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Laboratory Standardization:

Lessons Learned and Practical Approaches

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Abstract
Based on the experience of the USAID | DELIVER PROJECT in supporting countries during the laboratory standardization process, this paper provides a detailed definition and description of laboratory standardization, outlines the benefits, and offers some suggested approaches for implementing standardization in-country.

Cover photo: Laboratory equipment, testing, and personnel, taken during an assessment of a laboratory logistics system in Zambia. Photo credit to Farouk Adams Umaru, 2008.

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Abbreviations and Acronyms

ABO	antibodies blood group
AIDS	acquired immune deficiency syndrome
ALT	alanine aminotransferase
APTT	activated partial thromboplastin time
ART	antiretroviral therapy
ASOT	antistreptolysin O titer
ATLAS	Assessment Tool for Laboratory Services
CD4	T4 or helper lymphocytes, the quantitative count of these cells
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
CMS	Central Medical Stores
DBS	dry blood spot
EHNRI	Ethiopian Health, Nutrition & Research Institute
EID	early infant diagnosis
ELISA	enzyme-linked immunosorbent assay
EMLS	Essential Medical Laboratory Services
EQA	external quality assessment
ESR	erythrocyte sedimentation rate
FBC	full blood count
FSH	follicle-stimulating hormone
GGT	gamma-glutamyl transpeptidase
Hb	hemoglobin
HIV	human immunodeficiency virus
HTSS	Health Technical Support Services
JSI	John Snow, Inc.
LDH	lactate dehydrogenase
MOH	Ministry of Health
NGO	nongovernmental organization

PCR	polymerase chain reaction
QA	quality assurance
QC	quality control
Rh	Rhesus factor
SCMS	Supply Chain Management System
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic pyruvic transaminase
SOP	standard operating procedure
TB	tuberculosis
TPHA	treponema pallidum haemagglutination test
TSH	thyroid-stimulating hormone
TWG	technical working group
USAID	U.S. Agency for International Development
WBC	white blood cell
WHO	World Health Organization
ZN	Ziehl-Neelsen

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Executive Summary

The organizational structures of laboratories in limited-resource settings have evolved in response to HIV, tuberculosis (TB), and other infectious diseases, and more peripheral laboratories have become involved in providing routine testing. Consequently, the need for laboratory standardization has become more pronounced. Standardization for supply chain purposes is the process of setting test menus, techniques, and laboratory equipment for every level in the laboratory network. Standardization is an approach that can be used to manage laboratory services by enabling the rational allocation of limited resources to benefit the whole population. And although standardization is a policy rather than a supply chain intervention, the implications for the supply chain are significant.

The benefits of standardization are far-reaching. Clinically, for example, when different facilities use the same standard laboratory equipment and testing procedures, test results are comparable between facilities. Programmatically, having a greater number of the same machine and reagents results in economies of scale, which provide leverage to national laboratory programs in negotiating service and maintenance contracts. Additionally, having a smaller range of equipment and techniques facilitates the training of staff members. Finally, fewer products flowing through the supply chain enhance the agility, efficiency, and manageability of the national laboratory logistics system. For example, when facilities at the same level use the same techniques and equipment to conduct the same menu of tests, the correlated commodities are also the same. Alternatively, if machines break down or if a sudden change in consumption occurs, commodities can be redistributed to other facilities, thereby reducing the risk of expiries and stockouts.

A number of steps are involved in the process of defining and implementing national laboratory standards. The standardization process should begin with an assessment to establish the current context of the laboratory network. There should then be a workshop or series of meetings to introduce standardization. Setting test menus should be done in consultation with a wide range of participants, including laboratory personnel, clinicians, program managers, medical staff members, procurement officers, supply chain managers, and implementing partners. This step is critical for ensuring that the laboratory tests selected for each level of the system support the delivery of health services and fit within the current context, capacity, and infrastructure. The more-technical discussions to define techniques and equipment can be limited to a smaller group of laboratory experts.

Careful consideration should be given to the implementation plan for standardization. A detailed implementation strategy, which should be developed at the end of the standardization workshop, should include the time frame and the resources required to fully implement standards. A series of activities is required to implement the standards; these activities can be broadly categorized as policy, supply chain, and laboratory system interventions. Policy interventions include ensuring that the standardization decisions are documented and disseminated and that a standardization committee is formed to handle periodic reviews and updates to the standardized list. A number of supply chain interventions are needed to ensure that the commodities required to fulfill the standards are available when and where needed. Such interventions include selecting the appropriate products, designing and implementing a logistics system, conducting national quantification, and procuring the necessary

commodities. Finally, health systems interventions include the development of standard operating procedures (SOPs) to provide (a) guidance on how to run the standard tests while using the chosen techniques and equipment, (b) updated curricula to reflect the new standards and trainings for staff members on the new equipment, and (c) standardized techniques.

Case studies about experiences in Ethiopia, Malawi, and Zambia with standardization are included in the appendices. They provide practical examples of how the standardization process has been undertaken in those three countries.

Background

Standardization, as a policy intervention, represents a public health approach to managing laboratory services. In general, a public health approach promotes the most-efficient and cost-effective use of limited resources to serve the majority of the population. A public health approach to disease management requires the development of standardized operational guidelines to ensure therapeutically effective and economically efficient disease management. As a part of this approach, standard treatment guidelines are used in administering treatments for HIV, malaria, TB, and other diseases. When implemented effectively, standard treatment guidelines offer advantages to patients (facilitates easier understanding of disease progression and treatment benefits), providers (gives an opportunity to develop and monitor quality of care standards), supply managers (makes demand more predictable), and health policymakers (promotes efficient use of funds). But effective formulation and implementation of affordable and high-quality health service delivery require standardization beyond the development and implementation of standard treatment guidelines.

In an effort to provide health care to the most people possible, health service delivery has moved out of large health facilities down to the lowest levels possible. Program managers have increasingly emphasized the provision of primary care down to smaller, more rural, more basic health facilities. The focus on primary care has expanded to include disease management of HIV, malaria, and TB. Unfortunately, the expansion in scope of services provided has not been accompanied by the expansion of related laboratory tests required to manage those diseases. Laboratory services were not necessarily aligned to the need for health care services.

Laboratory services act as a cornerstone for public health programs by supporting diagnosis, monitoring, screening, and surveillance to control and manage diseases. Underdiagnosis and misdiagnosis of infectious diseases (such as TB and malaria), resulting from a lack of laboratory testing, can lead to incorrect prescribing of treatment, wastage of resources, and poor patient clinical management. Similarly, lack of testing to monitor disease progression can lead to delayed commencement of treatment, thus causing a poor prognosis, especially for HIV-positive patients.

Many laboratory tests are needed to provide the comprehensive package of testing required for public health programs. All these tests require commodities, functioning equipment, trained personnel, and infrastructure. Strategies to standardize and streamline the provision of testing services can help to simplify and fundamentally improve the efficiency, quality, and affordability of testing for both the service provider and the patient. Standardization of laboratory testing is, therefore, critical for strengthening laboratory services and systems in limited resource settings.

The lack of standards in laboratory testing in numerous countries can be, in large part, attributed to the decentralization of laboratory services that has evolved in response to disease specific programs. Previously, national reference laboratories provided all the testing services for public health programs. However, as the demand for such testing services increased, testing could not be confined to national reference laboratories alone. In the comprehensive management of HIV and AIDS, TB, and malaria, the entry point to the health services and laboratory testing has been extended to peripheral laboratories, which are usually located in district hospitals, health centers, and close-to-client settings. Although this extension carries measurable benefits in terms of scaling up and

expanding testing services for a public health response, it has also meant that the peripheral laboratories now conduct sophisticated routine testing. During this expansion, the absence of a standardized approach to laboratory testing at peripheral laboratories has resulted in a proliferation of different tests, techniques, and equipment—including the required commodities—across laboratories.

Presently, the peripheral laboratories, which have functioned in the past as stand-alone entities, are viewed more and more as part of the national networks in order to simplify their management and to rationalize the allocation of limited resources. Part of the evolution has involved centralizing the supply chain so that all laboratory commodities are sourced from a central warehouse. This approach marks a shift from the previous scenario in which each facility procured its individually selected equipment and then sourced the required commodities from various vendors. A single laboratory generates a relatively small amount of business for a supplier. As a result of sourcing supplies this way, the supplies are difficult to get; moreover, if supplies are available, sometimes the quality is questionable. This shift toward national procurement has significant supply chain implications. From a supply chain perspective, the greater the number of tests, techniques, and equipment in a system, the greater the number of corresponding commodities that are required to conduct those tests and the more complex the supply chain management.

In January 2008, a conference was convened in Maputo and was hosted by the World Health Organization (WHO) to discuss laboratory standardization. At this conference, 28 countries resolved to move standardization forward. Following the conference, countries have focused more on laboratory standardization as an important component in strengthening public health services. Central-level policymakers are able to prioritize resources to ensure that equipment, infrastructure, and commodities required to support defined essential laboratory services are available. Standardization is a crucial component in managing a national laboratory network with limited resources, thereby allowing resources to be maximized while preserving quality services. This guide is intended to provide the supply chain perspective to countries as they move forward with laboratory services standardization.

What is Standardization?

According to the approach taken by the USAID | DELIVER PROJECT, laboratory testing services standardization is the process of setting test menus, techniques, and laboratory equipment for every level in the laboratory network. Standardization is not a supply chain intervention; rather, it is a policy intervention with supply chain implications.

The first step of the process is to select a standard list of tests that are required for each level of health care delivery services. After the tests are selected, one should determine the most efficient way to do those tests in the laboratory; this process allows for the most appropriate technique to be chosen for each test and at each level of health care delivery (e.g., flowcytometry to conduct CD4 counts at the district level). Finally, one should select equipment that is most suitable for each technique and context (e.g., FACSCount™ CD4[1] machine for the district level). See appendix 9 for a practical example of the selection process for tests, techniques, and equipment that was used during the standardization workshop in Malawi.

Typically, a stark contrast exists between standardized and nonstandardized systems. The following scenarios can help clarify the concept of standardization.

Scenario #1: Nonstandardized Laboratory System

In a nonstandard setting, the potential exists for a proliferation of tests, techniques, and equipment. Each health facility may provide a different menu of tests, making it difficult for clinicians and patients to predict what is offered at which facility. Facilities at the same level of health system may offer the same tests but may use different techniques or equipment to conduct those tests. All the different tests, techniques, and equipment require a different set of correlated products. The variations among the tests, techniques, and equipment for each laboratory—and even for laboratories at the same level of a nonstandardized network—typically result in a wider variety of products that are used across the supply chain.

When the laboratory is responsible for selecting tests, techniques, and equipment, the equipment chosen will invariably suit the unique needs of that particular laboratory. For example, the tests ordered by the clinicians will be performed on equipment appropriate for the volume of testing for that particular laboratory. This approach can result in many different types of machines being used throughout a country for a similar test. Although this process may seem reasonable when viewing a laboratory as a stand-alone facility, it becomes unwieldy when the supplies for that equipment come from a central point and when the peripheral laboratories are part of a national network. The central warehouse has to manage a wide variety of commodities from varying manufacturers, which are required to run the various tests on the different equipment. This large variety of products in a nonstandardized system makes it difficult to allocate resources rationally, and it does not allow the country to benefit from economies of scale, both in the procurement of commodities and in the establishment of service and maintenance contracts. From a supply chain perspective, as countries shift from individual laboratories sourcing their own commodities to a model that entails a

1 Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.

centralized procurement mechanism, many challenges will arise as a result of the large number of products that must be accurately managed, ordered, distributed, and stored.

Scenario #2: Standardized Laboratory System

A standardized system is one in which each laboratory at the same level of the network will offer the same testing menus, using the same techniques and equipment. Standard operating procedures are developed at a national level; they guide managers, supervisors, and trainers in maintaining quality services. Clinicians can be certain that whatever health center or hospital they are working at will provide a consistent level of laboratory testing services; if patients transfer between facilities, their results can be compared. Laboratory staff members can also easily transfer between facilities because they are familiar with the techniques and equipment used at all facilities. Moreover, generalized refresher training courses can be provided for all staff members. And commodities can be managed through a central logistics system, thus rationalizing resources and benefiting from economies of scale.

The following sections will further expand on the benefits of a standardized system (scenario 2) and will describe some practical approaches to implement standardization in-country.

Benefits of Standardization

Numerous benefits are associated with the standardization of laboratory services. Standardization is an essential intervention; it is a prerequisite to designing, implementing, and strengthening laboratory logistics systems. Standardization streamlines and reduces the range of commodities that must be procured and distributed from a central place, thereby increasing the effectiveness of the system to deliver the high-quality commodities needed to provide testing services. However, the benefits of standardization reach far beyond just reducing the complexity of the supply chain; standardization yields benefits for the overall management of laboratory services across the country and for the programmatic and clinical aspects of laboratory services. Standardization almost always leads to improvements in both efficiency and effectiveness, because it is the basis for developing standard procedures and processes for operating the overall program or system.

Clinical Benefits of Standardization

Clinically, standardization facilitates uniform and consistent case definition and case management, thus improving service provision to clients. Test results can be compared and interpreted against results from different laboratories within the network, thereby facilitating referrals and transfer of cases and minimizing the duplication of services. For example, in the case of CD4 testing, different machines have been shown to give varying results; as a result, many clinicians prefer to have patients monitored on one brand of machine. This brand preference has resulted in the proliferation of equipment—it is not uncommon for a single country to have as many as eight different models of CD4 machines. In this scenario, given that different machines give different results, it is difficult to compare results across facilities. In a standardized system, patients and clients can attend any laboratory, and their clinician at the same level of the health system will be able to offer the same range of testing services performed on the same brand of equipment. This approach will maximize the use of health services offered at close-to-client settings, will avoid unnecessary referrals, and will offer patients a greater opportunity to access services near where they live or work. All these factors may help to reduce default rates.

Programmatic Benefits of Standardization

Standardization benefits the overall management of the program by enhancing its ability to predict resource requirements. Particularly in a scale-up environment, it is very important that programs estimate the required resources and plan adequately so that services are not interrupted. Central-level policymakers are able to prioritize resources to ensure that equipment, infrastructure, and commodities required to support defined essential laboratory services are available. Standardization is a crucial component in managing a national laboratory network with limited resources, thus allowing resources to be maximized while preserving quality services. In particular, three critical programmatic elements benefit from standardization: equipment maintenance, human resources, and quality assurance:

1. Equipment Maintenance

In many countries, machine breakdown is a common challenge to delivering testing services. If individual laboratories are procuring only one piece of equipment, they do not have the negotiation

power of a network of laboratories that is procuring a large number of the same machines. Thus, having machines of the same kind and centralizing the procurement functions will allow the program to negotiate better service and maintenance contracts with manufacturers, distributors, or both. In some countries, having a larger number of one type of equipment has allowed ministries of health to negotiate maintenance contracts with the purchase of reagents. Given that nonfunctional equipment is a major bottleneck to laboratory service delivery, the negotiation of service as part of the commodity contract is critical to the success of the laboratory program.

2. Training and Management of Human Resources

From a human resources perspective, standardization achieves greater efficiency in training and management of staff members because (a) the same testing techniques and equipment are used at each level of the system, (b) the training programs are uniformed and simplified, and (c) the staff members can more easily transfer between facilities. Furthermore, as equipment or techniques are updated, refresher training approaches can be designed and rolled out more quickly and efficiently. In addition, on-the-job training and supportive supervision can be provided in a more consistent, comprehensive manner.

3. Quality Assurance

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

> A quality assurance (QA) program must include daily quality control (QC) evaluation and documentation, on-site assessments or inspections, inventory management (sufficient supplies within expiration date), external quality assessment (EQA) with timely feedback of results, staff competency, and equipment maintenance.

Maintaining high-quality laboratory services involves looking at a number of aspects that affect quality of testing. The availability of reagents and consumable supplies is one such critical component. If supplies are coming from different sources and if different equipment is being used in a laboratory network, determining and ensuring the quality of results coming out of the various laboratories will be more complex. In a laboratory network, it is important to compare results between laboratories. If discrepancies exist, corrective measures are then instituted to help maintain high-quality testing in the network. Although individual laboratories strive to do quality control on their testing, it is important that they have external validation of their results in addition to their local quality control activities. This procedure is simplified in a standardized environment. Standardization allows for results to be compared across facilities, thus increasing the reliability and consistency of test results.

Supply Chain Benefits of Standardization

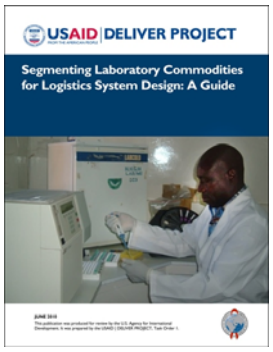
Standardization benefits the supply chain by streamlining the number of laboratory commodities that must be managed in the supply chain. Each test conducted using a different technique or equipment requires a unique set of products. The range of commodities required thus increases exponentially with each additional testing technique used. Standardization typically reduces the variety and range of products required, not the total volume; therefore, standardization may result in a larger volume for fewer commodities.

> A CD4 test run on an FACSCount™ machine requires 20 different items. If a country has 8 different types of equipment to conduct a CD4 count and if each requires 20 commodities, this number could equal more than 150 commodities required for CD4 testing alone. Consider the magnitude of this number within the context of all the other required HIV diagnosis, monitoring, and surveillance tests, as well as all the non-HIV testing requirements.

A laboratory test can be conducted in several ways or using different machines. Different machines will require reagents and consumables specific to that machine. For example, any of the following comparable machines can be used to do a CD4 test: FACSCount™, Partec CyFlow® Counter, Guava™, POCH™, Point of Care, and Sysmex KX21™. Suppose in one district all the different models are present and each machine will require 10–15 unique commodities; thus, the district will require around 75 unique commodities to run one test. If only two types of machines were used, that number would require about 25 commodities, an almost 70 percent reduction in the number of commodities to manage. If the range of different machines used to run a test like CD4 is not limited in some way, the number of corresponding commodities required increases exponentially. For manual methods, one also needs to limit the techniques, because a variety of techniques can be used to do the same test. If not standard across the laboratory network, modification of the same technique has implications on the usage of reagents and supplies.

A reduction in the number of supplies that must flow through the laboratory supply pipeline reduces congestion and complexity in the supply chain. Although overall volumes of products may not change—or even increase, the supply chain can still function more efficiently and effectively because it has to manage a smaller range of laboratory supplies. The following benefits are derived from the streamlining that occurs as a result of standardization.

1. Streamlines the selection of products following the standardization of tests, techniques, and equipment



Product selection is the process of deciding exactly which supplies are required for the tests, techniques, and equipment selected. After the standardization process is complete, the central warehouse will have fewer items to buy, can become more familiar with the commodities, and can ensure that the specifications meet the needs of the laboratories. In a standardized system, regularly updating the central warehouse catalog is more manageable, thereby improving communication between the laboratory staff and warehouse staff. Establishing the commodities required also simplifies the process of product segmentation, a process that is critical for a good logistics system design. For more detailed information on laboratory commodity segmentation, please refer to the USAID | DELIVER PROJECT's *Segmenting Laboratory Commodities for Logistics System Design: A Guide*.

2. Supports the development of a national logistics system and the central management of commodities

A reduction in the range of products allows for the development and implementation of a national coordinated logistics system because it allows for a central-level warehouse to monitor and maintain stock levels of all supplies necessary throughout the system. In addition, ordering and reporting forms for laboratory commodities can be designed to have the list of standard supplies preprinted to improve communication between the laboratory staff and the central warehouse, as well as to ensure that the right product is supplied.

3. Leads to the development of a priority list of commodities and a focus on ensuring the availability of those supplies

Standardization enables the creation of a priority list of commodities necessary to run the tests on the standard testing menus. The process of selecting tests, techniques, and equipment culminates in the development of a priority list of supplies required to carry out each of the tests. This process allows the central warehouse and the program to focus their attention on ensuring that this smaller priority list of supplies is available when and where required.

Zambia achieved a dramatic reduction in stockouts at the central warehouse following standardization. The warehouse committed to closely monitoring the smaller number of products and to ensuring that an ongoing supply would be available. Better stock manageability and a commitment to ensuring ongoing supply of the products resulted in a reduction of the stockout rate at the central level from 70 percent to 2 percent.

In one country, the transfer of reagents for a high-level chemistry analyzer from one of the Ministry of Health (MOH) laboratories to a partner laboratory as a result of equipment breakdown saved the MOH nearly $30,000, because the reagents would have expired by the time the machine was repaired. Instead, the reagents were able to be used at the partner laboratory, which was using the same type of chemistry analyzer.

4. Enables a redistribution of commodities in the supply chain

Standardization also allows redistribution of commodities throughout the laboratory network. In a standardized system, facilities at the same level will be conducting the same tests using the same techniques or equipment and will, therefore, require the same commodities. If one facility is undersupplied while another is oversupplied, stock can be transferred between the facilities because the products are uniform. This agility is especially important with laboratory reagents that have a short shelf life; it allows supply chain and program managers to minimize the risk of stockouts and expiries. This arrangement also avoids stock wastage caused by equipment breakdowns—if a facility has a sudden decline in the usage of reagents because of machine failure, it can transfer the reagents to another facility where the equipment is functioning. Transferring stock can save a program thousands of dollars by avoiding unnecessary wastage and expiries.

5. Simplifies forecasting and use of demographic data and service statistics for forecasting

In nonstandardized systems, conducting a national forecast for laboratory commodities can be extremely challenging. In most countries, consumption data—specifically data on the exact quantities of each product consumed—is not available for laboratory commodities. Thus, forecasting must be done using service statistics or demographic data, which will require the conversion of the forecasted number of tests (or a number of patients to number of tests) into products on the basis of assumptions about the techniques and equipment used to conduct each type of test.

In Kenya, a quantification for laboratory commodities had to be preceded by standardization. For most tests, consensus and standardization was achieved, and a national quantification and procurement plan was formulated, except for hematology equipment. A lack of consensus regarding hematology equipment resulted in each laboratory using a different hematology analyzer, which required different products. This lack of consensus meant that it was not possible to complete the national quantification for all of the hematology machines; ultimately, the procurement of hematology reagents and consumables had to be done by each laboratory individually.

In a standardized system, it may be possible to make assumptions about all facilities of a particular level of a system (e.g., all level 3 facilities will conduct 100 tests/month using a FACSCalibur™ machine[2]). In a nonstandardized system, one facility may be conducting different tests using different techniques and equipment from even a neighboring facility at the same level. It is impossible to make assumptions about a level in the system or a grouping of facilities when converting tests into products. Therefore, if one is to produce an accurate forecast in a nonstandardized system, assumptions about the commodities required for each technique and equipment used throughout the country must be made for each individual facility. This process makes a national quantification exceptionally time and resource intensive. Sometimes, as in the Kenya example, national quantification is not possible without standardization; therefore, the benefits of national planning and procurement cannot be realized.

6. Facilitates economies of scale in the procurement of commodities

Standardization facilitates access to more affordable commodity prices through economies of scale. As countries procure a larger quantity of a smaller number of products, the per-unit cost of each type of product is reduced. In the case of Kenya, instead of buying smaller quantities of 3,000 products, for example, larger quantities of only 300 supplies were procured at a lower price.

In Zambia, as a result of standardization, the equipment range was narrowed. Together, the MOH and cooperating partners negotiated maintenance contracts with the suppliers and linked this negotiation to the purchase of reagents to ensure sustainability of the maintenance contracts. Standardization had led to decreased overall procurement costs through economies of scale. With a reduction in the total number of laboratory commodities by approximately 80 percent, the procurement partners are obtaining more of each individual reagent rather than smaller quantities of many different reagents.

Individual facility orders may be so small that they may not attract suppliers, resulting in tests either not being available or being available at a very high cost. This occurrence negatively impacts the provision of services. Rather than individual laboratories with numerous small orders, large reagent

[2] Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.

orders will attract more businesses and will encourage competition. Larger orders enable the procuring countries to negotiate terms of the contract on stronger footing, thus getting better value for their money. Small and fragmented orders do not encourage businesses to come forward. In addition to facilitating better procurement practices, standardization helps to simplify budgeting at the national level. Putting numerous but very small amounts together can be challenging for management to justify. In a standardized laboratory network, quantities required at national level are usually significant.

Standardization Building Blocks: Test Menus, Techniques, and Equipment

Test menus, techniques, and equipment compose the building blocks of laboratory standardization. Those building blocks are used to review or create laboratory SOPs that outline the standard practices to be used throughout the national laboratory network. During the standardization process, it is important to keep in mind certain considerations about each element. Following is a brief explanation of each, of the relevant considerations, and of how they will affect the approach to standardization.

Test Menus

Test menus can be described as the defined list of tests that should be offered at a specific laboratory, or level of the laboratory network, as an integral part of the health system. Examples of tests to be included on test menus are hemoglobin (Hb), alanine aminotransferase (ALT), and malaria smear.

The test menus should reflect the needs of patients and should be consistent with the country's health service delivery standards for each level of the health system. In the absence of defined laboratory testing requirements, it is important that the clinicians, together with the laboratory staff, establish the laboratory tests list by levels that will enable clinicians to deliver services efficiently. Such tests should be in line with the country's standard treatment guidelines. In the current context, laboratories are often unable to offer the tests requested by clinicians because of constraints ranging from availability of personnel and equipment to policy restrictions. Consequently, when deciding how to approach standardization, both the providers and users of laboratory services should be involved in determining the tests so they can ensure that the services are appropriate and clinically significant for the country context. The review of the existing test menu is a first step in the standardization process; it serves to align the requirements of health services provision at each level of the health system with the laboratory capacity at the same level. See appendix 1 for an example of test menus by level.

Policymakers, laboratory staff members, and clinicians must reach consensus on the minimum testing package for each level of the system. Policymakers should secure funding to allow for the provision of standard testing services; clinicians should follow the agreed-to testing menu; laboratory staff members must endeavor to make those tests available while using the established standards. Ongoing discussions among policymakers, clinicians, and laboratory staff members will be required as new diseases emerge, as new technologies and testing capabilities are developed, and as laboratory capacity improves so that standards can be revised and updated. Because physicians are ultimately responsible for each patient in their care, it is important that they provide guidance on the test menus they would like for laboratories to provide. Failure to observe this guidance may result in laboratories providing tests that will not be used as well as failing to provide tests that are needed.

Techniques

Techniques can be generally defined as a specific method used to carry out a test that is based on an established protocol. Examples include enzyme-linked immunosorbent assay, microscopy, and rapid agglutination methods.

Common laboratory tests often have a large number of widely accepted or recommended techniques. For example, at least four different techniques exist for malaria testing, including light microscopy, fluorescent microscopy, flow cytometry, and chromatography. Laboratory personnel are best placed to decide on the most appropriate technique to adopt for the in-country setting. When selecting a technique, they will need to take into account technical considerations and also supply chain implications. From a scientific standpoint, some techniques will prove to be sound but they may have significant supply chain implications. For example, a technique that uses reagents that must be stored in frozen conditions at all times should not be selected for laboratories where keeping the products frozen during distribution and storage is not possible. An alternative technique, though perhaps not the most ideal technically may be more desirable under such a circumstance. The process of selecting techniques should be carried out carefully. A balance must be struck and a technique chosen that is scientifically sound but also appropriate to the infrastructure and staff capabilities available at the laboratories at that level of the system.

See appendix 2 for an example list of tests menus and techniques.

Equipment

Equipment comprises instruments or analyzers that are used in a laboratory to prepare samples, examine specimens, or conduct tests. These machines vary in size and complexity. Examples are centrifuges, microscopes, and CD4 machines. The equipment available in laboratories must match the test menu at the level of health system.

High costs are involved in procuring and operating equipment; therefore, the process of selecting equipment must be comprehensive, consultative, and transparent. Equipment is often procured by donor agencies and implementing partners; however, the machine will generally outlive funding cycles, and the operational cost of running equipment (e.g., maintenance, servicing, etc.) will be borne by the host Ministry of Health (MOH). Therefore, donors and partners and the MOH should work together to ensure the commitment of all parties to supporting the established equipment standards.

Several types of equipment, with varying levels of complexity, will be relevant during the standardization process. Basic lab equipment such as water baths, timers, and centrifuges do not usually pose a big problem because they do not require (a) extensive training for proper use, (b) specialized reagents, (c) consumables to operate, or (d) significant service and maintenance. The more complex analyzers are typically the main focus of the standardization exercise: They pose a number of special considerations because they are expected to produce very accurate results that are critical to patient management; they also require regular service and maintenance to keep them functioning at a scientifically acceptable level and to produce clinically useful information. The support needed to keep the equipment functional after it has been purchased is one very critical consideration. The provision of reagents, calibration, and quality control (QC) materials is another important factor that should be weighted carefully when selecting appropriate equipment.

The final selection of complex analyzers will be brand-specific because each brand of equipment usually has unique or brand-specific reagents and other commodities (as they are often closed systems) that must be used with that equipment. Therefore, it is extremely important that all rationale and discussions that lead to the decision are well-documented. Development of a

transparent and accountable process for selecting equipment and documenting that process will ensure that all stakeholders can have confidence that the process is equitable and leads to the best possible outcome for the laboratory services in the country. Laboratory personnel, biomedical engineers, equipment technicians, and procurement experts should work closely to ensure selection of the most suitable equipment.

Steps in Standardization

Standardization is a multistep process that should be deliberate, purposeful, and participatory. Moreover, standardization is a policy intervention that requires funding, human and institutional resources, and time; therefore, it requires commitment and leadership from the MOH. It is important that a strategy to achieve standardization be developed and documented in national laboratory policy documents. MOH should assume leadership of the process from the beginning to ensure continuity, as well as to secure the support of any other necessary ministries (for example, Ministry of Finance).

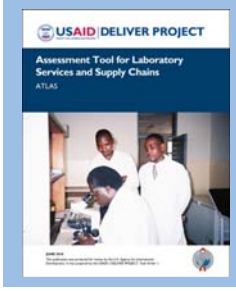
Although standardization has multiple supply chain benefits, it will have limited effect if it focuses only on the supply chain. Therefore, throughout the process, one must take into account the policy, service delivery, programmatic, clinical, and supply chain considerations. The standardization process should focus on meeting the needs of those accessing laboratory services and those delivering high-quality testing services in a way that maximizes limited resources.

Assessment

Conducting a baseline assessment to establish an understanding of the current state of laboratory services is the first step to standardization. As part of the assessment, it is important to identify and evaluate the—

- overall view of the laboratory system and how it interacts with the health system
- key stakeholders, including those that use the laboratory services and that provide funding, as well as the implementing partners and their role in providing laboratory services
- environmental factors, such as the procurement policies and the influence of the current suppliers with a view to how it may affect the standardization process
- tests menus, techniques, and equipment currently in use at different levels of the system

The Assessment Tool for Laboratory Services (ATLAS) is recommended for this type of assessment.



gaps in testing services identified by laboratory staff members, clinicians, and public health programs

This assessment will involve either (a) visiting sites and mapping the variety of test menus, techniques, and equipment in use or (b) distributing a survey to laboratories to solicit this information. A prestandardization questionnaire is included in appendix 3. The assessment provides an opportunity to begin sensitizing stakeholders to the concept of standardization. Presenting the findings of the assessment is typically an effective way to illustrate the need for standardization by demonstrating the variety of tests, techniques, and equipment in use throughout the country. The

analysis of the results of the assessment and the answers to the key issues will be used to facilitate decisionmaking during the standardization workshop.

- After procurement policies and related issues are identified during the assessment, dialogue with the procurement bodies within the government should also occur before the standardization workshop or meetings begin. Identifying policies that may be a barrier to standardization is essential so that strategies to overcome those barriers can be determined early in the process. Clear policies supporting standardization and, in particular, the procurement of brand-specific equipment need to be in place if standardization is to be properly implemented.

Planning a Standardization Workshop

Building consensus with stakeholders from all levels is critical throughout the standardization process. Without giving stakeholders an opportunity to contribute to the process and to agree on the outcomes, the implementation of standardization is likely to have many barriers.

Two options exist for building consensus about the standards. Either a workshop can be convened in which all stakeholders meet to agree on the standard practices, or multiple meetings can be held with various stakeholders. This section will discuss planning a workshop, but the same concepts can be used for the multiple meetings format.

Types of Participants

Getting acceptance from all stakeholders is essential to achieving standardization. Participants should include a wide range of stakeholders: This list is illustrative, and only the selection should be country specific.

- laboratory staff members from all levels of the system
- clinicians from all levels of the system
- nursing staff members from all levels of the system
- program managers
- implementing partners, such as NGOs and faith-based organizations
- procurement officers
- supply chain managers
- therapeutic committees and related groupings
- MOH staff members

It may not be necessary for all stakeholders to be present for the entire process of establishing test menus, techniques, and equipment. Both the expertise and the participation of policymakers, laboratory staff members, and clinicians are required when determining test menus. This involvement will ensure that the requirements of health services provision at each level of the health system align with the laboratory capacity at the same level. However, when one standardizes techniques and equipment, the number of participants can be reduced mostly to laboratory experts who understand the current best practices and equipment used in each field.

Planning the Schedule

The workshop schedule should be designed so that stakeholders with interest and expertise in certain areas can participate during key points where their input is required. Generally, it is critical to involve all stakeholders at the beginning of the workshop to gain their commitment to the process of standardization and to create a vision for laboratory testing services. However, for certain sections of the workshop that require laboratory technical skills—for example, during the selection of techniques—a smaller group of participants is required for an efficient process. Both an example of standardization workshop goals and objectives and a schedule are provided in appendices 4 and 5, respectively. One should factor in the aforementioned considerations about participation when developing the workshop materials and content.

a. Introduce Standardization

An introduction to standardization and the benefits of such a policy should be presented at the start of the workshop. After explaining the concept, participants should be given an opportunity to discuss the practicalities of such a policy and to establish a commitment to it. This first session must include all stakeholders, including laboratory personnel, clinicians, program managers, medical staff members, procurement officers, supply chain managers, and implementing partners. This is also an opportunity to identify barriers to standardization and to determine solutions to such barriers.

b. Review the Current Standards

After commitment has been achieved, the current context and standards should be reviewed. As part of this exercise, the findings of the assessment should be summarized and presented. In addition, participants from different cadres and levels of the health system should be given an opportunity to present information about the current context and to identify any gaps in testing services or any out-of-date tests that should be replaced. The focus of this session is to allow as many stakeholders as possible to have an opportunity to share their opinions and visions for the laboratory system and to provide as much detail and context as possible to be able then to define the new standards.

c. Set Test Menus by Level

After a discussion of the current situation, the next step is to set the test menus by level. When setting the test menus, the clinicians must be present to review the service delivery requirements provision and to determine the laboratory services required at each level of the health system. Failure to do so will result in clinicians requesting tests that the laboratory is not equipped to provide and, in the reverse, the laboratories having equipment and products to perform tests that are not requested. This misalignment results in a waste of valuable resources and substandard care for patients or clients.

To set the test menus, participants can be divided into groups, with each group given the task of setting tests menus for one level (e.g., central, regional, or district) of the system. Each group should include a mix of clinicians, laboratory staff members, program staff members, and partners. Participants should be assigned to the group that is selecting test menus for a level of the system that they currently either work in or supervise.

As they list the tests by level, participants should organize the tests according to testing areas (e.g., chemistry, hematology, etc.) to ensure that they have covered all the necessary categories for testing. The participants should categorize testing to reflect the testing areas used at the service delivery

points in that country; for example, what one country groups as all hematology tests may be divided into hematology and immunology in another country.

In deciding which tests will be offered at the various levels, such as central level and district level, the participants must consider the menu of health services provided at that level. For example, if the district-level health facility is mandated and equipped with capable staff members, equipment, and supplies to treat cardiac events, then the district-level laboratory also needs to be equipped with instruments, supplies, and technicians to measure cardiac enzymes, such as creatine kinase. In the reverse, if the treatment guidelines state that patients who present at a district hospital with a suspected cardiac event should be referred to a higher-level facility, then cardiac enzymes should not be included on the district laboratory's test menu.

In some instances, the lower-level facility is responsible for collecting samples and for monitoring patients who are treated at the upper level of the system. In that case, it is also important to document a referral mechanism whereby certain tests are provided only in referral laboratories because of the utilization, equipment cost, and scarcity of skills required to operate sophisticated laboratory instruments; however, the collection of samples does occur at the lower levels. Sample collection also requires the availability of commodities and trained staff members.

Cost-effectiveness of health delivery services and quality of care should be the guiding principles during the standardization workshop. To facilitate the process, a simple worksheet can be provided, outlining current testing services—a paper to which the groups can make edits. An example worksheet is provided in the appendix 6.

After the test menus for each level have been set by the individual groups, consensus between all participants must be achieved because support from all stakeholders is essential. Sufficient time must be allocated for members of each group to present their decisions to the larger group and for the other participants to offer their inputs and to reach consensus. This presentation often involves significant discussion and consultation, but it is necessary to ensure that the right test menus are chosen and that all stakeholders support the decisions, because the rest of the standardization process builds—by level—on the final test menu. See table 1 for an illustrative test menu, by level (central, district, and health center), for the hematology testing area.

Table 1. Example of Test Menus for Hematology

Laboratory Tests	Central Hospitals		District Hospitals		Health Centers	
	Send Out	On Site	Send Out	On Site	Send Out	On Site
Hemoglobin		√		√		√
Total white blood cell		√		√		√
Differential count		√		√	√	
Full blood count		√		√	√	
Sickle cell—screening		√		√		
Sickle cell—confirmatory		√	√			
Prothrombin time		√		√		
Activated partial thromboplastin time		√		√		
Fibrinogen test		√	√			
Reticulocyte count		√		√		

Laboratory Tests	Central Hospitals		District Hospitals		Health Centers	
	Send Out	On Site	Send Out	On Site	Send Out	On Site
Erythrocyte sedimentation rate		√		√		
Lupus erythromatous		√	√	□	□	□
CD4 Count		√		√	√	□
CD4 %		√		√	√	□

d. Define Techniques

After the test menus have been set, a smaller group of laboratory experts will deliberate on techniques appropriate for each test provided at each level of the system. This group of experts will include mostly laboratory staff members who have technical knowledge of the various techniques and equipment available to perform each type of test. Representatives from the different areas of laboratory work (such as hematology, biochemistry, and microbiology) and from the different types of laboratories (such as national reference laboratories, blood transfusion services, central-level laboratories, and district laboratories) should be included as part of this discussion. There should also be staff members from training institutes, NGOs, and mission laboratories.

The selected techniques must address the testing needs that the initial larger group agreed to. Techniques should be determined for each type of test on the basis of the staff's capacity and of the infrastructure available to support the technique at that level of the system.

Using the test menu for hematology from the earlier example (table 1), table 2 outlines the agreed-to techniques required to conduct each of the tests on the hematology test menu.

Table 2. Example of Techniques for Sample Hematology Tests

Test Menus	Techniques		
	Central Hospitals	**District Hospitals**	**Health Centers**
Hemoglobin	HemoCue®	HemoCue®	HemoCue
CD4 count	flow cytometry	flow cytometry	
CD4 %	flow cytometry	flow cytometry	

e. Select Equipment

The test menu and techniques will guide the selection of appropriate equipment that can be used for the required tests. Selecting which equipment is to be included on the standardized list is a challenging activity because many factors must be considered and because priorities for equipment differ widely between individual facilities and levels in the system. Participants must be aware that the equipment chosen must be the best for the majority of laboratories, and it may not necessarily be the best for each individual laboratory.

The same group of expert laboratory staff members who were involved with defining test menus and techniques should be involved in selecting equipment. Members of this group should first develop a list of criteria upon which to base their decision in order to ensure that the equipment selection process is rational, transparent, and consultative. A sample list of operational considerations or criteria adapted by USAID | DELIVER PROJECT from the Maputo Standardization Workshop (organized by the WHO) is provided in appendix 7. This list should be

adapted to be country-specific so that the equipment chosen meets the country needs. It is advisable for each country program to review the list, to select the relevant criteria according to the context, and to prioritize the criteria to help guide the selection process. Answering the questions that follow each program, equipment, and supply chain consideration can help decisionmakers define the current landscape and agree on criteria for appropriate equipment to meet program needs.

The assessment will help to map out the existing equipment by level. Table 3 provides an illustrative list of CD4 equipment in a particular country, where eight different machines are used across 10 facilities in a two-level system. The list of existing equipment in the country, as identified during the assessment, should first be evaluated using the criteria selected from the list of operational considerations. If possible, it is wise to select from the equipment that is currently in use in the country to avoid unnecessarily replacing equipment and establishing new relationships with service providers. However, if it is decided that the country needs to consider other alternatives—for example, if advances in technology have outdated existing equipment—then it is recommended that the participants look to the countries in the region and learn from their experiences. This approach requires additional research to find out what equipment neighboring countries use and then evaluating the research using the country-specific criteria.

Table 3. Example of Variety of CD4 Count Equipment[3] in One Country Pre-Standardization

	Western District	Eastern District	Northern District	Southern District	Central District
District Hospital	Cyflow® SL3	FACSCalibur™	Sysmex KX21	Cyflow® Counter	FACSCount™
Health Center	Guava	Refer samples to district-level laboratory	Coulter-manual	FACSCount™	POOCH

If a brand of equipment that is used extensively in the country is rejected by laboratory personnel, it is important to question why. If the rationale for discarding a brand of equipment is based on internal factors, such as staff members who are not properly trained in using the equipment, or if there have been insufficient supplies of reagents caused by in-country supply chain dysfunction, then the problems will not be solved by procuring new equipment. The internal factors must be addressed first and then the equipment can be reevaluated.

Based on a review of new and existing equipment, according to the established criteria, a standardized equipment list should be developed as part of the standardization exercise. Table 4 provides an example of a standardized equipment list, where the FACSCalibur™ and Sysmex KX21 machines were chosen as the primary and backup machines (respectively) at the district level; during the earlier discussion about test menus, it was decided that the samples would not be processed at the health center level but rather would be referred to the district.

[3] Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.

Table 4. Example of CD4 Count Equipment List Post-Standardization

	Western District	Eastern District	Northern District	Southern District	Central District
District Hospital	FACSCalibur™ Sysmex KX21[4]	FACSCalibur™ Sysmex KX21	FACSCalibur™ Sysmex KX21	FACSCalibur™ Sysmex KX21	FACSCalibur™ Sysmex KX21
Health Center	Refer samples to district-level laboratory	Refer samples to district-level laboratory	Refer samples to district-level laboratory	Refer samples to district-level laboratory	Refer samples to district-level laboratory

f. Create an Implementation Plan

Implementing the established standards takes time and resources. Ongoing review is required to accommodate changes in technologies and clinical practices. To create the implementation plan, participants should be asked to consider what activities will be required to ensure that the standards are disseminated and understood by all laboratory personnel and health staff members throughout the country. Because standardization is a policy intervention, it will require formulation, high-level endorsement, and promotion before implementation takes place.

In most instances, a standardization technical working group (TWG), consisting of key laboratory staff members who were involved with the workshop, should be established to formulate a relevant policy document, to follow endorsement and promotion, and to coordinate the implementation of the standards. This TWG will be required only for the initial stages of implementation until the standardization committee is formed and all the documents are in place.

Implementation of the Standards

- Activities associated with implementing standardization can be divided into three key areas: policy, laboratory systems, and supply chain. Ongoing commitment by stakeholders to enforce and update the standards is critical. The activities listed in this section are common interventions that have been used across a number of countries to implement the standards; however, because the context differs in each country, additional activities may also be required.

Policy Activities

Ministerial support, other high-level support, or both for implementing standardization is paramount. As part of the implementation plan, two main policy interventions are required:

1. ***Policy Documentation and Dissemination:*** The department of the MOH that is responsible for laboratory services must demonstrate its support by officially documenting and endorsing the standardization as policy. Once the policy is approved, the laboratory department should ensure that other government departments, such as procurement units, are aware of the policy and agree to support its implementation. Donors and implementing partners must also be provided with a copy of the standards and requested to support and comply with them.

- 2. ***Formation of a Standardization Committee:*** A standardization committee should be established that is responsible for overseeing the implementation process and for regularly updating the national standards. The committee should include a representation of clinicians,

[4] Note: All trademarked equipment brands referenced in this text are illustrative and in no way endorse a particular brand or product.

program and laboratory staff members, and implementing partners. The role of this committee will be to meet every two or three years to thoroughly review the list and to incorporate the latest in technologies and best practices in the field. This committee will also review ad hoc requests between the major reviews for additions or deletions to the standardized list and will be responsible for reviewing technical documents and evaluating new technologies and equipment, if deemed appropriate for inclusion on the list. Typically, the standardization committee is a stand-alone coordinating structure with broader and higher-level participation than the logistics technical working group, including clinicians and other specialists, in addition to commodity managers. However, in some cases, this committee may operate as a subset of a logistics technical working group or a laboratory technical working group; for example, specialized experts may be requested to attend technical working group meetings when standardization is discussed.

Supply Chain Activities

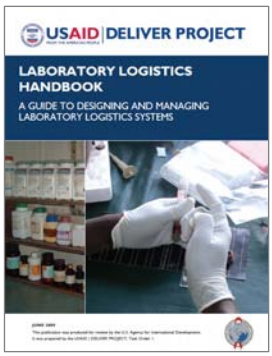
Once the standards have been established, it is then essential to ensure that the required commodities are available to fulfill the standards. Without a continuous and reliable flow of commodities, laboratories will quickly return to the old practice of procuring individually; standardization will not be properly implemented nor the benefits realized. Below is a list of one-time and ongoing supply chain system strengthening activities.

- ***1. Product Selection:*** Developing a product list is not technically part of the standardization exercise, because this list will not be included in the official policy, but it is an important step in implementing the standards. Once tests, techniques, and equipment have been chosen, it is necessary to select the products required to conduct the tests using the chosen techniques and equipment. Because the overall goal of standardization is to improve national laboratory services, it is important to ensure that the laboratories are adequately equipped with all necessary commodities to provide comprehensive testing services. SOPs for laboratory testing should be revised to accommodate the changes in tests, techniques, and equipment. The SOPs should list all the commodities that are needed to perform each test, if not they should be reviewed to include all the required commodities. The SOPs will form the basis for the final product list.

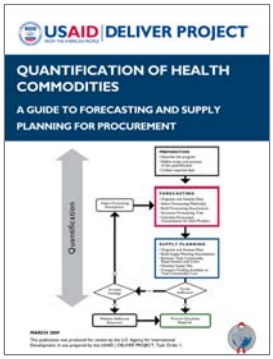
A smaller subset of the standardization workshop participants should be tasked with listing all the products, reagents, and consumables that are necessary to conduct the tests while using the techniques and equipment outlined in the standardized list. In selecting products, detailed specifications must be outlined to ensure that the correct products are procured. The template table in appendix 8 can help guide participants through the process of selecting correlated products for each test, technique, and piece of equipment; it will ensure that they have listed all categories of commodities (e.g., reagents, consumables).

When one is compiling this list of products, it is wise to have the current central warehouse catalog available in order to identify missing products and incorrect specifications of products. Once the products have been selected, the central warehouse catalog should be updated and disseminated because laboratory staff members typically refer to the catalog when ordering commodities. The smaller range of products achieved through standardization should enable the warehouse staff to keep this catalog up-to-date so that laboratory staff can order the correct products. The SOPs for laboratory testing should also be available to enable addition or deletion of commodities as necessary.

2. Design and Implementation of a National Laboratory Logistics System: After standardization takes place, a national logistics system can be designed and implemented to manage the commodities for all laboratories. A logistics system includes formal ordering and reporting practices plus inventory control procedures, including maximum and minimum stock levels that must be maintained. As part of this process, the final product list should be reviewed, and all products should be categorized and classified (e.g., slow-moving versus fast-moving) in order to determine how the products should be managed within the system. To read more on designing logistics systems for laboratory commodities following standardization that will ensure an adequate and constant supply of laboratory commodities, refer to the USAID | DELIVER PROJECT's *Laboratory Logistics Handbook: A Guide to Designing and Managing Laboratory Logistics Systems* (2009).



3. Institutionalization of National Quantification and Procurement Practices: Because it streamlines the tests, techniques, equipment, and therefore products required, standardization greatly reduces the complexity of conducting national quantifications of laboratory commodities. National quantification should be conducted annually and institutionalized at a national level. To read more about quantification of health commodities, refer to the USAID | DELIVER PROJECT's *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement (2009).*



As part of this process, procurement plans are developed and updated quarterly to ensure the flow of commodities into the country. Because procurement staff members do not always have the required laboratory expertise, laboratory personnel must work closely with procurement officers to provide the necessary technical specifications and to ensure that the right products are procured.

Laboratory System Activities

Laboratory personnel at all levels of the system (e.g., regional, provincial, and district) must be able to uphold the standards, meaning that the laboratory personnel can run the appropriate tests using the selected techniques and equipment. The following activities are representative of (a) the types of health system activities that will be required in order to build capacity in the system and (b) personnel to implement the standards. Depending on the country context, additional or fewer activities may be required.

1. ***Developing and Updating Laboratory SOPs:*** These SOPs will provide guidance on how to perform the selected tests; they will need to be updated to reflect the new standards if the techniques or equipment selected differ from the current SOPs. If SOPs are not currently available in the country, they need to be developed because those SOPs will serve as the operational documentation that guides laboratory staff members on the standards. SOPs are also critical for national forecasting exercise because they clearly spell out the specifications of the needed commodities.

2. ***Updating Training Curriculum to Reflect the Standards:*** Training curricula for laboratory scientists, technologists, technicians, and assistants must be reviewed to ensure that they are in line with the new standards. Where required, it will also be necessary to procure the standard equipment if the equipment is not currently available for training. Curricula for both in-service and preservice

training courses should be reviewed, because it is essential that new graduates and existing staff members are adequately trained in using the standard equipment.

3. ***Facilitating Refresher Trainings for Laboratory Staff:*** To reinforce the standards and to ensure that all staff members are competent to adhere to those standards, refresher courses on the standard techniques and on how to operate equipment should be provided for all members of the laboratory staff. The instruction should occur in both the in-service and preservice training settings.

Country Examples

Ethiopia, Malawi, and Zambia have all undertaken standardization activities. Each country has unique considerations and contexts; however, similarities can also be found. Individual case studies can be found in the appendices (Malawi is in appendix 9, Ethiopia in appendix 10, and Zambia in appendix 11). The similarities and differences are detailed in the section below.

Commonalities Across Countries

The MOH provides the leadership throughout standardization activities. In Zambia, the MOH created the Laboratory Technical Working Group with a specific subcommittee dedicated to Procurement and Logistics, and the MOH hosted the standardization workshop. In Ethiopia, the MOH (partnering with the Ethiopian Health, Nutrition, and Research Institute) is responsible for establishing and maintaining a public health laboratory system. In Malawi, the MOH has been spearheading all strengthening activities for the laboratory logistics system. All three countries were represented at the Maputo workshop on standardization, thus demonstrating political commitment and willingness to standardize.

Standardization works best when a participatory, consultative workshop is held. In all three countries, the standardization activity was conducted through a workshop, which was led by the MOH and included the participation of partners. For standardization to be effective, collaboration with implementing partners is essential, and consensus must be reached on critical decisions.

Standardization is a process. In all three countries, standardization was not a one-time event. Rather, the set standards will need continual revision and necessary updates. Existing equipment may become outdated or redundant, and new technologies are continually emerging. As the breadth of health services continue to expand to lower levels, the tests, techniques, and equipment at various levels need to be reviewed.

Having a national laboratory policy or strategic plan provides a critical framework under which standardization activities can take place. At the time of the initial standardization activity, all countries had policies or strategic plans in place. Ethiopia had created a National Laboratory System Master Plan. In Zambia, this achievement was the National Medical Laboratory Policy; in Malawi, it was the Essential Medical Laboratory Services Policy to Support National Health Plan Activities. Having documented plans in place showed purposefulness on the part of the national governments.

Standardization led to subsequent laboratory logistics system strengthening activities. All three countries recognized standardization as a prerequisite to related system-strengthening activities; the countries gained momentum for such activities through the standardization workshop. Establishing test menus, techniques, and equipment provided an opportunity for supply chain activities to occur in a focused and efficient way. Standardization allowed for supply chain designs that would be responsive in providing the needed commodities.

All three countries realized significant benefits in supply chain, service provision, and program management. All countries reduced stockouts; moreover, they simplified product selection and procurement. Notably, they negotiated and implemented improved service maintenance and

contracts. Benefits also now exist in terms of service provision. For example, waiting time for ART patients to have laboratory tests conducted in Ethiopia was reduced from months to hours. Improved communication between laboratory and doctors was noted in Malawi.

All countries established certain mechanisms or structures to continue the standardization work. Malawi set up a standardization committee to review additions or deletions of equipment from the standard equipment list in the future as a result of changes in technology or disease patterns and laboratory testing needs. Zambia's Procurement and Logistics Subcommittee will continue to review the standards. In Ethiopia, the Ethiopian Health, Nutrition, and Research Institute works with stakeholders to ensure standard laboratory practices.

One challenge common to all countries was equipment that was still in the country but not on the national standard equipment list. This was a significant challenge because equipment cannot be quickly replaced and is, in fact, quite expensive to replace. Zambia decided that cooperating partners supporting the sites with nonstandard equipment would procure and distribute reagents for those pieces of equipment; however, the goal is to equip the facilities with standard instrumentation or to review the standard equipment list to include some of these pieces of equipment. The University Teaching Hospital must validate new equipment before it can be included in the standard equipment list.

Differences Across Countries

Although similarities exist in the three countries, notable differences also exist.

The catalyst for conducting a standardization activity was different in each of the countries. In Ethiopia, it was logistics system design. During the laboratory logistics system design workshop, Ethiopians recognized that a standard list of products needed to be included. To do that, the test menus, techniques, operating procedures, and equipment must be standardized. In Zambia, a quantification activity was the catalyst. To quantify the number of laboratory products needed for the country's testing needs, the quantification team had to agree on the standard equipment by level and had to consider the test menus and techniques. Malawi conducted a national laboratory logistics system assessment, which found a variety of equipment across the country. One of the recommendations following the assessment was to standardize test menus, techniques, and equipment. Because the catalyst for doing standardization differed across countries, the type of workshop in which standardization was conducted also differed. In Ethiopia, it was during a system design workshop; in Zambia, it was during a quantification workshop; and in Malawi, it was in a stand-alone standardization workshop.

The scope of the standardization also varied across countries. In Ethiopia, the system design was specifically to support the HIV and AIDS care and treatment program in antiretroviral therapy (ART) sites (specifically, the laboratory monitoring hospitals). In Zambia, the impetus for working within laboratories came as part of the development of a comprehensive HIV and AIDS program. For Malawi, the laboratory logistics system as a whole was considered as part of standardization, and the scope of standardization was not disease-specific. In all cases, the standardization focused on equipment for CD4 testing, chemistry, and hematology but not necessarily on all tests that are offered on those pieces of equipment.

The degree of standardization found in the various systems also differed. In Zambia, the Laboratory Technical Working Group had already drafted the Essential Equipment List by facility level prior to the standardization workshop, and the list provided a useful starting point. In Ethiopia, the National

Health Laboratory System Master Plan outlined a standard health laboratory system for the country but not specific equipment or commodities.

Table 5 summarizes the standardization activities across countries. Although standardization was undertaken at different times, for different reasons, and in different contexts in all of three countries, similarities can be used to inform standardization exercises in other countries. Leadership and commitment from the MOH and a participatory and collaborative workshop are factors necessary for standardization to occur successfully. No matter the context, after a country undergoes a standardization exercise, benefits are realized and further logistics system strengthening activities are possible.

Table 5. Comparison of Standardization Process in Ethiopia, Malawi, and Zambia

Considerations	Ethiopia	Malawi	Zambia
Who was involved in the process?	Ethiopian Health Nutrition and Research Institute, MOH, SCMS, and partners	MOH, USAID |DELIVER PROJECT, and partners	MOH, SCMS, and partners
When was standardization done?	March 2007	April 2009	September 2006
Was a national laboratory policy or strategic plan in place at time of standardization?	National Health Laboratory System Master plan and accompanying guidelines that had been developed	Essential Medical Laboratory Services policy to support National Health Plan activities, which ended in 2002, plus Strategic Plan that concluded July 2009	National Medical Laboratory policy and 5-year implementation plan developed in 1997
What was the initial laboratory logistics strengthening activity	Laboratory logistics system design	Laboratory logistics system assessment that was conducted using ATLAS, followed by strategic planning workshop	Laboratory Technical Working Group that was formed with a subcommittee on procurement and logistics
What encouraged the focus on standardization?	During system design, when there was recognition of a need to reduce the range of equipment	Assessment conducted to reveal a variety of equipment issues, plus standardization recommended to address this problem	During a national laboratory quantification, recognition of need existed to reduce the range of commodities
What was the process of standardization?	During system design test menus when techniques and equipment were defined	During standardization workshop, the test menus, techniques, and equipment that had been defined earlier	During national quantification, the test menus, and techniques that had been defined, plus the equipment list initiated and agreed on by the TWG
What were the benefits?	Elimination of stockouts; waiting time for patients reduced from months to hours; reduction in product range, simplified product selection, and improved service maintenance	Current procurement of equipment on the basis of the standard list; CMS catalog updated; improved communication between laboratory and doctors; logistics system design that followed; national quantification that was done	Service contracts that are negotiated; stockouts eliminated at the central warehouse; reduction in procurement costs; stock transfer between facilities now possible

Considerations	Ethiopia	Malawi	Zambia
Scope of standardization	Initial focus that was on tests for the ART program	Focus was on laboratory services in general	Initial effort that was to standardize tests for ART scale-up
Challenges	Keeping a standard equipment list in light of rapidly changing technology	Dealing with equipment not on a list but already in use in the country	Selection of equipment that is still ongoing as additions from existing equipment take place
Next steps for standardization	EHNRI adapting Maputo guidelines to country context; working with stakeholders to maintain standardization	Standardization committee that will be set up to review and update standards	New equipment that requires validation before acceptance into the system
Next steps for logistics systems strengthening	Laboratory logistics system design and quantifications	Laboratory logistics system design and quantifications	Laboratory logistics system design and quantifications

Note: ART = antiretroviral therapy; ATLAS = Assessment Tool for Laboratory Services; CMS = Central Medical Stores; EHNRI = ; MOH = Ministry of Health; SCMS = Supply Chain Management System; TWG = technical working group.

Conclusion

Standardization is the process of selecting a standard list of tests, techniques, and equipment at each level of the system, a process that ultimately results in streamlining the range of required commodities. Standardization aligns the human resources, infrastructure, and funding requirements at each level of the health system. In this way, standardization is a policy intervention that enables the adoption of a public health approach to managing laboratory services in resource-limited settings, because it allows the organization of testing services to serve the greatest number of people with the resources available. Standardization almost always leads to improvements in both efficiency and effectiveness of the entire level of the health system. In addition to having significant supply chain benefits, standardization can also lead to clinical benefits and cost-effective outcomes.

Standardization is a long-term process that requires time; resources; political will, as well as the leadership and commitment of the MOH; and participation by donors and other partners. Several key steps exist in the standardization process. As a first step in the process, a baseline assessment serves both (a) to define the tests, techniques, and equipment currently being used in the system and (b) to provide important information about the structures, stakeholders, and policies that will influence the process. The assessment findings inform the standardization process.

Once the standards are selected, an implementation plan, which takes into consideration the resources and steps required, should be developed. Three distinct categories of next steps exist following the standardization workshop, including policy, supply chain, and laboratory systems activities. Policy activities include (a) the documentation of the outcome of the standardization workshop; (b) the drafting or revising of national policy documents; and (c) the development of structures, including the formation of a standardization committee to periodically review and update the standards. The development of standards also provides a solid foundation for implementing a number of supply chain strengthening activities, including product selection, product segmentation, design and implementation of a logistics systems to manage laboratory commodities, and national quantification and procurement of commodities. Finally, if one is to ensure that staff members will be able to implement the new standards, a number of health systems interventions are required, including the development of clinical standard operating procedures and curricula to be used in training staff members about the new standards.

Because the implementation process takes time and resources, an ongoing commitment by stakeholders to enforce and update the standards is critical. The benefits accruing from standardization, which are numerous from technical, programmatic, clinical, and supply chain aspects, make it imperative that standardization is implemented to improve public health programs overall. Countries looking to strengthen public health programs that are supported by sound laboratory services will need to give a serious consideration to standardization because it is a beneficial process.

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Appendix I

Example of Test Menu by Level

Central Hospital	District Hospital	Health Center
Hematology	***Hematology***	***Hematology***
Full blood count	Full blood count	Hemoglobin
Differential count	Differential count	White blood cell count
Sickle cell screening	Sickle cell screening	
Sickle cell confirmatory test	Sickle cell differential test	
Hemoglobin	Hemoglobin	
Prothrombin time	Prothrombin time	
Activated partial thromboplastin time	Activated partial thromboplastin time	
Fibrinogen test	Erythrocyte sedimentation rate	
Erythrocyte sedimentation rate	Reticulocyte count	
Reticulocyte count	CD4 %	
Lupus erythromatous		
CD4 count		
CD4 %		
Blood Bank	***Blood Bank***	***Blood Bank***
ABO grouping	ABO grouping	ABO grouping
Rh grouping	Rh grouping	Rh grouping
Cross match testing	Cross match testing	
Direct Coombs test	Direct Coombs test	
Indirect Coombs test	Indirect Coombs test	
Du test	Du test	
Microbiology	***Microbiology***	***Microbiology***
TB microscopy - Z-N	TB microscopy - Z-N	TB microscopy - Z-N
TB microscopy - fluorescence	TB microscopy - fluorescence	Gram stain
Culture and sensitivity	Culture and sensitivity	Wet prep
Blood	Blood	
Pus swabs	Pus swabs	
Stool	Stool	
Urine	Urine	
Sputum	Sputum	
CSF	CSF	
Aspirates	Aspirates	
Cervical	Cervical	

Central Hospital	District Hospital	Health Center
Eye	Eye	
Nasal	Nasal	
Ear	Ear	
Throat	Throat	
Wet prep	Wet prep	
HVS	HVS	
Urine	Urine	
Cell count	Cell count	
CSF	CSF	
Aspirates	Aspirates	
India ink	India ink	
Gram stain	Gram stain	
KOH	KOH	
Wayson stain	Semen analysis	
Occult Blood		
Mycology silver stain		
Mycology Lactophenol blue		
Mycology Grocotts'		
Parasitology	Parasitology	Parasitology
Malaria RDT	Malaria RDT	Malaria RDT
Malaria microscopy	Malaria microscopy	Malaria microscopy
Urine chemistry	Urine chemistry	Trypanosoma
Urine microscopy	Urine microscopy	Filaria - blood film
Stool microscopy	Stool microscopy	Urine
Skin Snips for microfilaria	Skin Snips for microfilaria	Stool
Filaria - blood film	Filaria - blood film	
	Trypanosoma/Borelia testing	
Serology	***Serology***	***Serology***
Cryptoccocal antigen test	Cryptococcal antigen test	HIV test rapid
HIV test (ELISA)	HIV test rapid	Syphilis (TPHA) test
HIV test rapid	Syphilis (TPHA) test	Hepatitis B rapid
Syphilis (TPHA) test	Hepatitis B rapid	Hepatitis C rapid
Hepatitis B rapid	Hepatitis C rapid	Pregnancy test
Hepatitis C rapid	Pregnancy test	Pregnancy test
Measles	Pregnancy test	
Rubella		
ASOT		
Rheumatoid factor		
Pregnancy test		
Biochemistry	***Biochemistry***	***Biochemistry***
Acid phosphatase	Acid phosphatase	Urine chemistry
Albumin	Albumin	Blood glucose

Central Hospital	District Hospital	Health Center
Alkaline phosphatase	Alkaline phosphatase	
Amylase	Amylase	
Blood gases	Blood glucose	
Blood glucose	Calcium	
Calcium	Chloride	
Cholesterol	Cholesterol	
Creatine kinase	Creatine kinase	
Creatinine	Creatinine	
CSF protein	CSF protein	
CSF glucose	CSF glucose	
CSF globulin	CSF globulin	
Direct bilirubin	Direct bilirubin	
GGT	GGT	
Glycosylated Hb	Indirect bilirubin	
Immunoglobulin electrophoresis	Lactic acid	
Indirect bilirubin	LDH	
Iron	Phosphorus	
Lactic acid	Potassium	
LDH	SGPT (ALT)	
Magnesium	SGOT (AST)	
Phosphorus	Sodium	
SGOT (AST)	Total bilirubin	
SGPT (ALT)	Total protein	
Total bilirubin	Triglycerides	
Total protein	Urea	
Triglycerides	Uric acid	
Urea		
Uric acid		
Thyroid hormones T3		
Thyroid hormones T4		
FSH		
TSH		
Tumor markers		
Prostate antigen		
Carcinogenic embryonic antigen		
Alpha fetoprotein		
Sodium		
Lithium		
Potassium		
Chloride		
Histology / Cytology	***Referred Tests***	***Referrals***
Hematoxylin-and-Eosin	Histological samples	HIV EID (DBS preparation)

Central Hospital	District Hospital	Health Center
Pap stain	EID HIV DNA-PCR	CD4 -collection of samples
Prussian stain	Hormones	
ZN	antibody screening & identification	
Molecular biology		
PCR – DNA		
PCR - RNA (viral load)		

Appendix 2

Example of Tests and Techniques by Level

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Hematology			
FBC	Hematology analyzer	Automated	
WBC			HaemoCue
Differential count	Manual	Manual	
Sickle cell screening	Sodium metabisulphate	Sodium metabisulphite	
	Sodium dithionate	Solubility	
Sickle cell confirmatory test	Electrophoresis		
Hemoglobin	HaemoCue	HemoCue	HaemoCue
PT	Automated machine		
APTT	Automated machine	Tube method	
Fibrinogen test	Automated machine		
ESR	Westergreen	Westergreen	
Reticulocyte count	Brilliant cresol blue	Brilliant cresol blue	
	New methylene blue	New methylene blue	
	Automated machine		
Lupus erythromatous	Latex agglutination		
CD4 count	Flowcytometry	Flowcytometry	
CD4 %	Flowcytometry	Flowcytometry	
Blood Bank			
ABO grouping	Tube method/Tile method	Tube method/Tile method	Tile method
Rh grouping	Tube method	Tube method	Tile method
Cross match testing	Tube method	Tube method	
Direct Coombs test	Tube method	Tube method	
Indirect Coombs test	Tube method	Tube method	
Du test	Tube method	Tube method	

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Microbiology			
TB microscopy – Z-N	ZN stain	ZN stain	ZN stain
TB microscopy - fluorescence	Auramine O stain	Auramine O stain	
Culture and sensitivity			
Blood	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	Co2	Co2	
Pus swabs	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	Co2	Co2	
Stool	Aerobic	Aerobic	
Urine	Aerobic	Aerobic	
Sputum	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
CSF	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Aspirates	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Cervical	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Eye	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Nasal	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Ear	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	
Throat	Aerobic	Aerobic	
	Anaerobic	Anaerobic	
	CO2	CO2	

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Wet prep			
HVS	Direct microscopy	Direct microscopy	
Urine	Direct microscopy	Direct microscopy	
Cell count			
CSF	Counting chamber	Counting chamber	
Aspirates	Counting chamber	Counting chamber	
India ink	Direct microscopy	Direct microscopy	
Gram Stain	Microscopy	Microscopy	Microscopy
KOH	Microscopy	Microscopy	
Wayson stain	Microscopy		
Occult blood	Microscopy		
Mycology silver stain	Tablet		
Mycology Lactophenol blue	Microscopy		
Mycology Grocotts'	Microscopy		
Parasitology			
Malaria rapid	Rapid - chromatography	Rapid - chromatography	Rapid - chromatography
Malaria microscopy	Microscopy	Microscopy	Microscopy
Urine chemistry	Multistix	Multistix	
Urine	Microscopy - sedimentation	Wet prep microscopy - sedimentation	Wet prep microscopy - sedimentation
Stool	Microscopy - formal - ether concentration	Microscopy - formal - ether concentration	
	Microscopy - direct - normal saline	Microscopy - direct - normal saline	Microscopy - direct - normal saline
	Microscopy - direct - iodine	Microscopy - direct - iodine	Microscopy - direct - iodine
Skin Snips for microfilaria	Microscopy - direct - normal saline	Microscopy - direct - normal saline	
Filaria - blood film	Microscopy	Microscopy	Microscopy
Trypanosoma/ Borelia testing		Microscopy - Field stain A & B	Microscopy - Field stain A & B
Serology			
Cryptococcal antigen test	Latex agglutination	Latex agglutination	
HIV test	Semi/Fully automated - ELISA		
HIV test rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Syphilis (TPHA) test	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Hepatitis B rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Hepatitis C rapid	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Pregnancy test	Latex agglutination	Latex agglutination	Latex agglutination
Pregnancy test	Rapid -chromatography	Rapid -chromatography	Rapid -chromatography
Measles	ELISA		
Rubella	ELISA		
ASOT	Latex agglutination		
Rheumatoid factor	Latex agglutination		
Biochemistry			
Acid phosphatase	Auto analyzer	Auto analyzer	Multistix
Albumin			
Alkaline phosphatase			
Amylase			
Blood gases			
Blood glucose			Hemocue
Calcium			
cholesterol			
Creatine kinase			
Creatinine			
CSF protein			
CSF glucose			
CSF globulin			
Direct bilirubin			
GGT			
Glycosylated Hb			
Immunoglobulin electrophoresis			
Indirect bilirubin			
Iron			
Lactic Acid			
LDH			
Magnesium			
Phosphorus			
SGOT (AST)			
SGPT (ALT)			
Total bilirubin			
Total protein			
Triglycerides			
Urea			
Uric acid			

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Thyroid hormones T3			
Thyroid hormones T4			
FSH			
TSH			
Tumor markers			
Prostate antigen			
Carcinogenic embryonic antigen			
Alpha fetoprotein			
Sodium			
Lithium			
Potassium			
Chloride			

Appendix 3

Pre-Standardization Questionnaire

1. Tests Performed at Health Center Laboratory		
Laboratory Test: Check if performed by laboratory	**Technique: Check if performed by laboratory**	**Equipment: Check if used to perform test by laboratory**
❒ Hemoglobin estimation	❒ Oxyhemoglobin, lovibond comparator ❒ Cyanmethemoglobin, Sahli ❒ (other): _____	
❒ Blood slide for haemoparasites	❒ Field stain ❒ (other): _____	
❒ Stool microscopy for parasites	❒ Direct saline, iodine ❒ (other): _____	
❒ Sputum for AFB	❒ ZN stain ❒ Oramine O ❒ Other_____	
❒ Skin slit for AFB	❒ ZN stain _____	
❒ Urine sediment microscopy	❒ Direct microscopy	
❒ Urine protein, sugar	❒ Uristix ❒ (other): _____	
❒ Syphilis screening	❒ RPR/VDRL carbon antigen ❒ TPHA _____	
❒ Sickle cell screen	❒ Sodium metabisulphite ❒ (other): _____	
❒ Genito-urinary tract specimens	❒ Wet prep ❒ Gram stain ❒ KOH ❒ (other): _____	
❒ Pus swabs	❒ Gram stain ❒ Culture: _____	

❒ Bubo aspirate (plague)	❒ Wayson staining	
❒ HIV screening	❒ Rapid screening kits ❒ ELISA_____ ❒ Western Blot	
❒ Blood grouping	❒ Tube method ❒ Tile method	
❒ Rhesus typing	❒ Tube ❒ Tile method _____	
❒ Total white cell count	❒ Manual, hemocytometer using Turk's fluid ❒ (other): _____	
❒ Differential white cell count	❒ Manual, using stained thin film ❒ Auto analyzer _____	
❒ Cerebrospinal fluid microscopy	❒ Gram stain ❒ Leishman ❒ Turk's fluid ❒ India ink: ❒ Cryotococal antigen _____	
❒ Cerebrospinal fluid chemistry	❒ Turbidimetric _____	
❒ (other): _____	❒ (other): _____	
❒ (other): _____	❒ (other): _____	
❒ (other): _____	❒ (other): _____	

2. Additional Tests Performed at District Hospital Laboratory		
Laboratory Test: Check if performed by laboratory	**Technique: Check if performed by laboratory**	**Equipment: Check if used to perform test by laboratory**
❒ Concentration technique ❒ Blood ❒ Stool	❒ Buffy coat (knotts) ❒ Formal ether ❒ (other): _____	
❒ Urine qualitative chemistry (protein, sugar, ketones, blood bilirubin, urobilinogen)	❒ Dipstix	
❒ Skin snip for microfilaria	❒ Saline direct ❒ (other): _____	

❒ Collection and fixation of cytological smears	❒ Formalin ❒ (other): _____	
❒ Collection and fixation of histological specimens	❒ Formalin	
❒ (other): _____	❒ (other): _____	
❒ (other): _____	❒ (other): _____	

3. Additional Tests Performed at the Regional Hospital Laboratory

Laboratory Test: Check if performed by laboratory	**Technique: Check if performed by laboratory**	**Equipment: Check if used to perform test by laboratory**
❒ Hemoglobin estimation ❒ Total white cell count ❒ Differential blood counts	❒ Hematology analyzer ❒ (other): _____	❒ **Sysmex KX21 N** ❒ **Sysmex XT 1800** ❒ **ABX Micros** ❒ **: ABX Pentra 60** ❒ **Coulter ACT Diff 5** ❒ **Coulter ACT Diff 8** ❒ **MS4** ❒ **MS9** ❒ **other_____**
❒ Platelet count ❒ Reticulocyte count ❒ Blood indices	❒ Hematology analyzer ❒ (other): _____	❒ **SysmexKX21N** ❒ **Sysmex XT1800** ❒ **ABX Micros:** ❒ **ABX Pentra 60** ❒ **Coulter ACT Diff 5** ❒ **Coulter ACT Diff 8** ❒ **other_____**
❒ CD4/CD8 count	❒ Flow cytometery ❒ Non-cytofluorimetric ❒ Manual ❒ (other): _____	❒ **FACScount** ❒ **FACS Calibur** ❒ **Partec Cyflow counter** ❒ **Partec SL3** ❒ **EPIC** ❒ **Point of Care** ❒ **Guava** ❒ **other_____**

❒ Viral load	❒ HIV RNA ❒ Real-time PCR ❒ Heat-dissociated p24 antigen ❒ Cavidi RT ❒ (other): _____	❒ **Roche** ❒ **Carvidi RT** ❒ **other**_____
❒ Sickle cell screening test	❒ Sodium metabisulphite ❒ Electophoresis ❒ Other_____	
❒ Blood slide examination for parasites	❒ Manual microscopy (field) ❒ Concentration ❒ (other): _____	
❒ Film comment	❒ Manual microscopy-Romanosky_____	
❒ Stool microscopy	❒ Direct saline ❒ iodine concentration ❒ (other): _____	
❒ HIV screening	❒ Rapid screening kits ❒ ELISA ❒ Western Blot _____	
❒ Hb types	❒ Electrophoresis ❒ (other): _____	
❒ Serum proteins	❒ Electrophoresis ❒ (other): _____	
❒ Hepatitis B screening	❒ ELISA ❒ Latex agglutination ❒ (other): _____	
❒ Syphilis screening	❒ RPR/VDRL carbon antigen ❒ TPHA _____	
❒ Serum bilirubin ❒ SGOT (serum) ❒ SGPT (serum) ❒ Alkaline phosphatase (serum) ❒ Renal function tests ❒ Blood glucose ❒ Serum electrolytes	❒ Chemistry auto-analyzer ❒ manual photometer ❒ (other): _____	❒ **Cobas mira** ❒ **Cobas integra** ❒ **Humastar 180** ❒ **Keylab** ❒ **CX5** ❒ **CX9** ❒ **Humalyser 2000** ❒ **Humalyser 3000**

❒ Total protein		❒ **Vitros DT 60** ❒ **Olympus AU 400** ❒ **Other_____**
❒ Examination of CSF for yeast	❒ Negative staining-India ink ❒ (other): _____	
❒ Examination of CSF, pus, deposit, etc., micro-organisms	❒ Gram stain ❒ (other): _____	
❒ Culture	❒ Aerobic ❒ Anaerobic ❒ CO_2	
❒ Drug sensitivity	❒ Disc diffusion ❒ (other): _____	
❒ Microscopy for plague	❒ Wayson staining	
❒ Processing biopsy	❒ Haematoxylin and eosin ❒ Other _____	
❒ Semen analysis	❒ Microscopy _____	
❒ Cytology	❒ Microscopy ❒ Pup smear _____	
❒ Sputum for TB	❒ ZN stain ❒ (other): _____	
❒ Urine sediment microscopy	❒ Direct microscopy	
❒ Urine chemistry	❒ Dipstix ❒ (other): _____	
❒ Genito-urinary track specimens	❒ Wet prep ❒ Gram ❒ KOH ❒ (other): _____	
❒ Blood group	❒ Tube method ❒ Tile method	
❒ type and cross matching	❒ Tube method	
❒ Skin snip for microfilaria	❒ Saline direct ❒ (other): _____	
❒ Examination for fungi	❒ KOH ❒ (other): _____	

❒ Confirmatory test for syphilis	❒ TPHA ❒ (other): _____	
❒ Routine screening of food handlers ❒ Bacteriological examination of water, foods, and beverages	❒ Standard public health methods ❒ (other): _____	
❒ (other): _____	❒ (other): _____	
❒ (other): _____	❒ (other): _____	

Appendix 4

Example of Goals and Objectives for Standardization Workshop

Ministry of Health
Standardization Workshop for Laboratory Commodities

Goals and Objectives

Workshop Goal:
Participants will begin the process of standardizing testing services in the country.

Workshop Objectives:

By the end of this workshop, participants will be able to—

1. Describe the concept and benefits of standardization and committed to the process of standardization.

2. Describe the vision for testing services.

3. Set the tests for each level of the system.

4. Agreed on technique and priority equipment, by level, to fulfill test menus.

5. Identify the products that correspond to the agreed-to testing technique and equipment, by level, which will become the standard list.

6. Developed next steps for standardization.

Appendix 5

Example of Standardization Workshop Schedule

Monday	Tuesday	Wednesday	Thursday	Friday
8:30–9:30	**8:00–9:00**	**8:00–10:00**	**8:00–10:00**	**8:00–10:00**
Introduction to standardization & Maputo declaration	Ice breaker/Review Monday activities	Group activity 2: Presentation and consensus on techniques	Group activity 3: Presentation and consensus on equipment selection	Group activity 4: Product list development
9:30–10.00	**9:00–10:00**			
Introduction to logistics	Group review of testing menus			
10:00–10:15	**10:00–10:30**	**10:00–10:30**	**10:00–10:30**	**10:00–10:30**
Break	Break	Break	Break	Break
10:15–10:45	**10:30–12:00**	**10:30–12:00**	**10:30–12:00**	**10:30–12:00**
Advantages of standardization	Supply chain considerations	Group activity 3: Determining equipment criteria	Group activity 3: Presentation and consensus on equipment selection	Planning for implementation
11:15–12:00	**11:00–12:00**			
Panel session vision for lab services in Malawi	Introduction to defining techniques			
12:00-1:00	**12:00–1:00**	**12:00–1:00**	**12:00–1:00**	**12:00-1:00**
Lunch	Lunch	Lunch	Lunch	Lunch
1:00–3:15	**1:00–3:00**	**1:00–2:00**	**1:00–3:00**	**1:00–3:00**
Group activity 1: Setting test menus	Group activity 2: Defining techniques	Group activity 3: Equipment evaluation	Group activity 4: Product list development	Final presentation of results to stakeholders
3:00–3:15	**3:00–3:15**	**3:00–3:15**	**3:00–3:15**	**3:00–3:15**
Break	Break	Break	Break	Break
3:15–5:00	**3:15–5:00**	**3:15–5:00**	**3:15–5:00**	**3:15–5:00**
Group activity 1: Presentations and consensus on test menus	Group activity 2: Defining techniques	Group activity 3: Equipment evaluation	Group activity 4: Product list development	Wrap up and closing

Appendix 6

Setting Test Menus Worksheet

Laboratory Tests	Urban Health Centers		District Hospitals		Central Level
	Send Out	On Site	Send Out	On Site	
Hematology					
Hemoglobin		√		√	√
Total WBC and differential				√	√
Blood Bank					
Blood transfusion screening				√	√
Microbiology					
TB microscopy		√		√	√
HIV screening		√		√	√
Urine microscopy		√		√	√
Stool microscopy		√		√	√
Antenatal syphilis screening		√		√	√
Parasitology					
Malaria microscopy		√		√	√
Biochemistry					
Urine chemistry		√		√	√
Blood glucose				√	√
CSF Analysis					
Microscopy (cell count)				√	√
Indian Ink				√	√
Gram stains				√	√
ZN stains				√	√
Protein				√	√
Glucose				√	√

Appendix 7

Operational Considerations for Equipment Selection

Adapted from the Maputo Workshop on Standardization, hosted by WHO

	Operational Considerations for Equipment Selection	
	Critical	
	Equipment assessed, in-country, CDC ,WHO etc., and report available	
	Equipment uses existing regular power supply	
	Operator manual available in appropriate language	
	Technical manual available in appropriate language	
	Training offered on installation	
	Supplier installs and commissions equipment	
	Equipment in current production	
	Services engineers available	
	Throughput is appropriate for workload	
	Important and Desirable	
Technical	Machine will run as single platform	I
	Equipment can run stat (ad hoc) samples	I
	Machine has stable calibration settings	I
	Machine can store test results	I
	Machine can store QC results	I
	Few operator-initiated maintenance activities	I
	Minimal sample preparation before running on the machine	I
	Machine is self-calibrating	I
	Machine can interface with computer	I
	Equipment used in the region	I
	Reagents ready to use (no reagent preparation required)	D
	Load and walk away system	D
	Equipment can run sample batches	D

	Machine can be upgraded	D
	Equipment can self-diagnose	D
	Machine has in-built printer	D
	Same equipment in existence and use in-country	D
	Technology has been used elsewhere	D
Program Needs	Equipment meets any program plans to increase testing	I
	Maximum sample age (how long can the sample be stored before use)	D
	Training on use of equipment less than 1 week	I
Supply Chain	Reagent with shortest shelf life in kit is >6 months	I
	Reagents and supplies of equipment can be stored in existing space	I
	Existing cold chain distribution can accommodate equipment reagents	I
	Existing cold storage can accommodate reagents	I
	Open system	I
	Does not require additional accessories	I
	Bulk reagents not used on machine (20-liter containers)	D
	Equipment has no unique consumables, e.g., sample cups, cuvettes	D
	Supplier lead time for supply of equipment (months)	
	Supplier lead time for supply of reagents and consumables (months)	
Service & Maintenance	Machine can be switched off when not in use	I
	Local agent available for product support	I
	Equipment has spares kit, e.g., replaceable tubes, valves, filters, etc.	I
	Equipment comes with 5–10 yrs. spares guarantee from manufacturer	I
	Supplier has regional presence	D
Infrastructure Requirements	Equipment fits in existing space	I
	Existing generator can support equipment	I
	Complements existing equipment	I
	Works well in existing temperature range	I
Price	Purchase price	
	Cost of start-up kit	
	Cost of accessories	
	Cost of consumables to run 1,000 tests	
	Cost of quality control materials specific to equipment required for 1,000 tests run	
	Cost of service contract	

Appendix 8

Example of Template for Developing Product List

Test Menus	Techniques	Equipment	Durables	Reagents	Specimen Type	Consumables	CMS

Appendix 9

Malawi Standardization Case Study

Background

In February 2009, the Malawi MOH conducted a laboratory assessment to find ways to strengthen laboratory services in Malawi. Among the recommendations made during this assessment was the need for laboratory standardization. The Malawi MOH decided to proceed with standardization and, as a first step, conducted a standardization workshop in April 2009.[5] The purpose of the workshop was to standardize test menus, test techniques, and equipment used in Malawi.

The Workshop

The standardization activity focused on establishing standards for the central, district, and health center laboratories. The standardization workshop was conducted in two distinct parts. The first part of the workshop was a plenary session where ideas and visions for laboratory testing services were shared by all stakeholders; following this visioning, test menus, by level, were determined. The second part, took place during the following four days of the workshop, during which a smaller group of laboratory staff were tasked with providing detail to the standard test menus, including setting the techniques and equipment. Each of the sessions of the workshop is described in greater detail below.

a) Introduction to the Standardization

The large group of stakeholders invited to the plenary session included clinicians, nursing staff, and laboratory staff representing all levels of the system and specialties, as well as program staff, implementing partners, procurement officers, and supply chain mangers. During this part of the workshop, the participants were introduced to the concept of standardization and its benefits from a programmatic, clinical, and supply chain perspective. Following this, participants representing different cadres and levels of the health system gave a brief presentation on the current state of and perceived gaps in testing services. Presentations were made by laboratory personnel from the central level; district laboratories and blood transfusion services; program staff from HIV, tuberculosis, and malaria programs; and nursing and medical staff and development partners.

b) Vision for Laboratory Testing Services

Medical and laboratory staff from the central- and district-level facilities identified perceived needs for testing services at various levels of the system. For example, it was perceived that malaria microscopy was needed at all health facilities and the capability to perform microbiology culture and

[5] Malawi Ministry of Health and USAID | DELIVER PROJECT, Task Order 1. 2009. *Malawi: Laboratory Standardization Workshop—Standardization of Laboratory Tests, Techniques, and Equipment.* Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.

sensitivity testing should be available at the district-level laboratories. These discussions helped to identify the vision for which laboratory tests should be available at every level of the system.

c) Determining Test Menus

The introduction to standardization and development of a vision for laboratory testing services served to stimulate discussion and decisions regarding which tests should be available at each level of the system. The larger group was split into smaller groups, which were each assigned a level of the system (central, district, and health center), and asked to determine the testing menus appropriate for that level. Each group was provided with a table of all tests currently included in the Essential Medical Laboratory Services (EMLS).

After each group created a comprehensive list of tests to be offered at their level of the system, the testing menus were reviewed by the larger group and then expanded, taking into account the presentations in the plenary session. The tests for hematology chosen for the district and central hospitals were very similar, except that the central level offers a few more specialized tests. This was the case for most testing categories as the differences between the central and district hospital services were minimal. At the health center–level, a small number of basic tests were included, which reflects the staffing capacity and infrastructure of these facilities. Table 6 shows the test menu selected for the hematology testing area, by level, in the system.

Table 6. Test Menu for Hematology by Level in Malawi

Central Hospital	District Hospital (Incl. Community Hospital)	Health Center
Full blood count	Full blood count	Hemoglobin
Differential count	Differential count	White blood cell count
Sickle cell screening	Sickle cell screening	
Sickle cell confirmatory test	Sickle cell confirmatory test	
Hemoglobin	Hemoglobin	
Prothrombin time	Prothrombin time	
Activated partial thromboplastin time	Activated partial thromboplastin time	
Fibrinogen test	Erythrocyte sedimentation rate	
Erythrocyte sedimentation rate	Reticulocyte count	
Reticulocyte count	CD4 count	
Lupus erythromatous		
CD4 count		
CD4 %		

d) Setting Techniques

In setting the techniques, the smaller group of lab staff was divided into the three levels of the system—central, district, and health care center—to select appropriate techniques for each level. The list of techniques chosen for the selected hematology tests for each level of the system (outlined in table 6) is shown in table 7

Table 7. List of Techniques for Hematology in Malawi

Test Menus	Techniques		
	Central Hospital	**District Hospital**	**Health Center**
Full blood count	Hematology analyzer	Hematology analyzer	
Differential count	Manual	Manual	
White blood cell count			HemoCue
Sickle cell screening	Sodium metabisulphate	Sodium metabisulphite	
	Sodium dithionate	Solubility	
Sickle cell confirmatory test	Electrophoresis		
Hemoglobin	HemoCue	HemoCue	HemoCue
PT	Hematology analyzer	Tube method	
APTT	Hematology analyzer	Tube method	
Fibrinogen test	Hematology analyzer		
ESR	Westergreen	Westergreen	
Reticulocyte count	Brilliant cresol blue	Brilliant cresol blue	
	New Methylene blue	New Methylene blue	
	Hematology analyzer		
Lupus erythromatous	Latex agglutination		
CD4 Count	Flowcytometry	Flowcytometry	
CD4 %	Flowcytometry	Flowcytometry	

e) Selecting Equipment

The participants were provided with an example list of criteria (see appendix 7) based on the recommendations from the Maputo Standardization Workshop; they were asked to decide which criterion was relevant to Malawi and, then, which was critical, important, or desirable. The participants then evaluated the equipment currently in use in the country using this list. Once the participants had evaluated the existing equipment, and if it was determined that these did not meet the country's need, the group then evaluated other equipment that was being used elsewhere in southern Africa.

The equipment chosen to be included in the standardized list in Malawi was carefully evaluated and compared with other similar equipment. Through discussion with participants and valuable input from implementing partners, the participants selected the equipment for biochemistry, hematology, and CD4 listed in table 8.

Table 8. List of Standard Equipment

Type of Analyzers	Central	District
Biochemistry	Humastar 180 / Humalyte ISE	Humalyzer 3000
	Keylab	
Hematology	Sysmex XT 1800	Sysmex KX21
	Sysmex KX21	
CD4	EPICS	Partec Cyflow SL3
	Partec Cyflow SL3	FACS count

f) Listing the Products

The participants then selected the products that were required to perform each test, using the technique agreed-to and the equipment selected. When compiling this list of the products, the participants were referred to both the draft SOPs and the current Central Medical Stores (CMS) catalog to guide decisions and to identify any discrepancies or gaps in either of these documents.

When all of the reagents and consumables required for all tests at all levels were listed, they totaled approximately 385 products. Currently, the CMS list includes only 250 products. It was found in compiling this list that many of the items were missing from the CMS catalog and many were duplicated with slightly different names. These discrepancies may result in the procurement of the wrong product by CMS, or in some items being listed out of stock, when in fact they are available centrally. Therefore, reviewing and updating the list is a critical step in the process.

Recommendations and Implementation Plan

The participants identified the list of activities below as the next steps in implementing standardization. The participants identified a small technical group that will be responsible for leading the next steps, summarized below.

Activity	Date	Responsible
Draft standardized list of tests, techniques, equipment, consumables, and reagents, by level, to be edited by all participants and coordinated by a smaller technical group of central laboratory managers.	June	Standardization TWG (all central-level managers)
Final list to be sent to the Deputy Director for Health Technical Support Services (HTSS) Diagnostics Department for approval and formal documentation.	June	Standardization TWG (all central-level managers)
Liaise with procurement unit to assist in implementation of standardization.	June	USAID | DELIVER PROJECT – Local Laboratory Advisor
Dissemination of new standards to laboratory staff and refresher trainings to staff at all level to ensure they have the skills to provide the tests.	December	USAID | DELIVER PROJECT, in collaboration with implementing partners

Activity	Date	Responsible
Orientation of stakeholders including clinicians, nursing staff, and development partners of the new standards for laboratory services.	July	USAID | DELIVER PROJECT
Incorporation of the standard techniques and analyzers into training programs.	December	USAID | DELIVER PROJECT, in collaboration with implementing partners and training institutes
Formation of a standardization committee	June	MOH
Annual reviews of the standardized list.	Annually	Standardization committee

Appendix 10

Case Study: Impact of the Ethiopian National Laboratory Logistics System on the Harmonization of Laboratory Items

July 2009

Case Study: Impact of the Ethiopian National Laboratory Logistics System on the Harmonization of Laboratory Items

Background

Laboratory commodities are used in the provision of HIV/AIDS prevention, care and treatment services in Ethiopia. These services are provided through a variety of public health facilities offering antiretroviral therapy (ART) and voluntary counseling and testing (VCT) sites including hospitals, health centers and regional laboratories providing ART monitoring and testing. These sites order laboratory commodities using standard inventory control system procedures and receive commodities from Pharmaceutical Fund and Supply Agency (PFSA), a public sector responsible for storing and distributing all health commodities to public facilities. As a public sector partner, the Ethiopian Health, Nutrition & Research Institute (EHNRI) of the Federal Ministry of Health (MOH) is responsible for establishing and maintaining a public health laboratory system, setting policies and standards for the management of laboratory commodities, standardization and providing technical support and monitoring laboratory logistic system performance, as well quantifying laboratory commodities.

EHNRI in collaboration with the Ministry of Health and other key stakeholders developed the National Health Laboratory System Master Plan and accompanying Guidelines with the objective of establishing a standard health laboratory system in the country. EHNRI's operational plan for the National HIV/AIDS laboratory services was developed and elaborated to fit into and implement the laboratory activities envisaged in the Road Map for accelerating access to HIV/AIDS treatment in Ethiopia. EHNRI, being the country's National Reference Center, was seen as having the comparative advantage to undertake leadership in the National ART Laboratory Service Program.

The development of the countries National Laboratory System Master Plan and Guidelines on communication for the national HIV/AIDS Laboratory program was concurrently launched with the MOH's National Logistics Master Plan for commodities The latter builds upon the premise that a systemic response is needed to meet the supply needs of public sector service facilities and their clients, and that efficient mechanisms for reaching these sites are key, including a model of direct-delivery-to-site from central level.

Prior to the logistics system design, the Ethiopian laboratory logistics system was weak, consistently being hampered by several systemic challenges that caused frequent stockouts of critical items that impeded continuous and quality testing for patients. The laboratory logistics system was characterized by an inadequate supply of required reagents and supplies, which in turn was affected by the lack of information on these commodities for procurement and re-supply decisions. In addition, distribution systems for laboratory commodities were not systematically designed, strengthened nor supported. Patients were requested to wait 2-3 months or longer at hospitals for critical commodities such as CD4 reagents. Laboratory machine failure and PFSA's limited capacity to deliver reagents were among the major problems that affected the national laboratory logistic system in the country

Standardization Process

Many of the afore mentioned logistics problems were traced back to the fact that the system then managed multiple variations of commodities while reporting and ordering remained unstandardized. Some testing practices also remained unstandardized making PFSA's role in commodity management equally challenging. To address these difficulties, the Supply Chain Management System (SCMS) project was requested to lead the design of a standardized laboratory logistics system as a means of solving the logistics obstacles and supporting EHNRI's Master Plan and the MOH National Logistics Master Plan. Following that exercise in March 2007, a robust laboratory logistics system was designed to support the scale up of the HIV/AIDS care and treatment program including up to 470 ART sites in the country. Among these, 107 are laboratory monitoring hospitals including regional laboratories providing direct and referral laboratory services. More than 1500 VCT facilities are providing HIV testing and counseling services

During the design of the laboratory logistics system, special attention was made on ensuring that the commodities managed in the logistics system would be a standard list of products, used in line with standard treatment and testing guidelines for ART monitoring. The process harmonized test menus, test techniques, operating procedures, and laboratory equipment for each type of test and ART facility in the system. By doing so, a total of 64 regularly used, stored and distributed laboratory commodities were chosen for the newly designed logistics system. For CD4 testing, 9 reagents were chosen, 14 for chemistry and 12 including controls and calibrators for hematology. The consumables list consisted of 23 commodities, 3 rapid tests and an additional 3 tests. Restricting the number of commodities in the logistics system was a key first step in ensuring that a standardized list of laboratory commodities are used to support in HIV/AIDS treatment services. The standardized list of equipment chosen by testing area is provided in Table 1 below.

Table 1: Standardized List of Laboratory Equipment, March 2007

CD4 Equipment	Chemistry Equipment	Haematology Equipment
FACSCalibur FACSCount	Humastar 80	Cell Dyne 1800 Cell Dyne 3700

The Autolab was recently added to the list of approved chemistry equipment and so too the Sysmex KX-21N and Sysmex 1800i on the haematology list.

To ensure the designed standardized system would work well, SOPs were developed and rolled out. A training of trainers (TOT) was provided to 25 professionals from the Ministry of Health and national partners. These trainees in turn conducted regional trainings at 107 ART monitoring sites, successfully reaching 296 professionals trained through TOT and rollouts. On the job training was also provided to 568 professionals to fill the gap in the implementation of the logistics system. In addition to that, sensitization workshops were also organized in the five major regions of the country to discuss on the implementation of the laboratory logistics system in which 769 public health leaders participated. Throughout this process, emphasis was placed on using and ordering a standardized set of commodities.

Ongoing Standardization Processes

In January 2008, the international laboratory community converged for a meeting in Maputo, Mozambique to develop recommendations for clinical laboratory testing harmonization and standardization. Central to the theme of this workshop was the call to promote the standardization of laboratory supplies at each tiered level of the laboratory network. Standardization is the process of harmonizing test menus, test techniques, operating procedures, and laboratory equipment for each type of test and for each level in the system. In response to the Maputo conference, EHNRI has began the process of adapting the Maputo guidelines to Ethiopia's context and working with key stakeholders towards maintaining a standardized system across Ethiopia.

Benefits and Challenges

The standardized logistics system was set up as a means of eliminating the logistics challenges that existed prior to its design. Since May 2007, no stockouts have occurred for ART laboratory monitoring tests and emergency orders have dropped dramatically. Less commodity wastage is also being recorded. Laboratory reagents and related supplies are arriving on time in the quantities needed. Wait time for tests for patients has been reduced significantly, from two to three months to within hours. Today, the logistics system is positively impacting more than 132,835 ART patients (as of Jan 09 HAPCO/MOH) The laboratory commodities distribution system is now integrated with other HIV/AIDS commodities such as ARVs; ensuring patients receive a comprehensive package of services. Reporting and Requisitioning through the laboratory logistic information system (LMIS) has been standardized in the country by developing reporting formats which can easily be completed at all levels of the system.

From the supply chain perspective, standardization has helped enhancing laboratory commodity manageability by streamlining the number and range of laboratory products. PFSA's central and regional hubs were previously overburdened by the sheer number of commodities they had to manage. Through standardization, the lists of commodities were drastically reduced by retaining only commonly used products per ART program testing guidelines. Reducing the number of commodities that PFSA has had to manage has eased the burden on distribution and the inventory control systems that now exist at the site level. Last but not least, standardization has further enables rational decision making throughout the supply chain, particularly in product selection, forecasting, quantification, and procurement. It also facilitated easier service and maintenance by reducing the number of types of equipment that the EHNRI's biomedical engineers and clinical staff have had to service. Maintaining the current set of standardized equipment has however proved challenging especially in an age where technologies are rapidly changing.

Conclusions and Lessons

Laboratory logistics systems have shown to be viable solutions to addressing many different supply chain challenges in resource limited settings, especially when it comes to the issue of ensuring consistent commodity availability for testing services. Standardization has also been shown to be an integral part in the success of any logistics systems. Standardization efforts will continue to strengthen laboratory capacity by building sustainable laboratory capabilities that will provide access to high quality, rapid, and affordable diagnostic tests for the care, treatment, prevention and surveillance of HIV/AIDS amongst other diseases.

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Appendix 11

Case Study: Harmonization of Laboratory Items in Zambia

SCMS Providing quality medicines for people living with and affected by HIV and AIDS

PEPFAR Implementing Partner

USAID FROM THE AMERICAN PEOPLE | DELIVER PROJECT

June 2009

Case Study: Harmonization of Laboratory Items in Zambia

Background

In 1997, the Zambian Ministry of Health (MOH) developed a National Medical Laboratory Policy. The policy included a 5-year implementation plan, one step of which was to achieve standardization of laboratory procedures and equipment. Around 1999, the MOH developed an Essential Equipment List for Level 1, 2, 3 and Health Centres. This list documented the specifications for various instruments as well as the proposed make of the instrument. Based on this list, the MOH secured funding through the Japan International Cooperation Agency (JICA) to procure standard equipment, including heamatology and chemistry analysers.

The Republic of Zambia is now in the midst of rapid expansion of the national HIV and AIDS programme. In particular, it has been recognized that reliable laboratories are critical to the success of a comprehensive HIV and AIDS programme.

To develop a truly effective HIV and AIDS programme, it is recognized that a full array of HIV and AIDS tests, including clinical chemistry, haematology, and CD4, must be available to diagnose and monitor patients.

In December 2005, a Laboratory Technical Working Group (TWG) was formed to develop a coordinated approach to improving laboratory services in Zambia. In May 2006, the TWG created the Operational Plan for the National Laboratory System, 2006-2008. TWG subcommittees were formed in the following areas to plan on a larger scale:

- Program Management
- Procurement and Logistics
- Instrumentation and Infrastructure
- Quality and Data Management
- Human Resources and Training

Table 1: Laboratories by Level

Level	Level Description	Number of labs
Health Centre	Periphery	124
Level 1 Laboratory	Intermediate (district)	70
Level 2 Laboratory	General (province)	18
Level 3 Laboratory	Referral/teaching	4
	Total:	**216**

The Instrumentation and Infrastructure TWG subcommittee was tasked with updating the Essential Equipment List by facility level, including identification of new types of equipment needed such as CD4. Zambia currently has 216 active labs in the public sector. Table 1 shows the number and organization of laboratories by level in Zambia.

Standardization Process

Following the May 2006 Operational Planning meeting, the Instrumentation and Infrastructure TWG subcommittee developed a list of potential standard equipment by facility level to include in the review and update. The subcommittee included members from the Ministry of Health as well as key cooperating partners. The main criteria that the subcommittee agreed to review are listed below.

- Instrument capacity, requirements and appropriateness
- Current technologies
- Instrument reliability
- Maintenance and support
- Costs for instrumentation, maintenance and reagents and consumables
- Supply chain implications

In September 2006, the MOH, with support from the PEPFAR funded USAID SCMS project, both members of the Procurement and Logistics TWG subcommittee, hosted a national laboratory commodity quantification workshop. The quantification brought together a team of representatives from the central-level MOH, different facility levels in the country, and cooperating partners. Although the nature of the new standard equipment was still in discussion, the quantification team agreed on some key elements in order to build assumptions about the quantities of laboratory products needed for the countries testing needs. These elements included agreement on the test menus by level, identification of the standard techniques implemented for each test by level, and agreement on the standard equipment to include by level. The test menus and standard technique definition followed the Zambia Standard Operating Procedures for the National Laboratory System for health centres, level 1, 2 and 3 laboratories. The standard equipment list by level that the quantification team agreed upon at the 2006 quantification workshop can be found in Table 2.

Table 2: Standard Laboratory Equipment, 2006

	CD4	Chemistry	Haematology
Health Centre	Dynabeads	Humalyzer	Sysmex PocH 100i
Level 1	FACSCount	Humalyzer	ABX Micros 60
Level 2	FACSCount	Cobas Integra 400 Vitros DT 60	ABX Micros 60
Level 3	FACSCount FACSCalibur	Olympus AU 400	ABX Micros 60 ABX Pentra

After the 2006 laboratory commodity quantification, the MOH made a commitment to following this standard equipment list. The cooperating partners were encouraged to follow this list as a guide for all new equipment procurement.

The standard list was reviewed slightly in 2007 when the Dynabeads and Vitros DT60 were removed from the health centre level CD4. A number of health centres now have the FACSCounts.

Challenges

As can be expected, this process has had many challenges. In 2008, there remained a large amount of non-standard equipment in the country. As agreed upon with the MOH, the cooperating partners supporting the sites with these non-standard equipment will procure and distribute reagents for all non-standard equipment. This approach is not sustainable and efforts are being made to either equip these facilities with standard instrumentation or review the standard equipment list to include some of the equipment currently omitted from the original standardized list.

Before new equipment can be reviewed for possibly inclusion in the standard equipment list, the University Teaching Hospital (UTH) must validate the equipment. The supplier of the equipment is required to pay the fees for this validation process.

Benefits

Development of the standard equipment list in Zambia allowed for a number of improvements to the national laboratory system.

1. Maintenance Contracts

The Ministry of Health and cooperating partners worked together to negotiate maintenance contracts with the suppliers and link this with the purchase of reagents to ensure sustainability of the maintenance contracts. Since there are a significant number of each equipment in the country with more expected, the group was able to negotiate a fair contract with the local suppliers.

2. Cost Savings

Although it is not possible to estimate the exact amount of cost savings, standardization has led to decreased overall procurement costs through economies of scale. With a reduction in the total number of laboratory commodities by approximately 80%, the procurement partners are procuring more of each individual reagent rather than smaller quantities of many different reagents.

Zambia has experienced additional indirect costs savings from having a standard equipment list by transferring stocks between facilities. In one such instance, reagents were procured for the ABX Pentra which is at level 3 teaching/referral hospitals. One of the main ABX Pentras was not functioning and therefore some of the reagents procured for this equipment were going to expire. Another facility using the ABX Pentra, which was not part of the national system, offered a stock transfer so they could use the shorter expiry products before they were wasted. This stock transfer saved approximately $30,000 worth of reagents from expiring.

3. National Laboratory Commodity Logistics System

Consistent availability of laboratory reagents has been a known problem with the Zambian Laboratory System. The Procurement and Logistics TWG subcommittee identified the need for development of a national laboratory commodity logistics system. A logistics system design workshop was held in Oct. 2007. The design team, consisting of MOH representatives from all levels and key cooperating partners, recognized that it is not possible to design a rational logistics system for more than 200 commodities. To agree on the priority commodities to include in the logistics system, the design team reviewed the list of standard tests/equipment and the resulting

reagents and consumables. In the end, a list of 185 priority laboratory commodities was identified for the new National ART Laboratory Logistics System.

The design of the National ART Laboratory Commodity Logistics System is being rolled out in 2008-2009. The system is expected to significantly improve the laboratory commodity management at the facility and central level, thus improving laboratory services.

4. Stock Availability

With the rollout of the national logistics system for laboratory commodities and standardization of laboratory equipment, the management of these commodities is streamlined and simplified and facilities are able to transfer stocks from a facility with too much stock risking expiry to a facility with low or no stocks.

In 2007, it was estimated that 70% of the 185 priority laboratory commodities were out of stock at the central level warehouse, Medical Stores Limited. Standardization has increased the focus on these supplies and the stockout rate has dropped to 2% at the end of 2008.

Conclusions and Lessons

Standardization in Zambia has been an iterative process. At the annual forecast and quantification, the standard list of tests, techniques and equipment is reviewed. Additionally, the Instrumentation and Infrastructure TWG subcommittee reviews the list as needed. Currently, the Instrumentation and Infrastructure TWG subcommittee is reviewing new chemistry equipment for lower level laboratories as well as other potential equipment.

With this in mind, the Zambian experience has a few key lessons learned and recommendations:

1. Standardization is an iterative process. Commitment of human resources and time are key factors to make the process successful.
2. The process must be collaborative and should include representation from key partners and staff from different level laboratories. The laboratory staff working at the health facilities may be able to identify very practical reasons why certain equipment are not appropriate for their facility. Ensuring that there is commitment to the agreed standard equipment list from NGO and government partners will avoid disputes about equipment procurement.

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