrophoresis	
<input type="checkbox"/> Serum proteins	<input type="checkbox"/> Electrophoresis	
<input type="checkbox"/> Hepatitis B screening	<input type="checkbox"/> Rapid <input type="checkbox"/> ELISA	
<input type="checkbox"/> Syphilis screening	<input type="checkbox"/> RPR/VDRL carbon antigen	

4. Tests Performed at District/Community Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Measles	<input type="checkbox"/> ELISA	
<input type="checkbox"/> Renal Function	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Liver Function (LFT)	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Blood glucose	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Examination of CSF for yeast	<input type="checkbox"/> Negative staining-India ink	
<input type="checkbox"/> Examination of CSF, pus, deposit, etc., micro-organisms	<input type="checkbox"/> Gram stain/ Leishman/Turks'fluid/ India ink	
<input type="checkbox"/> Cerebrospinal fluid chemistry	<input type="checkbox"/> Turbidimetric <input type="checkbox"/> Enzymatic	
<input type="checkbox"/> Crypto LA test	<input type="checkbox"/> Agglutination	
<input type="checkbox"/> Culture	<input type="checkbox"/> Aerobic <input type="checkbox"/> Anaerobic <input type="checkbox"/> CO ₂	
<input type="checkbox"/> Drug sensitivity	<input type="checkbox"/> Disc diffusion	
<input type="checkbox"/> Microscopy for plague	<input type="checkbox"/> Wayson staining	
<input type="checkbox"/> Processing biopsy	<input type="checkbox"/> Haematoxylin and eosin	
<input type="checkbox"/> Pregnancy test	<input type="checkbox"/> Immobilized anti HCG antibody (strip)	
<input type="checkbox"/> Semen analysis	<input type="checkbox"/> Microscopy	
<input type="checkbox"/> Cytology	<input type="checkbox"/> Microscopy <input type="checkbox"/> Pulp smear	
<input type="checkbox"/> Sputum for TB	<input type="checkbox"/> ZN stain <input type="checkbox"/> Auramine O	
<input type="checkbox"/> Urine sediment microscopy	<input type="checkbox"/> Direct microscopy	
<input type="checkbox"/> Urine chemistry	<input type="checkbox"/> Uristix	
<input type="checkbox"/> Genito-urinary track specimens	<input type="checkbox"/> Wet prep <input type="checkbox"/> Gram <input type="checkbox"/> KOH	
<input type="checkbox"/> Blood group, type and cross matching	<input type="checkbox"/> Tube method	
<input type="checkbox"/> Direct Coombs Test	<input type="checkbox"/> AHG	

4. Tests Performed at District/Community Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Indirect Coombs Test	<input type="checkbox"/> AHG	
<input type="checkbox"/> Skin snip for microfilaria	<input type="checkbox"/> Saline direct	
<input type="checkbox"/> Examination for fungi	<input type="checkbox"/> KOH	
<input type="checkbox"/> Confirmatory test for syphilis	<input type="checkbox"/> TPHA	
5. Are there documented SOPs for the tests performed at this facility? <input type="checkbox"/>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
6. Do the testing procedures at this laboratory follow the national SOPs?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

7. Tests Performed at the Central Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Complete Blood Count (CBC)	<input type="checkbox"/> Hematology analyzer	
<input type="checkbox"/> CD4/CD8 count	<input type="checkbox"/> Flow cytometer <input type="checkbox"/> Non-cytofluorimetric <input type="checkbox"/> Manual	
<input type="checkbox"/> Viral load	<input type="checkbox"/> HIV RNA <input type="checkbox"/> Real-time PCR <input type="checkbox"/> Heat-dissociated p24 antigen <input type="checkbox"/> Cavid RT	
<input type="checkbox"/> PCR	<input type="checkbox"/> Roche	
<input type="checkbox"/> Sickle cell screening test	<input type="checkbox"/> Sodium metabisulphite	
<input type="checkbox"/> Blood slide examination for parasites	<input type="checkbox"/> Manual microscopy (field)	

7. Tests Performed at the Central Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
	<input type="checkbox"/> Concentration	
<input type="checkbox"/> Film comment	<input type="checkbox"/> Manual microscopy <input type="checkbox"/> Field stains, Giemsa stain or Leshman	
<input type="checkbox"/> Stool microscopy	<input type="checkbox"/> Direct saline/ iodine concentration	
<input type="checkbox"/> HIV screening	<input type="checkbox"/> Rapid screening kits <input type="checkbox"/> ELISA	
<input type="checkbox"/> Hb types	<input type="checkbox"/> Electrophoresis	
<input type="checkbox"/> Serum proteins	<input type="checkbox"/> Electrophoresis	
<input type="checkbox"/> Hepatitis B screening	<input type="checkbox"/> Rapid <input type="checkbox"/> ELISA	
<input type="checkbox"/> Syphilis screening	<input type="checkbox"/> RPR/VDRL carbon antigen	
<input type="checkbox"/> Measles	<input type="checkbox"/> ELISA	
<input type="checkbox"/> Renal Function	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Liver Function (LFT)	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Blood glucose	<input type="checkbox"/> Chemistry auto-analyzer (or manual photometer)	
<input type="checkbox"/> Examination of CSF for yeast	<input type="checkbox"/> Negative staining-India ink	
<input type="checkbox"/> Examination of CSF, pus, deposit, etc., micro-organisms	<input type="checkbox"/> Gram stain/ Leishman/Turks'fluid/ India ink	
<input type="checkbox"/> Cerebrospinal fluid chemistry	<input type="checkbox"/> Turbidimetric <input type="checkbox"/> Enzymatic	
<input type="checkbox"/> Crypto LA test	<input type="checkbox"/> Agglutination	
<input type="checkbox"/> Culture	<input type="checkbox"/> Aerobic <input type="checkbox"/> Anaerobic <input type="checkbox"/> CO ₂	
<input type="checkbox"/> Drug sensitivity	<input type="checkbox"/> Disc diffusion	
<input type="checkbox"/> Microscopy for plague	<input type="checkbox"/> Wayson staining	

7. Tests Performed at the Central Hospital Laboratory

Laboratory Test: Check if performed by laboratory	Standard Technique: Check if performed by laboratory	Record reason(s) for not using the standard technique or for not doing the test
<input type="checkbox"/> Processing biopsy	<input type="checkbox"/> Haematoxylin and eosin	
<input type="checkbox"/> Pregnancy test	<input type="checkbox"/> Immobilized anti HCG antibody (strip)	
<input type="checkbox"/> Semen analysis	<input type="checkbox"/> Microscopy	
<input type="checkbox"/> Cytology	<input type="checkbox"/> Microscopy <input type="checkbox"/> Pulp smear	
<input type="checkbox"/> Sputum for TB	<input type="checkbox"/> ZN stain <input type="checkbox"/> Auramine O	
<input type="checkbox"/> Urine sediment microscopy	<input type="checkbox"/> Direct microscopy	
<input type="checkbox"/> Urine chemistry	<input type="checkbox"/> Uristix	
<input type="checkbox"/> Genito-urinary track specimens	<input type="checkbox"/> Wet prep <input type="checkbox"/> Gram <input type="checkbox"/> KOH	
<input type="checkbox"/> Blood group, type and cross matching	<input type="checkbox"/> Tube method	
<input type="checkbox"/> Direct Coombs Test	<input type="checkbox"/> AHG	
<input type="checkbox"/> Indirect Coombs Test	<input type="checkbox"/> AHG	
<input type="checkbox"/> Skin snip for microfilaria	<input type="checkbox"/> Saline direct	
<input type="checkbox"/> Examination for fungi	<input type="checkbox"/> KOH	
<input type="checkbox"/> Confirmatory test for syphilis	<input type="checkbox"/> TPHA	
8. Are there documented SOPs for the tests performed at this facility?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
9. Do the testing procedures at this laboratory follow the national SOPs?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

IV. QUALITY ASSURANCE TESTS

1. Are there written quality assurance policies and procedures available in this laboratory?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
2. Does the laboratory undertake the following internal quality control procedures:	
a. Calibrate equipment, as indicated. <i>(If any machines are being calibrated as required, tick Yes. If some are not, make note in comments section.)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
b. Check each batch of reagents using known positive and negative specimens?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
c. Include commercially prepared controls whenever a batch of tests is run?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
d. Include in-house prepared controls whenever a batch of tests is run?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
e. Countercheck test reports with another colleague before dispatch?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
3. Does the laboratory participate in any external quality assurance scheme?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. If yes, which scheme? _____ How often in a year? _____	
5. What percentage of supplies is needed for quality assurance?	

Comments:

V. EQUIPMENT AVAILABILITY AND MAINTENANCE

Equipment List	Central Hospital		District/Community Hospital		Heath Center	
	Number available	Number functioning	Number available	Number functioning	Number available	Number functioning
a) Anaerobic jars						
b) Autoclave (fixed)						
c) Portable autoclave (kerosene or charcoal)						
d) Portable autoclave (electric)						
e) Microtome disposable blade						
f) Automatic micro pipettes						
g) Automatic tissue processor						
h) Bunsen burner						
i) Chemistry auto analyzer						
j) Spectrophotometer/ colorimeter						
k) Deep freezer (-20° C)						
l) Deep freezer (-70° C)						
m) Desktop computer and printer (office)						
n) Differential counter						
o) Electric digital balance						
p) Manual weighing balance						
q) Electrophoresis system						
r) ELISA reader						
s) ELISA washer						
t) Flow cytometer CD4						
u) Viral load instrument						
v) Hematology auto-analyzer						
w) Incubator (dry) ordinary						
x) Microtome						
y) pH meter						
z) Pipette washer						

Equipment List	Central Hospital		District/Community Hospital		Heath Center	
	Number available	Number functioning	Number available	Number functioning	Number available	Number functioning
aa) Tally counter						
bb) Tissue embedder						
cc) Vacuum pump						
dd) Voltage stabilizer						
ee) Kerosene stove						
ff) Binocular microscope (daylight)						
gg) Binocular-powered microscope						
hh) Blood bank refrigerator						
ii) Laboratory refrigerator						
jj) Hemaglobinometer						
kk) Haemacue						
ll) Bench top electric centrifuge						
mm) Haematocrit centrifuge						
nn) Blood mixer						
oo) Class II biosafety hood						
pp) Haemocytometer (Neubauer)						
qq) Hot air oven						
rr) Steam sterilizer (pressure cooker)						
ss) Manual centrifuge						
tt) Spirit lamp						
uu) Colorimeter (mains/12V)						
vv) VDRL shaker						
ww) Water still						
xx) Water bath						
yy) Water filter						
zz) Thermometer (-20° C)						
aaa) Wwire loop with holder						

1. Is the equipment in this laboratory standardized (similar to the equipment found in the same level laboratories), as recommended by the central level?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
---	---

2. List the type and brand of equipment specifically used for:

- o Automated chemistry: _____
- o Automated hematology: _____
- o Automated immunology: _____

Comments:

Maintenance

1. Do you have a maintenance schedule for the equipment, other than daily cleaning?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
---	---

2. Do you have a maintenance record?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
--------------------------------------	---

3. In case of a breakdown, how are repairs handled?

4. Do you routinely maintain records of refrigerator/freezer temperatures?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
--	---

Comments:

VI. LABORATORY SUPPLIES LOGISTICS

A. INVENTORY MANAGEMENT

1. Who in this facility is responsible for the management of laboratory supplies?	<input type="checkbox"/> Laboratory Technologist <input type="checkbox"/> Laboratory Technician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Store Manager <input type="checkbox"/> Other (specify): _____
2. Does the laboratory have a set minimum stock level for reagents and consumables at which orders need to be placed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
3. Does the laboratory have a set maximum stock level for reagents and consumables above which the inventory level should not go?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure
4. Who determines how much to order for the facility?	<input type="checkbox"/> Laboratory <input type="checkbox"/> Pharmacy <input type="checkbox"/> Other (specify) _____
<i>If the general store (or pharmacy) of a hospital orders reagents, ask the hospital store questions 5-12.</i>	
5. Which data elements do you use to calculate how much to order? DO NOT READ LIST. PROMPT "ANYTHING ELSE?" (Check all that apply.)	<input type="checkbox"/> Average monthly consumption <input type="checkbox"/> Number of tests performed <input type="checkbox"/> Stock remaining in the laboratory <input type="checkbox"/> Set maximum stock level for reagents <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Don't know/not sure
6. Where does this facility send its order for resupply? (Check all that apply.)	<input type="checkbox"/> National medical stores <input type="checkbox"/> Regional medical stores <input type="checkbox"/> District medical stores <input type="checkbox"/> Private supplier/Open market <input type="checkbox"/> Other (specify) _____

7. How often do you place orders?	<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Every 6 months <input type="checkbox"/> Other (specify) _____
8. How many emergency orders have you placed in the last year?	Number: _____
9. Under normal circumstances, how long does it take from the time you place an order to the time the supplies are available for use?	_____ days <input type="checkbox"/> Don't know/not sure
10. In the last year, did you have an order that took longer than usual to fill?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to Q.13) <input type="checkbox"/> Don't know/not sure (go to Q.13)

11. For this order, how long did it take you to receive your supplies from the time of order?

12. What were the reasons for the delay in receiving the supplies?

13. How often is a physical inventory of laboratory reagents and consumable supplies conducted?	Every _____ months
14. In your current system, do some stains need to be reconstituted at the regional or district level as ready to use for health centers?	<input type="checkbox"/> Yes (specify below) <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

If yes to question 14, specify why:

- Lack of technical expertise
 - Lack of weighing balances
 - Other: (specify) _____
- _____
- _____

Comments:

B. LOGISTICS MANAGEMENT INFORMATION SYSTEM

<p>1. What type of forms does the laboratory use to keep track of reagents and consumables in stock? DO NOT READ LIST. PROMPT "ANYTHING ELSE?" (Check all that apply and verify.)</p>	<p><input type="checkbox"/> Stockcards <input type="checkbox"/> Ledgers <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> None</p>
<p>2. How is the information from the forms used? DO NOT READ LIST. PROMPT "ANYTHING ELSE?" (Check all that apply.)</p>	<p><input type="checkbox"/> Calculate use of supplies <input type="checkbox"/> Calculate order quantities <input type="checkbox"/> Report on use to the higher levels <input type="checkbox"/> Other (specify) _____ <input type="checkbox"/> Not used</p>
<p>3. What type of forms does the laboratory use for ordering and receiving supplies? DO NOT READ LIST. PROMPT "ANYTHING ELSE?" (Check all that apply and verify.)</p>	<p><input type="checkbox"/> Order book <input type="checkbox"/> Delivery note <input type="checkbox"/> Requisition/Issue voucher <input type="checkbox"/> Other (specify) _____</p>
<p>4. Does the laboratory have standard printed test requests and reporting forms?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure</p>
<p>5. If no, what supports or forms are used for lab test requests and test results recording? (specify)</p>	
<p>6. Does this laboratory send reports on the following: (Read list and check all positive responses.)</p>	<p><input type="checkbox"/> Stock status <input type="checkbox"/> Lab tests performed <input type="checkbox"/> Surveillance reports <input type="checkbox"/> Other (specify) _____</p>
<p>7. How often are these reports sent?</p>	<p><input type="checkbox"/> Monthly <input type="checkbox"/> Bimonthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other (specify) _____</p>

8. Where are these reports sent? (Read list and check all positive responses.)	<input type="checkbox"/> To the central laboratory coordinator (HTSS) <input type="checkbox"/> To the regional/zonal laboratory coordinator <input type="checkbox"/> To the district laboratory focal person <input type="checkbox"/> Other (specify) _____
9. Is the logistics management information system integrated with the laboratory management information system?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure

Comments:

C. TRANSPORT

1. Do all of your laboratory supplies come from the same source? Is the distribution of laboratory supplies integrated across all programs or is it vertical?	<input type="checkbox"/> Fully integrated <input type="checkbox"/> Partly integrated <input type="checkbox"/> Vertical (go to Q.2)
a. Explain which program's products (e.g., HIV/AIDS, TB) are distributed together and which are distributed separately.	
2. How do lab supplies usually arrive at the laboratory? DO NOT READ LIST. Specify any differences for vertical programs (e.g., HIV/AIDS, TB).	<input type="checkbox"/> Laboratory picks them up <input type="checkbox"/> Higher level (e.g., district, regional) delivers them <input type="checkbox"/> National medical store delivers them <input type="checkbox"/> Private supplier delivers them <input type="checkbox"/> Other (specify) _____
3. Does the facility have a vehicle to pick up the supplies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Does the facility have the funds for fuel to pick up the supplies?	<input type="checkbox"/> Yes <input type="checkbox"/> No

5. *What are the major problems you have experienced related to transport in the last year?*

- a. _____
- b. _____
- c. _____

Comments:

D. AVAILABILITY OF SAMPLE REAGENTS AND INFECTION CONTROL COMMODITIES

SAMPLE REAGENTS	STOCKOUT ON DAY OF THE VISIT (YES/NO)	STOCKOUT IN THE LAST 30 DAYS (YES/NO)	TICK IF NEVER STOCKED
Field Stain A			
Field Stain B			
Gram Stain Reagent, Crystal Violet			
Gram Stain Reagent, Iodine			
Gram Stain Reagent, Alcohol			
Gram Stain Reagent, Safranin			
Zn – Carbol Fuchsin			
Zn – Methylene Blue Stain			
Zn – Acid Alcohol			
Zn – Phenol Crystals			
a) Sodium Chloride			
b) Rpr Antigen			
c) Immersion Oil			
d) Uristix			
e) Methanol			
f) Xylene			
g) Hiv Test Kit (Determine)			
h) Hiv Test Kit (Uni-Goldtm)			
i) Blood Group/Type Antisera			
j) Acetic Acid, Glacial			
k) Formalin, Solution			
l) Ether			

SAMPLE REAGENTS	STOCKOUT ON DAY OF THE VISIT (YES/NO)	STOCKOUT IN THE LAST 30 DAYS (YES/NO)	TICK IF NEVER STOCKED
m) India Ink			
n) Potassium Hydroxide, Reagent			
o) Pregnancy Test Kit			
p) Viral Load Reagents			
q) Cd4 Test Reagents			
r) Rpr/Vdrl Kit			
s) Hepatitis Screening Kit			
t) Chemistry Autoanalyser Reagent Kit, Glucose			
u) Chemistry Autoanalyser Reagent Kit, Creatine			
v) Chemistry Autoanalyser Reagent Kit, Got (Ast)			
w) Hematology Autoanalyser Reagent Kit			
x) Culture Media			
A. Blood Agar			
B. Mcconkey			
C. Muller Hinton			
D. Powder Hb			
E. Tsi (Triple Sugar Iron Agar)			
y) Oxidase Reagents			
z) Sensitivity Antibiotic Discs			
aa) Distilled/Deionized Water			
bb) Disinfectant			

What laboratory supplies have been most frequently stocked out and for the longest period of time during the past year? List up to five supplies, including frequency and duration.

Infection Control Commodities

<i>Commodities</i>	<i>Unit</i>	<i>Average Quarterly Use</i>	<i>Quantities Available</i>
a) Hand soap	1 bar of soap		
b) Unused sharps boxes	1 box		
c) Gloves	1 pair		
d) Waster receptacle liners	1 liner		
e) Waste receptacle	1 receptacle		
f) Goggles	1 pair of goggles		
g) Mask	1 mask		
h) Apron (plastic)	1 apron		
i) Laboratory coats	1 coat		

Does the mechanism for obtaining these supplies differ from other laboratory supplies? (*specify*)

Comments:

E. STORAGE

1. Where are majority of laboratory supplies stored?

- Laboratory
- Laboratory Storeroom
- Pharmacy Storeroom
- Other (specify): _____

Inspect the storage area of the laboratory for questions 2–6. Write the relevant comments in the space provided.

Storage Conditions	Yes/No/ DK	Comments
2. Written guidelines for storing laboratory supplies according to their specifications (flammable, caustic, etc.) exist. (<i>Are Material Safety Data Sheets available?</i>)		

3. Flammable and hazardous chemicals are stored in specialized storage areas.		
4. Reagents are stored according to the first-to-expire, first-out practice in the laboratory.		
<i>For questions 5–7, if no damaged or expired products are evident, ask the stock keeper to explain the accepted practice for such products. Verify the practice to the extent possible.</i>		
5. The laboratory makes it a practice to separate damaged and/or expired supplies from good products.		
6. The laboratory makes it a practice to remove damaged and/or expired supplies from inventory.		
7. The laboratory makes it a practice to follow guidelines for disposal and/or destruction of damaged and/or expired laboratory supplies.		
8. Cold chain items are always stored at appropriate temperatures. If not, list items and how they were found.		
9. Have there been any problems with storing laboratory supplies?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10. If yes, list the three major problems with storing laboratory supplies? (<i>Start with the highest priority.</i>)	1. _____ 2. _____ 3. _____	

Comments:

VII. LABORATORY INFRASTRUCTURE

Interviewer's Guide to Inspecting the Laboratory Area

If the answer for any of the questions is no, describe the status of the area in the comments box.

Question 11—Note that the incinerator should be functioning and used to destroy all hazardous waste.

Identify any areas in need of improvement and the type of improvement needed and note in the comments box.

Laboratory Area	Yes	No	Comments
1. Laboratory area is maintained in good condition (e.g., clean, all trash removed, shelves are sturdy, etc).			
2. Laboratory is secured with a lock and key but is accessible during normal working hours.			
3. Laboratory has shelves and lockable cupboards; access			

Laboratory Area	Yes	No	Comments
is limited to authorized personnel.			
4. Laboratory has sufficient space to perform the work required.			
5. Laboratory has sufficient space to adequately store existing supplies.			
6. Laboratory has:			
a. Running water			
b. Access to filtered rainwater (for HC only)			
7. Laboratory has a consistent power supply and/or a generator with a guaranteed supply of petrol or solar power.			
7 a. Record average number of hours per day electric power is available.			
8. Laboratory has an adequate number of power points (sockets).			
9. Laboratory has separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials.			
10. Laboratory has drainage from laboratory sinks that are closed and that lead to either a septic tank or deep pit.			
11. Laboratory has a functioning incinerator or other nationally acceptable waste management (e.g., a protected pit) to correctly dispose of all hazardous waste (e.g., needles, toxic materials) and fuel for the incinerator (if applicable).			
12. Laboratory floors are in good condition without the need for repair.			
13. At all times, roof is maintained in good condition to avoid sunlight and water penetration.			
14. Internal walls are in good condition without the need for repair.			
15. External walls are in good condition without the need for repair.			
16. Laboratory is well lit.			
17. Laboratory is well ventilated and cross-ventilated.			
18. Windows and doors are in good condition without the need for replacement or repair.			
19. Laboratory has firm built-in benches with leveled tops in good condition.			
20. Laboratory has firm shelves to store supplies and reagents.			
21. There is adequate glassware and/or plastic ware.			
22. Distilled/deionized water is available.			

Laboratory Area	Yes	No	Comments
23. Windows have security bars.			
24. There is an adequate number of laboratory stools.			
25. The laboratory has an indoor patient waiting area with seats.			
26. Lab staff have access to clean toilet facilities.			
27. Lab staff have access to safe drinking water supply.			
28. Laboratory has a working fire extinguisher.			

Comments:

END OF QUESTIONNAIRE

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